

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1577-P]

RIN 0938-AQ27

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make certain revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2012. This proposed rule would also set forth proposed requirements for the ESRD quality incentive program (QIP) for payment years (PYs) 2013 and 2014. In addition, this proposed rule would revise the ambulance fee schedule regulations to conform with statutory changes. Finally, this proposed rule would revise the definition of durable medical equipment (DME) by adding a 3-year minimum lifetime criterion 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. (See the Table of Contents for a listing of the specific issues addressed

in this proposed rule.)

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of display in the **Federal Register**].

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Centers for Medicare & Medicaid Services,
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7500 Security Boulevard,
Baltimore, MD 21244-1850.

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Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

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Rochel Kujawa, (410)786-9111, for issues related to ambulance services.

Heidi Oumarou, (410)786-7942, for issues related to the ESRD market basket.

Shannon Kerr, (410)786-3039, for issues related to the quality incentive program.

Sandhya Gilkerson, (410)786-4085, for issues related to the definition of durable medical equipment (DME).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules appeared in the **Federal Register**. However, beginning with this CY 2012 proposed rule, the Addenda of the annual proposed and final rules will no longer appear 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.

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Regulations Text

Acronyms

In addition, because of the many terms to which we refer by acronym in this proposed 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 |
| 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 |
| 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 Pub. L. 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

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) 2011 End-Stage Renal Disease (ESRD)

Prospective Payment System (PPS)

A. Background for the End-Stage Renal Disease Prospective
Payment System (ESRD PPS) for calendar year (CY) 2012

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 prior basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

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, for 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 (for those ESRD facilities that elected to receive blended payments during the transition) period 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 are using 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.
- A 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 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 qualifies 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 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. Routine Updates and Proposed Policy Changes for

CY 2012 ESRD PPS

In this proposed rule, we propose to (1) make a number of routine updates for CY 2012, (2) implement the second year of the transition, and (3) make several policy changes under the ESRD PPS, as well as technical changes to the CY 2011 ESRD PPS final rule.

1. Proposals Related to the Composite Rate Portion of the ESRD PPS Blended Payment

This proposed rule would implement the second year of the transition period for those ESRD facilities that elected to go through the transition rather than electing to receive payment based on 100 percent of the payment amount under the ESRD PPS. Specifically, we would implement in CY 2012 the second year of the transition where 50 percent of payment is based on the basic case-mix adjusted composite payment system and the remaining 50 percent of payment is based on the payment amount under the ESRD PPS.

As a result of the transition period under the ESRD PPS, we must continue to update the composite rate portion of the blended payment, which would include updates to the drug add-on adjustment required by section 1881(b)(12)(F) of the Act, as well

as the wage index values (which include a budget-neutrality factor) used to adjust the labor component of the composite rate. The proposed updates to the drug add-on adjustment under the composite rate portion of the blended rate can be found in section I.C.6.d of this proposed rule and the wage index is discussed in section I.C.d.7 of this proposed rule.

Also, the ESRD bundled (ESRDB) market basket increase factor (which is further reduced, beginning in 2012, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act) is used to update the composite rate portion of the blended payment in accordance with section 1881(b)(14)(F)(ii) of the Act. A discussion of the proposed market basket increase factor for CY 2012 can be found in section I.C.2 of this proposed rule. A discussion of the proposed productivity adjustment can be found in section I.C.2.c of this proposed rule. We are also proposing to update the second part of the transition budget-neutrality adjustment for CY 2012 that is applied to both the blended payments under the transition and payments under the ESRD PPS. The discussion regarding the proposed transition budget-neutrality adjustment can be found in section I.C.4 of this proposed rule.

In this proposed rule, we also are proposing to add the \$.49 for the Part D drugs to the composite rate portion of the blended payment during the transition, which represents the

first part of the transition budget-neutrality adjustment, and update it using the ESRDB market basket minus productivity adjustment. We discuss this proposal in the update to the composite rate and the proposed CY 2012 transition budget-neutrality adjustment in I.C.1.a and I.B.4, respectively, of this proposed rule.

Finally, we are proposing to revise the national average used in calculating the BSA adjustment under the basic case-mix adjusted composite payment system. This change is discussed in detail in section I.C.9 of this proposed rule.

2. Proposals Related to the ESRD PPS

As discussed above in section I.A, 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, requires the ESRD bundled payment amounts 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, in CY 2012, an ESRD market basket increase factor that is reduced by a productivity adjustment would be applied to the ESRD PPS payment rate portion of the blended payment under the transition and under the full ESRD PPS. A discussion of the proposed market basket increase factor for CY 2012 can be found in section I.C.2 of this proposed rule. A discussion of the

proposed productivity adjustment can be found in section I.C.2.c of this proposed rule.

We are also proposing to update the transition budget-neutrality adjustment for CY 2012 which is applied to both the blended payments under the transition and payments under the full ESRD PPS. The discussion regarding the proposed transition budget-neutrality adjustment can be found in section I.C.4 of this proposed rule.

This proposed rule would also update the wage index which is applied to both the ESRD PPS portion of the blended payments under the transition and payments under the full ESRD PPS. We are proposing to apply a wage index budget-neutrality adjustment factor to the ESRD PPS base rate. The discussion regarding the wage index can be found in section I.C.7 of this proposed rule.

Also, for CY 2012, we are proposing the following revisions to the ESRD PPS outlier policy: (1) eliminate the drug-specific list of eligible outlier services; (2) make modifications to the computation of the separately billable Medicare Allowable Payment (MAP) amounts to exclude access management drugs that are composite rate drugs and include certain anemia management drugs; and (3) stop using the 50 percent rule and eliminate the Automated Multi-Channel Chemistry (AMCC) laboratory tests from the definition of outlier services. In addition, we are proposing to consider anti-infective drugs when used at home by

a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis as non-composite rate ESRD-related drugs, and reiterating that under the current regulation, all non-composite rate ESRD-related drugs are considered outlier services. That is, all non-composite rate ESRD-related drugs are considered outlier services for purposes of determining outlier payments. The discussion regarding the proposed changes to the outlier policy can be found in section I.C.10 of this proposed rule.

3. Clarifications and Proposals Regarding the Low-Volume Adjustment Policy Under the ESRD PPS

In this proposed rule, we are clarifying that the term "payment year" is the period of time that we use for determining payment to ESRD facilities, which is a calendar year. We propose to establish a process for CY 2012 and each year thereafter that facilities would need to follow, when submitting its attestation to notify its FI/MAC that it is eligible for the low-volume adjustment. We are clarifying the term "year" that is used for purposes of establishing the treatment threshold for low-volume eligibility. A discussion of the low-volume payment adjustment can be found in section I.c.5 of this proposed rule.

4. Technical Corrections to the CY 2011 ESRD PPS Final Rule

In the CY 2011 ESRD PPS final rule, we inadvertently made two technical errors: (1) the training add-on amount was listed

incorrectly as \$33.38 instead of \$33.44; and (2) the composite rate laboratory test, "Assay of protein by other source," which is identified by the Current Procedural Terminology code 84157, was inadvertently omitted from the list of ESRD-related laboratory tests. For more information regarding these technical corrections please see section I.B.4 of this proposed rule.

5. Clarifications Regarding the ESRD PPS

In this proposed rule, we are clarifying the method for updating ICD-9-CM codes in accordance with ICD-9-CM annual updates and clarifying whether certain renal dialysis service furnished in an emergency room or department are considered renal dialysis services covered under the ESRD PPS.

C. Provisions of the Proposed Regulations for the ESRD PPS

1 Proposed Updates to the Composite Rate and ESRD PPS Base Rate

a. Proposed Composite Rate

Under section 1881(b)(14)(E)(i) of the Act, we are required to provide a 4-year transition under the new ESRD PPS. For CY 2012, under 42 CFR §413.239(a)(2), facilities that go through the transition will receive a blended rate equal to the sum of 50 percent of the full ESRD PPS amount and 50 percent of the basic case-mix adjusted payment amount. Accordingly, we continue to need 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 ESRD PPS blended rate, please see the CY 2011 Physician Fee Schedule (PFS) final rule (75 FR 40164) and the CY 2011 PFS proposed rule (75 FR 40164 through 40168). In addition, we discuss the proposed 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.

As discussed in section i.B.2 of this proposed rule, 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, provides that, for years during which the transition applies, the composite rate portion of the blend shall be annually increased by the ESRDB market basket 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 sections I.C.2.b and I.C.2.c of this proposed rule, we describe the basis for the proposed CY 2012 ESRDB market basket increase of 3.0 percent, and the productivity offset of 1.2 percent, yielding a proposed forecasted rate of increase in the base rate of 1.8 percent. In addition, as discussed in the transition budget-neutrality adjustment in section I.C.a of this proposed rule, we are proposing 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. The basis for the first part of the transition budget-neutrality adjustment (that is, the calculation of the \$0.49 Part D add-on) was set forth in the CY 2011 ESRD PPS final rule at 75 FR 49082.

Consequently, for CY 2012, the composite rate portion of the ESRD PPS blended payment would be \$141.52. The \$141.52 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 ESRD market basket minus productivity ($\$138.53 + 0.49 = \139.02 ; $\$139.02 \times 1.018 = \141.52).

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) under Medicare regulations at 42 CFR §§413.220 and 413.230. The CY 2011 ESRD PPS final rule has a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of reduction 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 per treatment base rate is adjusted for, the patient-specific case-mix adjustments, any applicable facility adjustments, wages to reflect ESRD facility differences in area wage levels using an area wage index, as well as any outlier payment or training add-on. For CY 2011, the ESRD PPS base rate was \$229.63 (75 FR 49082).

As discussed previously, 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, provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the rate of increase in the ESRD market basket, reduced by the productivity adjustment. Accordingly, we applied the 1.8 percent increase to the CY 2011 ESRD PPS base rate of \$229.63, which results in a CY 2012 ESRD PPS base rate of \$233.76 ($\$229.63 \times 1.018 = \233.76). The proposed CY 2012 ESRD PPS Base Rate applies to the ESRD PPS portion of the blend.

In addition, as discussed in section I.C.7.c of this proposed rule, we are proposing to apply the wage index budget-neutrality adjustment factor of 1.001126 to the CY 2012 ESRD PPS base rate (that is, \$233.76), yielding a proposed CY 2012 ESRD PPS wage-index budget-neutrality adjusted base rate of \$234.02

(\$233.76 X 1.001126 = \$234.02).

2. ESRD Bundled Market Basket

a. Overview and Background

Under 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. Proposed 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, effective beginning CY 2012 (and for purposes of the transition, effective beginning CY 2011), 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.

For this proposed rule, we have used 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. Using this method and the IHS Global Insight, Inc. (IGI) forecast for the first quarter of 2011 of the CY 2008-based ESRDB market basket, the proposed CY 2012 ESRDB market basket increase factor is 3.0 percent. IGI is an economic and financial forecasting firm that contracts with CMS to forecast the components of providers' market baskets.

The labor-related share of a market basket is determined by identifying the national average proportion of its operating costs that are related to, influenced by, or vary with the local labor market. In the CY 2011 ESRD PPS final rule, we finalized a labor-related share for CY 2011 of 41.737 percent using the base year cost weights for the CY 2008-based ESRDB market basket (75 FR 49161 through 49162). Table 1 below contains the calculation of the labor-related share. This labor-related share represented the sum of Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the cost weight for Professional Fees, and 46 percent of the cost weight for Capital-related Building and Equipment expenses. The 87 percent of Professional fees was determined based on a survey that CMS conducted of ESRD facilities. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. The 46 percent of Capital-related Building and Equipment expenses is based on regressions run for the inpatient hospital capital PPS (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

Table 1—ESRDB Market Basket Labor-Related Share

| Cost Category | 2008-based ESRDB Labor-Related Share (Percent) |
|----------------------------------|---|
| Wages and Salaries | 26.755% |
| Benefits | 6.754% |
| Housekeeping and Operations | 2.029% |
| All Other Labor-related Services | 1.219% |
| Professional Fees Labor-related | 1.549% |
| Capital Labor-related | 3.431% |
| Total | 41.737% |

In this proposed rule, we are not proposing to make any further changes to the labor-related share since we have not proposed to update the cost weights of the ESRDB market basket. Therefore, we are proposing to continue to use a labor-related share of 41.737 percent for CY 2012 for the ESRDB PPS.

If an ESRD facility elected to transition to the bundled PPS system, then the CY 2012 payment to these providers will be based on a 50/50 blended payment of the composite rate and the ESRD PPS bundled rate. The labor-related share under the composite portion of the blended payment is 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). We propose to continue to use the labor-related share of 53.711 for the ESRD composite rate portion of the ESRD payment for all years of the transition. This labor-related share is consistent

with the mix of labor-related services paid under the composite rate and is consistent with the method finalized in the CY 2011 ESRD PPS final rule (75 FR 49116).

c. Proposed Productivity Adjustment

Section 3401(h) of the Affordable Care Act requires that, in CY 2012 (and in subsequent calendar years), the market basket percentage under the ESRD prospective payment system as described in section 1881(b)(14)(F) of the Act be annually adjusted by changes in economy-wide productivity. Specifically, section 3401(h) of the Affordable Care Act amends section 1881(b)(14)(F)(i) of the Act to add clause (II) which sets forth the application of this productivity adjustment, which is defined 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 Bureau of Labor Statistics (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 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 2 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 2—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>.

During the development of this proposed rule, the BLS published a historical time series of private nonfarm business MFP for 1987 through 2009, with 2009 being a preliminary value. Using this historical MFP series and the IGI forecasted series, IGI has developed a forecast of MFP for 2010 through 2021, as described below.

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the "non-housing, 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 2010 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:"

$$\text{MFP} = \text{Total output growth} - ((\text{labor input growth} * \text{labor compensation share}) + (\text{capital input growth} * \text{capital income share}))$$

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.

d. Multifactor Productivity-Adjusted Market Basket Update

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, the Secretary "shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services". Also, under section 1881(b)(14)(F)(ii)(II), as amended by section 3401(h) of the Affordable Care Act, for years in which the transition of the payment system is applicable, the Affordable Care Act states that the Secretary "shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i)(I)" subject to this factor being reduced by a productivity adjustment beginning in 2012.

As described in section I.C.2.b of this proposed rule, we are proposing to estimate the ESRDB market basket percentage for CY 2012 based on the CY 2008-based ESRDB market basket. Section 3401(h) of the Affordable Care Act amends section 1881(b)(14)(F)(i) of the Act by adding a new clause (II), which requires that after establishing the percentage for a calendar year 2012 (and each subsequent year), "the Secretary shall reduce such percentage by the productivity adjustment described

in section 1886(b)(3)(B)(xi)(II)" (which we refer to as the multifactor productivity adjustment or MFP adjustment).

In order to calculate the MFP-adjusted update for the ESRDB market basket during the transition period, we propose that the MFP percentage adjustment be subtracted from the CY 2012 market basket update calculated using the CY 2008-based ESRDB market basket. We propose 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 ESRDB PPS and the ESRD composite rate 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 propose that the MFP adjustment be calculated as the 10-year moving average of changes in MFP for the period ending December 31, 2012. We propose 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).

The market basket percentage we are proposing for CY 2012 for the ESRDB market basket is based on the 1st quarter 2011 forecast of the CY 2008-based ESRDB market basket update, which is estimated to be 3.0 percent. This market basket percentage would then be 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 MFP-adjusted ESRDB market basket update is equal to 1.8 percent, or 3.0 percent less 1.2 percent. We propose that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the CY 2012 market basket update and MFP adjustment in the CY 2012 ESRD PPS final rule.

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 the number of ESRD facilities that we believed would elect to receive payment under 100 percent ESRD PPS. We explained that 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 also indicated that based on the simulation of estimated payments, a 3.1 percent reduction would be applied to all payment 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 on 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 will respond to comments submitted on the interim final rule in the CY 2012 ESRD PPS final rule.

4. Proposed Transition Budget-Neutrality Adjustment for CY 2012

As we discussed in the background section of this proposed rule, 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." Also, we indicated that instead of using the term "phase-in", we are using the term "transition" to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permits 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 for renal dialysis services provided by ESRD facilities 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 under the basic case-mix adjusted composite payment system portion of the blended rate during the transition to account for the per treatment costs of drugs that are currently 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 the estimated total amount of payments that would otherwise occur without such a transition. In this proposed rule, we are addressing both parts of the transition budget-neutrality adjustment.

For the first part of the transition budget-neutrality adjustment, for CY 2012, we propose to add the \$0.49, which represents the CY 2011 Part D payment amount, to the composite rate portion of the ESRD PPS blended payment. We then propose to apply the ESRDB market basket minus productivity adjustment to the updated composite rate (which includes the \$0.49). Since the composite rate is updated by the ESRDB market basket minus productivity and we are proposing to add the \$0.49 to the composite rate, it would be consistent to use the same update. We believe that 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 discuss the addition of the \$0.49 to the composite portion of the ESRD PPS payment in section I.c.1.a of this proposed rule.

For the first part of the transition budget-neutrality adjustment, we are seeking 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.

For the second part, as described in the CY 2011 ESRD PPS proposed rule (74 FR 49946), to calculate the transition budget-neutrality adjustment, we first determined the estimated increases 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. 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) published in the **Federal Register**, however, we revised 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 0 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 of the transition, we must update the transition budget-neutrality adjustment for CY 2012, the second year of the transition. As discussed in detail below, and in accordance with section 1881(b)(14)(E)(iii) of the Act, that requires an

adjustment to be made to payments so that total payments under the transition equal total payment amounts without such a transition, that results in the reduction of 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 this proposed rule, we are not proposing for CY 2012 to change the methodology used to calculate the second part of the budget-neutrality adjustment. We are, however, proposing to use more updated data.

For CY 2012, we started with 2009 utilization data from claims, as 2009 is the latest complete year of claims data available. We updated the CY 2009 utilization data to CY 2011 and CY 2012 payments by using the price growth factors for CY 2011 and CY 2012, as discussed in the impact analysis in section VII of this proposed rule. We then took the estimated payments under the full CY 2012 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 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

0 percent. Therefore, for CY 2012, we are proposing a 0 percent reduction to all payments made to ESRD facilities (that is, the 0 percent adjustment would be applied to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS) for renal dialysis items and services furnished January 1, 2012 through December 31, 2012. We solicit comments on the proposed second part of CY 2012 transition budget-neutrality adjustment.

5. Proposed Low-Volume Facility Provisions

In the CY 2011 ESRD PPS final rule, we established a low-volume payment adjustment as required by section 1881(b)(14)(D)(iii) of the Act, 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" (75 FR 49117).

We explained in the CY 2011 ESRD PPS final rule (75 FR 49120) that we analyzed the effect of facility size on cost by analyzing the total treatment counts from ESRD facility cost reports for 2006, 2007, and 2008. We used all treatments including non-Medicare treatments from the cost reports because we believe that inclusion of all treatments regardless of payer

type represents the true volume of treatments that an ESRD facility furnishes (75 FR 49122). 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 because we believed that this timeframe provided us with a sufficient span of time to view consistency in business operations through the data (75 FR 49123).

Our analysis showed that when compared to larger facilities, facilities that would be eligible for the low-volume adjustment are more likely to be located in a rural area, less likely to be part of a large dialysis organization (LDO), more likely to be hospital-based, likely to have a somewhat higher percentage of Medicare patients, more likely to be a pediatric facility, more likely to have previously received an isolated essential facility composite rate payment exception, and more likely to concentrate on home dialysis (75 FR 49120).

Under 42 CFR §413.232(b), a low-volume facility is as 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), for purposes of determining the number of treatments furnished by the ESRD facility, the

number of treatments shall be equal to the aggregate number of treatments furnished by the 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 medicare administrative contractor (FI/MAC) that the facility has met 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). The regulation at §413.232 provides the criteria that an ESRD facility must meet to be eligible for the low-volume adjustment and uses the term "payment year." Although we believe the meaning of this term is clear, in response to questions that we received subsequent to the publication of the CY 2011 ESRD PPS final rule demonstrating confusion between the payment year and eligibility year, we are clarifying that the term "payment year" is the period of time that we use for determining payment to ESRD facilities, which is a calendar year. We are also clarifying that the eligibility years means the 3 years preceding the payment year and that the eligibility years are based on cost reporting years. We are

making 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).

In this proposed rule, we also are proposing 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. The attestation is required because: (1) the 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 will need to rely on the attestation for that year. If an ESRD facility believes that it is eligible for the low-volume adjustment, we are proposing that the ESRD facility would be required to submit an attestation to its respective FI/MAC no later than November 1st of each year. This timeframe provides 60 days for a FI/MAC to verify the cost report information and update the systems. For example, for payment year 2012 (January 1, 2012 through December 31, 2012), ESRD facilities that believe they are eligible for the low-

volume adjustment must submit an attestation to their respective FI/MAC no later than November 1, 2011 (with regard to its low-volume status based on services furnished in its cost reporting period ending in 2009, 2010, and 2011).

ESRD facilities that are receiving the low-volume adjustment for the CY 2011 payment year 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. Thus, for an attestation applicable to the 2012 payment year, the ESRD facility would attest that it meets the low-volume facility requirements based on its cost reporting periods ending in 2009, 2010, and 2011. The ESRD facility would 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.

As we indicated above, we propose that attestations be submitted to the FI/MAC no later than November 1 preceding each payment year to allow the FI/MACs time to review the attestation and ensure that accurate payment is made for renal dialysis services provided on or after January 1. We suggest that ESRD facilities submitting a low-volume attestation verify that the attestation has been received by the appropriate FI/MAC prior to the November 1 deadline. In the event that 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.

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.

In this proposed rule, with regard to the deadline for attestation submission, we are proposing to amend the regulation text at §413.232(f) to require an ESRD facility to submit its attestation no later than November 1. This requirement would provide FI/MACs time to review and verify ESRD facilities low-volume eligibility. We are soliciting comment on the proposed regulation text changes at §413.232(f).

Under §413.232(b)(1) and (b)(2), a low-volume facility is defined as an ESRD facility that "furnished less than 4,000 treatments in each of the 3 years preceding the payment year" and "has not opened, closed, or had a change in ownership in the 3 years preceding the payment year" (emphasis added). In response to comments we received subsequent to the CY 2011 ESRD PPS final rule, we are clarifying the meaning of the term "years" in this regulation, with regard to the treatment threshold that determines low-volume eligibility, and how it

relates to the "payment year." We are providing this additional clarification to emphasize because there are ESRD facilities that do not have cost reporting periods that fall on a calendar year period (January 1 through December 31), and there may be confusion about how the eligibility year relates to the payment year. Specifically, we emphasize again that for the purpose of low-volume eligibility, the term "years" refers to cost reporting periods because low-volume eligibility is determined based on the ESRD facility's cost report. For example, an ESRD facility's cost reporting period could span a fiscal year rather than a calendar year. However, the low-volume payment adjustment is paid according to the ESRD PPS payment year (that is, the calendar year). Accordingly, FI/MACs are reviewing the ESRD facility's cost reporting periods ending in the 3 years preceding the payment year for low-volume eligibility, and those cost reporting periods may not necessarily be calendar years (January 1 to December 31).

We believe that it is also important to reiterate that the ESRD facility's cost reports for the cost reporting periods ending in the 3 years immediately preceding the payment year, as discussed above, must report costs for 12-consecutive months. For example, an FI/MAC would 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 would look at its 12-consecutive month cost reports for the cost reporting periods that end in the 3 years immediately preceding the payment year.

We acknowledge that the FI/MAC may not have a final-settled cost report for all 3 years needed to complete the ESRD facility's verification. For example, using a June 30th cost reporting period year end, for purposes of determining low-volume eligibility, the ESRD facility would need to have met the low-volume criteria for their cost reporting periods ending on June 30, 2009, June 30, 2010, and June 30, 2011, to begin to receive the low-volume adjustment January 1, 2012. The FI/MAC should have the ESRD facility's cost reports for 2009 and 2010 and both years should be either final-settled or as-filed (that is, submitted to and accepted by the FI/MAC) and such cost reports should be for 12-consecutive months in each of the 2 years. The facility would be required to submit an attestation for all 3 years, including the third eligibility year because the cost report for that year is not available and no cost report has been submitted.

Therefore, in this rule, we propose to amend the regulations text at §413.232(b)(1) and (b)(2) to clarify the type of year that is used for determining low-volume

eligibility. This change in the regulations text also provides clarification to the ESRD facilities and the FI/MACs 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 are soliciting comment on the proposed changes at §413.232(b)(1) and (b)(2).

Continuing with the example discussed above in which we address an ESRD facility with a cost reporting year that ends on June 30, the ESRD facility attests to its FI/MAC that it met the low-volume criteria for its cost reporting periods ending in 2009 and 2010 and that it expects to meet the low-volume criteria for its cost reporting period ending in 2011. The ESRD facility's cost report for its cost reporting period ending in 2011 is the third year that is needed to meet the criteria specified at §413.232 for purposes of the 2012 payment year. If the FI/MAC receives the ESRD facility's cost report for 2011 and finds that the ESRD facility did not meet the low-volume criteria in its cost reporting period ending on June 30, 2011 (that is, the third eligibility year), the FI/MAC will

discontinue application of the low-volume adjustment to the facility's payments for CY 2012 because the facility was not eligible for the adjustment. 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 will not be eligible for the low-volume adjustment until it can demonstrate again that for 3 years (12-consecutive month cost reporting periods) it met the low-volume criteria.

6. Proposed 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, the application of the wage index, and an update to the composite rate portion of the

ESRD PPS blended payment amount for the second year (CY 2012) of the ESRD PPS. The proposed wage index and composite rate portion of the ESRD PPS blended payment are discussed in sections I.C.7 and I.C.1.a of this proposed rule.

As required under section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system includes 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, in this proposed rule, we are not proposing any changes to the methodology but are merely updating 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.

In order to account for increases in drug prices and utilization, since we now have 5 years of drug expenditure data

based on ASP pricing, for CY 2012, we continue estimating growth in drug expenditures based on the trends in available data. 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). For the CY 2012 PPS final rule, we intend to use additional updated CY 2010 claims with dates of service for the same timeframe. This updated CY 2010 data file will include claims received, processed, paid, and passed to the National Claims History File as of June 30, 2011. While the CY 2010 claims file used in this proposed rule is the most current available, we recognize that it does not reflect a complete year, as claims with dates of service towards the end of the year have not all been processed. To more accurately

estimate the update to the drug add-on, completed aggregate drug expenditures are required.

Next, for CY 2012, based on an analysis of the 2009 claims data, we inflated the CY 2010 drug expenditures to estimate the June 30, 2011 update of the 2010 claims file. We used the relationship between the December 2009 and the June 2010 versions of 2009 claims to estimate the more complete 2010 claims that will be available in June 2011 and applied that ratio to the 2010 claims data from the December 2010 claims file. The net adjustment to the CY 2010 claims data is an increase of 11.62 percent to the 2010 expenditure data. This adjustment allows us to more accurately compare the 2009 and 2010 drug expenditure data to estimate per patient growth.

Using the completed full-year 2010 drug expenditure figure, 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. We used this 1.4 percent increase to project drug expenditures for both 2011 and 2012.

b. Estimating Per Patient Growth

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. 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 is a per-patient growth factor equal to 0.973 ($1.014/1.042 = 0.973$). Thus, we are projecting a 2.7 percent decrease ($2.7\% = .027 = 0.973 - 1$) in per patient growth in drug expenditures between 2011 and 2012.

c. Applying the Proposed 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, for CY 2012, we are again proposing no update to the per treatment drug add-on amount of \$20.33 established in CY 2008.

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

As discussed above, we estimate a 1.4 percent increase in drug expenditures between CY 2011 and CY 2012. Combining this increase with a 4.2 percent increase in enrollment, as described above, we are projecting a 2.7 percent decrease in per patient growth of drug expenditures between CY 2011 and CY 2012.

Therefore, we are projecting 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 2.7 percent decrease to the CY 2011 drug add-on of \$20.33. This would result 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 14.4 percent drug add-on. However, similar to last year and as indicated above, we are proposing a zero update to the drug add-on adjustment. We believe 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 propose to apply a zero update and maintain the \$20.33 per treatment drug add-on amount for CY 2012. We are seeking comment on our proposed zero update to the drug add-on.

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. As discussed in section I.c.2.b of this proposed rule, section 1881(b)(14)(F) of the Act requires that an ESRDB market basket minus productivity adjustment be used to update the composite rate portion of the ESRD PPS payment (forecast of 1.8 percent in 2012 effective January 1, 2012), resulting in a decrease to the CY 2012 drug add-on adjustment from 14.7 to 14.4 percent 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 proposed 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 proposing a drug add-on adjustment to the composite rate for CY 2012 of 14.4 percent.

7. Updates to the Wage Index Values and Wage Index Floor For the Composite Portion of the ESRD PPS Blended Payment and Under 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 in the index referred to in section 1881(b)(12)(D), as the Secretary determines appropriate. 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 Office of Management and Budget's (OMB's) Core Based Statistical Area (CBSA)-based geographic area designations to define urban/rural areas and corresponding wage index values. 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 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. We wish to point out that this and all subsequent 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 have adopted a wage index floor during the transition, though as we previously noted, we intend to gradually reduce the ESRD wage index floor (75 FR 49117, 75 FR 73486). We also use the labor-related share for both the ESRD PPS and the composite rate portion of the blend, as measured by the ESRDB market basket (see section I.c.2.b of this proposed rule). 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 rural definitions and corresponding wage index values.

With regard to the transition, as we noted in the CY 2011 PFS final rule (75 FR 40163), because ESRD facilities could elect to receive a blended payment during the transition, we would continue to update the composite rate portion of the ESRD PPS blended payment, including adjusting payments for geographic differences in area wage levels, as noted above. We also discussed the application of the wage index budget-neutrality adjustment factor to the area wage index values for the composite rate portion of the ESRD PPS blended payment. In this proposed rule, we are not proposing any changes to the methodology for the wage index used to adjust the composite rate portion of the ESRD PPS blended payment. However, we are proposing 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.

In addition, in this proposed rule, we are not proposing 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). However, we are proposing a wage index budget-neutrality adjustment factor to be applied in CY 2012 and in

subsequent years for the ESRD PPS which is discussed in detail below.

a. Proposed Reduction to the ESRD Wage Index Floor

In the CY 2011 ESRD PPS final rule, we stated our intention to continue to reassess the need for a wage index floor (75 FR 49117). The wage index floor for CY 2011 is 0.600. For CY 2012 and CY 2013, we propose 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). The ESRD wage index floor value of 0.550 would be applied to areas that are below the proposed wage index floor of 0.550. Beginning January 1, 2014, we propose that the wage index floor would no longer be applied because the wage index floor would be equal to or lower than areas with low wage index values. 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.

b. Proposed Policies for Areas With no Hospital Data

In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the same methodology we have used for areas with no hospital data in the past, that is, we compute the average wage

index value of all urban areas within the State and use that value as the wage index. In this proposed rule, we are not proposing to change the methodology that we have used in the past to compute a wage index value for areas with no hospital data

We are for CY 2012 and for future years, proposing to continue to use the methodology we adopted for identifying the small number of ESRD facilities in both urban and rural geographic areas where there are no hospital wage data from which to calculate ESRD wage index values that we have used for CYs 2006 through 2010 under the composite payment system and for CY 2011 and which we described in the ESRD PPS final rule (75 FR 49116). Thus far, we note the following affected areas: rural Puerto Rico, Yuba, CA (CBSA 49700) and the urban area Hinesville-Fort Stewart, GA (CBSA 25980).

For rural Puerto Rico, because all wage index values in Puerto Rico are below the wage index floor, we previously used the wage index floor as the wage index value for Puerto Rico. For CY 2012 and CY 2013, we propose to continue to use the methodology we have previously used for computing the wage index for Puerto Rico, that is, use the ESRD wage index floor.

c. Proposed Wage Index Budget-Neutrality Adjustment

As noted above, 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 adjustment payment system as an example. We have previously interpreted the statute for the prior 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 (for purposes of the ESRD PPS geographic payment adjustment under section 1881(b)(14)(D)(iv)(II) of the Act), we propose to apply the wage index in a budget-neutral manner under the ESRD PPS using a wage budget-neutrality adjustment factor. However, as we discuss in greater detail below, with regard to the application of the wage index budget-neutrality adjustment factor, we are proposing that under the ESRD PPS, we would apply a 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 transition, we are not proposing to change the application of the wage index budget-neutrality adjustment to the wage index of the composite rate portion of the ESRD PPS blended payment, because we do not believe that we should make changes to the methodology for updating the composite rate portion of the ESRD PPS blended payment as the composite rate portion of the blended payment will no longer apply after the transition ends in CY 2014. We believe 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 that they are accustomed to and one that may have been the basis for facilities electing to receive a blended payment during the transition. However, under the ESRD PPS, we believe by applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate, we would be consistent with the application of the wage index budget-neutrality adjustment factor in other prospective payment systems. We also believe 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 are seeking 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 ESRD PPS payments during the transition.

As discussed above, we are not proposing any changes to the wage index budget-neutrality adjustment factor application for the composite rate portion of the ESRD PPS payment. We would continue to apply the wage-index budget-neutrality adjustment factor directly to the ESRD wage index values for the composite rate portion of the ESRD PPS 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 portion of the composite rate portion of the ESRD PPS 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).

As we discussed above, in CY 2012, we are proposing to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate. That is, the wage index budget-neutrality adjustment factor, which includes 41.737 percent labor portion

of the ESRD PPS payment rate.

To compute the proposed CY 2012 wage index budget-neutrality adjustment factors, we used 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 Web page on the CMS Website 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 Website at <http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp>. The wage index data are located in the section entitled, "FY 2012 Proposed Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA."

For this proposed rule, using treatment counts from the 2009 claims and facility-specific CY 2011 payment rates, we computed the estimated total dollar amount each ESRD provider 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 proposed 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. One factor would be applied to the ESRD PPS base rate. The second factor would be applied to the wage index value for the composite rate portion of the ESRD PPS payment. Therefore, in this proposed rule, for CY 2012, we are proposing a wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment of 1.002096, which would be 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 proposing to apply a wage index budget-neutrality adjustment factor of 1.001126 to the ESRD PPS base rate.

Because we are proposing to apply the wage index budget-neutrality adjustment factor to the wage index values to ensure budget-neutrality under the composite rate portion of the ESRD PPS blended payment, we also applied the wage index budget-neutrality adjustment factor to the wage index floor of 0.550

which results in an adjusted wage index floor of 0.551(0.550 x 1.002096) for CY 2012.

d. ESRD PPS Wage Index Tables

The CY 2012 ESRD proposed 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 Website 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 portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied. Another 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 are proposing to 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, therefore, 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 drugs or biologicals used for the treatment ESRD-related conditions would be considered a renal dialysis service and, therefore, not eligible for separate payment. This policy also applies to any drug or biological that may be developed in the future.

Since the publication of the CY 2011 ESRD PPS final rule, we received numerous comments indicating that Vancomycin is indicated for both ESRD and non-ESRD conditions, such as skin infections. After consultation with our medical experts, we concur with our commenters. Therefore, in this proposed rule, we are proposing 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 note 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 are soliciting 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.

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 which includes 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 have 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 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).

This Part B provision applies under the ESRD PPS. ESRD facilities receiving blended payments under the ESRD PPS transition will 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 based on ASP. Therefore, ESRD facilities may only report units and charges for drugs or biologicals actually purchased.

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

Section 1881(b)(14)(D)(i) of the Act requires that 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 CY 2017 ESRD PPS final rule, 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 (75 FR 49089 through 49090). 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 (1.02).

In this proposed rule, we are proposing 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 for those dialysis facilities that undergo the transition. We believe this change is necessary because we believe that the BSA national average used to compute payment under the composite portion of the ESRD PPS blended rate and under the ESRD PPS should be both the most recent and consistent measurement available. For CY 2011, the BSA adjustment we calculated for the composite rate portion of the ESRD PPS blended rate 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 reflects the 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. We are proposing that for CY 2012 and in subsequent years, to use one national average for computing the BSA under the composite 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. If, for

example, 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 used for the CY 2011 ESRD PPS BSA computation using 1.87 would yield a BSA adjustment factor of 1.0258, or 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 ages 18 and older by increasing the BSA reference value from 1.84 to 1.87.

The impact on facility payments of increasing the composite rate BSA reference value from 1.84 to 1.87 is shown in Table 3 for each year from 2011 to 2014. These results apply only to dialysis facilities that go through the transition. The impact on facility payments would have been greatest in 2011, where the blended payment during the transition period was weighted more heavily towards the composite rate/separately billable system, and declines through 2014 when there is no impact on facility payments under a fully implemented expanded PPS.

The impact on the average payment in 2012 was calculated as $-0.0108 * 0.9979 * 0.6498 * 0.50 = -0.350$ percent. That is, the average facility payment for those facilities electing the ESRD PPS transition would be reduced by approximately 0.35 percent in 2012. We derived the -0.350 percent reduction from the

following factors: the estimated reduction in BSA multipliers due to the increase in the BSA reference value (-0.0108); the proportion of patients 18 and older (0.9979); the percentage of composite rate and separately billable payments that are composite rate payments (0.6498); and the percentage of composite rate payments in CY 2012 (0.50). This reduction only applies to those ESRD facilities that elected to receive blended payments during the transition.

Table 3
Impact on average facility payments of increasing the composite rate BSA reference value from 1.84 to 1.87

| Year | CR/SB portion of total facility payments during transition period | Change in average facility payment |
|-------------|--|---|
| 2011 | 0.75 | -0.525% |
| 2012 | 0.50 | -0.350% |
| 2013 | 0.25 | -0.175% |
| 2014 | 0.00 | 0.000% |

Therefore, we are proposing for CY 2012, 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 ESRD PPS blended payment and for the ESRD PPS. We are also proposing that we will review the BSAs on CY 2012 claims (and every 5 years thereafter) to determine if any adjustments to the national average will be required in the future. We are seeking comments on the proposal to use one national BSA average to compute the BSA under the composite

portion of the ESRD PPS blended payment and under the ESRD PPS. We are also seeking comment on the proposal to review CY 2012 ESRD claims and every 5 years thereafter, to determine if a change to the BSA national average is warranted.

10. Proposed 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) MAP 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. Proposed 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. These drugs are classified under the categories of anemia management, antiemetics, anxiolytics, bone and mineral metabolism, cellular management, pain management, and anti-infectives (see Pub. 100-04, Chapter 8, section 60.2.1.1). Attachment 3 also identified 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.

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 have since concluded that any CMS prepared lists of drugs and biologicals recognized as outlier services may be difficult to keep up-to-date. This is attributed to the lag in the receipt of claims data; changes in ESRD practice patterns; and inadvertent omissions and oversights. Because of the number of Part B drugs and biologicals that may be considered ESRD outlier services, we are proposing to eliminate the issuance of a list of former separately payable Part B drugs and biologicals that would be eligible for outlier payments.

Medicare regulations at §413.237(a)(1)(i) and (iv) specify that any ESRD-related drug or biological furnished by an ESRD facility that was or would have been considered separately

billable under Part B or formerly covered under Part D prior to January 1, 2011, is an ESRD outlier service, excluding ESRD-related oral-only drugs. 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. In addition, 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 note 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 for ESRD outlier services.

Under current policy, antibiotics furnished in the home are considered to be composite rate drugs and therefore, not eligible for outlier payment. As discussed above, 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 were considered separately payable in accordance the Medicare Claims Processing Manual, Pub. 100-04, chapter 8, section 60.2.1.1.

In addition, 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 will not pay any entity or supplier other than ESRD facilities for covered items and services furnished to a Medicare beneficiary. Therefore, payment to medical equipment suppliers for antibiotics under Method II could 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, we do not believe that it is 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 ESRD PPS 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. Consequently, we are proposing 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 ESRD PPS blended payment for ESRD facilities receiving payment during the transition. We are also proposing that antibiotic drugs used at home to treat catheter site infections or peritonitis associated with peritoneal dialysis will qualify as separately billable and eligible as ESRD outlier services. Antibiotics furnished in facility would continue to be recognized as separately billable for ESRD outlier payment purposes.

We are soliciting comments on our proposal to recognize

antibiotics furnished in the home for catheter infections or peritonitis as ESRD outlier services and eligible for outlier payment. As we indicated above, we would no longer issue a list of ESRD-related drugs and biologicals eligible for outlier payments. However, under separate administrative issuances, 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. We believe that the elimination of a list of certain ESRD outlier services drugs we mentioned above and the inclusion of antibiotics used by home dialysis patients as outlier services would 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.

Accordingly, we are soliciting 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.

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 are 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.

We are also proposing two modifications to the computation of the separately billable MAP amounts used to calculate outlier payments for the reasons described below. 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. As discussed in the ESRD Benefit Policy Manual, Pub. 100-02, chapter 11, section 30.4.1, drugs that are 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, as a composite rate drug, could be used for access management, any drug or biological used for the same purpose may not be separately paid. As 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 have recalculated the average outlier services MAP amounts to exclude these composite rate drugs.

In developing the outlier service MAP amounts for 2011, we excluded testosterone and anabolic steroids. We have 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 outlier eligible drugs 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 4, 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 increase to the outlier service MAP amounts by \$2.21 for adult patients and a decrease of \$4.58 for pediatric patients.

b. Proposed 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 3-year 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 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 payment rate, then all submitted tests are included within the composite payment and, therefore, no 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.

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 as an ESRD outlier service 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 for an outlier payment are determined by the 50 percent rule, we believe that in the interests of administrative simplification and to minimize confusion, we propose to eliminate use of the 50 percent rule for the outlier policy and exclude the 23 AMCC laboratory tests, from the definition of eligible outlier services and from the computation of outlier payments. The elimination of the 50 percent rule for the ESRD PPS outlier payment policy with respect to the AMCC panel tests would result in the de facto treatment of those tests as composite rate tests. Accordingly, we propose to revise §413.237(a)(1)(ii) of the regulations accordingly to exclude these laboratory tests from the definition of ESRD outlier services. The 50 percent rule would continue to apply 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 which have elected to receive payments under the ESRD PPS blended rate. Because the transition period under the ESRD PPS ends on January 1, 2014, this provision would be time limited, and would expire when the transition period ends. This would occur because all ESRD payments would be under the ESRD PPS, there would no longer be a need to maintain the distinction between composite rate and separately billable laboratory services for application of the 50 percent rule, because the transition period will have ended. We are seeking comment on our proposal to exclude the AMCC laboratory tests and the 50 percent rule from the definition of eligible ESRD outlier services.

c. Impact of Proposed Changes to the Outlier Policy

Table 4 shows the impact of modifying the ESRD PPS outlier payment policy 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. The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect projected 2011 prices for outlier services for the first three columns (that is, outlier policy based on the current definition for ESRD outlier services, the revised ESRD outlier services

definition with regard to drugs, and the revised ESRD outlier services definition plus the exclusion of the AMCC laboratory tests). The revised ESRD outlier services definitions are described in the first footnote to Table 4. For the last column, which describes the impact of the revised ESRD outlier services definition and the exclusion of the AMCC laboratory tests for CY 2012, the outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect projected 2012 prices for outlier services.

Table 4

Outlier policy: Impact of revising the ESRD outlier services definition and excluding separately billable AMCC laboratory tests[^]

| | Outlier policy based on current definition for ESRD outlier services, price inflated to 2011* | | Revise ESRD outlier services definition, price inflated to 2011* | | Revise ESRD outlier services definition and exclude AMCC lab tests, price inflated to 2011* | | Revise ESRD outlier services definition and exclude AMCC lab tests, price inflated to 2012** | |
|---|---|-----------|--|-----------|---|-----------|--|-----------|
| | Age < 18 | Age >= 18 | Age < 18 | Age >= 18 | Age < 18 | Age >= 18 | Age < 18 | Age >= 18 |
| Average outlier services MAP amount per treatment ¹ | \$50.85 | \$85.62 | \$45.14 | \$84.71 | \$44.67 | \$84.40 | \$46.27 | \$87.83 |
| Adjustments | | | | | | | | |
| Standardization for outlier services ² | 1.0136 | 0.9728 | 1.0136 | 0.9728 | 1.0136 | 0.9728 | 1.0136 | 0.9728 |
| MIPPA reduction | 0.98 | 0.98 | 0.98 | 0.98 | 0.98 | 0.98 | 0.98 | 0.98 |
| Adjusted average outlier services MAP amount ³ | \$50.51 | \$81.62 | \$44.84 | \$80.75 | \$44.37 | \$80.46 | \$45.96 | \$83.73 |
| Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold ⁴ | \$113.99 | \$139.20 | \$77.72 | \$136.93 | \$77.60 | \$136.88 | \$82.58 | \$145.25 |
| Patient months qualifying for outlier payment | 3.9% | 5.6% | 5.0% | 5.6% | 5.1% | 5.6% | 5.0% | 5.5% |

[^] The revised ESRD outlier services definition 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 2011 prices for outlier services.

** The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect projected 2012 prices for outlier services.

¹Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts are based on 2009 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.

²Applied to the average outlier MAP per treatment. Standardization for outlier services is based on existing Case Mix Adjusters for adult and pediatric patient groups.

³This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.

⁴The fixed dollar loss amounts were calculated using 2009 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

Based on these proposals, using the average outlier service MAP amount per treatment which is based on payment amounts reported on 2009 claims and adjusted to reflect projected prices for 2011, in CY 2012, the average outlier services MAP per treatment amounts would be increased from \$85.62 to \$87.83 for adult patients and a reduction from \$50.85 to \$46.27 for pediatric patients. The primary reason for the difference in directionality of the changes is that there are differences in the types of outlier services that tend to be used by each age group. In particular, the exclusion of vascular access management drugs from the ESRD outlier services definition leads to a much larger decrease in the outlier services MAP amounts for ages <18 (decrease from \$50.85 to \$45.14) versus ages 18 and older (decrease from \$85.62 to \$84.71). This reflects relatively greater use of separately billable vascular access management drugs among ages <18. Unlike ages 18 and older, the decrease in the outlier services MAP for ages <18 when excluding

these drugs is large enough to more than offset the increase that results in the last step when we adjust for 2012 price inflation.

Similarly, the fixed dollar loss amounts which were added to the predicted MAP amounts per treatment to determine the outlier thresholds would be revised from \$139.20 to \$145.25 for adult patients and from \$113.99 to \$82.58 for pediatric patients. We estimate that the patient months qualifying for outlier payments under the current policy (5.6 percent of those adult patient facility months and 3.9 percent of the pediatric patient facility months previously estimated to be eligible for outlier payments), would remain approximately the same for adult patients (5.5 percent), but would increase for pediatric patients (5.0 percent) in CY 2012 under our proposed revised outlier payment policy.

The variation seen in the pediatric fixed dollar loss amounts tend to be lower based on the 2009 data used for this proposed rule as compared with the 2007 data used in CY 2011. There is generally greater sensitivity in pediatric results due to the relatively small number of pediatric patients. This is even more true 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 much lower pediatric fixed

dollar loss amounts based on data from 2009 (as compared with 2007), reflect the tendency to have less extreme high cost cases for pediatric patients in the 2009 claims. The expected result based on this update is that more pediatric claims will qualify for outlier payments based on 2009 data, but the average outlier payment among the pediatric outlier cases will be lower.

With the exception of the proposed revisions to the average outlier services MAP amounts per treatment and changes in the fixed dollar loss amounts, as set forth in Table 4, we are not proposing to make any other changes to the methodology for the calculation of outlier payments. These proposed revisions would only affect the ESRD PPS portion of the blended payment, not the basic case-mix adjusted portion. Because of the limited 3-year period in which the basic case-mix adjusted portion of the blended payment amount will apply, the 50 percent rule would automatically expire when the fully implemented ESRD PPS applies to all facilities. We believe the proposed changes to our outlier payment policy would simplify the identification and reporting of eligible outlier services.

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. We inadvertently listed an incorrect

training add-on amount of \$33.38. The correct training add-on amount is \$33.44. Therefore, in this proposed rule, we are correcting the training add-on amount to \$33.44 for costs associated with self-dialysis training on or after January 1, 2011. The geographic wage index will be 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.

2. ESRD-Related Laboratory Test

In the CY 2011 ESRD PPS final rule (Table F: ESRD-Related Laboratory Tests of the Appendix), we finalized a specific list of routine ESRD-related laboratory tests included as part of consolidated billing (75 FR 49213). However, we inadvertently omitted an ESRD-related laboratory test from Table F of the CY 2011 ESRD PPS final rule. In this proposed rule, we are correcting Table F by adding the "Assay of protein by other source," which is identified by the Current Procedural Terminology code 84157. This laboratory tests 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 through the ESRD PPS

payment rate.

E. Clarifications to the CY 2011 ESRD PPS

1. ICD-9-CM Diagnosis Codes

In the CY 2011 ESRD PPS final rule, we discussed the ICD-9-CM diagnosis codes that are eligible for the co-morbidity payment adjustments (75 FR 49094 through 49107). We explained that it is important for ESRD facilities to report all patient co-morbidities accurately, regardless of whether or not these codes are or are not eligible for an ESRD PPS adjustment. We stated that the ICD-9-CM diagnosis codes should be reported in compliance with coding requirements on the ESRD 72x claim as well as the official ICD-9-CM Coding Guidelines (75 FR 49095).

In the CY 2011 ESRD PPS final rule, 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 (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.

In this proposed rule, we are clarifying 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. 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 response to comments we have received, we believe that it is important to reiterate the discussion of co-morbidities that was detailed in the CY 2011 ESRD PPS final rule. ESRD facilities should continue to provide documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment as this is a requirement to receive the co-morbidity payment adjustment (75 FR 49097). As we discussed in the CY 2011 ESRD PPS final rule, we have been and will continue to monitor the prevalence of any co-morbidity diagnoses recognized for the co-morbidity payment adjustment 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 (75 FR 49099). We are monitoring the co-morbidities eligible for payment adjustment to determine if the co-morbidity adjustments need to be refined in future rulemaking.

2. Emergency Services to ESRD Beneficiaries

As we explained in the CY 2011 ESRD PPS final rule (75 FR

49056), 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), 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 rate payment system, is no longer made to entities (such as laboratories and DME suppliers)

other than the ESRD facility.

Subsequent to the publication of the CY 2011 ESRD PPS final rule, we have 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 are providing additional clarification below.

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 recognize 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 reasons other than ESRD (that is, as part of the assessment of the patient to obtain a diagnosis of the underlying condition which required emergency intervention). For example, an ESRD beneficiary in an emergency department because the beneficiary is unconscious or otherwise in crisis may have a CBC and other laboratory tests ordered to arrive at a diagnosis. Although such tests also may 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 do 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 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 this 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.

The exclusion of laboratory tests ordered in hospital emergency rooms or emergency departments from the consolidated billing edits does 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 ESRD-related laboratory tests, referring ESRD patients to the emergency room or emergency department for ESRD-related laboratory tests would be inappropriate. We note 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) or the administration of ESRD-related drugs that are considered renal dialysis services under the ESRD PPS. We are monitoring the provision of renal dialysis services to ESRD patients in an emergency room or emergency department.

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

1. Overview of Quality Monitoring Initiatives

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. We view the ESRD Quality Incentive Program (QIP), required by section 1881(h) of the Social Security Act (the Act), as the next step in the evolution of the ESRD quality program that began more than three decades ago. Our vision is to continue to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established. The payment year (PY) 2012 ESRD QIP was finalized in two regulations: one that finalized the three 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, including the scoring methodology and payment reduction scale (76 FR 628 through 646) (hereinafter referred to as the "2012 ESRD QIP final rule").

2. Statutory Authority for the ESRD QIP

Section 1881(h) of the Act, as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established for certain specified measures. As provided under this section, payment

reductions of up to 2.0 percent of the payments otherwise made to providers and facilities under section 1881(b)(14) of the Act will apply to payment for renal dialysis services furnished on or after January 1, 2012. Under section 1881(h)(1)(C) of the Act, payment reductions will only apply with respect to the year involved for a provider/facility and will not be taken into account when computing future payment rates for the impacted provider/facility.

For the ESRD QIP, section 1881(h) of the Act generally requires the Secretary to: (1) select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures for a performance period; and (5) apply an appropriate payment reduction to providers and facilities that do not meet or exceed the established total performance score.

3. Payment Year (PY) 2012 ESRD QIP

As required by section 1881(h)(2)(A)(i) of the Act, we selected three measures for the payment year (PY) 2012 QIP. We finalized two anemia management measures that reflect the labeling approved by the Food and Drug Administration (FDA) for the administration of erythropoiesis stimulating agents (ESAs)

and one hemodialysis adequacy measure. 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 <10.0g/dL (Hemoglobin Less Than 10g/dL Measure)
- Percentage of Medicare patients with an average Hemoglobin >12.0g/dL (Hemoglobin Greater Than 12g/dL Measure)
- Percentage of Medicare patients with an average Urea Reduction Ratio (URR) \geq 65 percent (URR Hemodialysis Adequacy Measure).

A full description of the methodologies used for the calculation of the measures can be reviewed at:

www.dialysisreports.org/pdf/esrd/public/DFRGuide.pdf (see the "Facility Modality, Hemoglobin, and Urea Reduction Ratio" section of the document).

Other aspects of the PY 2012 ESRD QIP finalized in the PY 2012 ESRD QIP final rule included 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 10g/dL Measure at 50 percent of the score, while the other hemoglobin measure and the URR Hemodialysis Adequacy Measure were 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. Provisions of the Proposed Regulations for End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2013 and PY 2014

This proposed rule proposes to adopt new ESRD QIP requirements for payment years (PYs) 2013 and 2014. We believe that this approach is the most efficient way to make improvements to the program, adopt additional measures for the program in a timely fashion, and provide sufficient notice to ESRD providers and facilities so that they can most effectively and efficiently implement any changes needed to meet the requirements of the ESRD QIP.

1. Proposed PY 2013 ESRD QIP Requirements

a. Overview of the Proposed PY 2013 ESRD QIP

This section summarizes the requirements that we are proposing implement for the PY 2013 ESRD QIP. We are proposing that ESRD providers and facilities that do not meet these

requirements would receive a reduction 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. In general, for the PY 2013 ESRD QIP, we propose to calculate individual total performance scores ranging from 0-30 points for providers and facilities based on two of the three measures that we adopted for the PY 2012 ESRD QIP. We propose to weight the total performance score for each provider/facility such that the proposed Hemoglobin Greater Than 12g/dL measure makes up 50 percent of the total performance score and the proposed URR Hemodialysis Adequacy measure makes up 50 percent of the total performance score. We are proposing that a provider/facility that does not meet or exceed a total performance score of 30 would receive a payment reduction in PY 2013 ranging from 0.5 percent to 2.0 percent, depending upon how far below this minimum total performance score its performance falls. Our specific proposals are discussed below.

b. Proposed 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 for maximizing the placement of arterial venous fistula. As explained in detail below, we are proposing to adopt a number of new measures for the PY 2014 ESRD QIP, including a Kt/V measure, a vascular access infections measure, a vascular access type measure, a Standardized Hospitalization Ratio (SHR) Admissions measure, a patient experience of care reporting measure, a bone mineral metabolism reporting measure, and a NHSN dialysis event blood stream infection reporting measure. We are also continuing to develop additional measures on topics such as fluid weight management and pediatric ESRD treatment. However, 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), and that it is not feasible to adopt any of the measures mentioned above until the PY 2014 ESRD QIP, we have determined that there are no new measures available for adoption at this time.

We also carefully reexamined the three measures that we adopted for the 2012 ESRD QIP, and for the reasons discussed below, we are proposing to continue including only two of them, the Hemoglobin Greater Than 12g/dL measure and the URR Hemodialysis Adequacy measure, in the PY 2013 ESRD QIP measure

set. We are proposing to retire the Hemoglobin Less Than 10g/dL measure beginning with the PY 2013 ESRD QIP.

We have recently reassessed the evidence for the use of 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. We found that randomized, controlled trials targeting patients to higher, rather than lower hemoglobin levels, or comparing the effect of ESAs against a placebo have indicated 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. The mechanism underlying this increased risk is not yet fully understood but could result from the actual hemoglobin level itself, the rate at which the hemoglobin level rises, the variability in hemoglobin levels achieved as a result of ESA use, or the ESA dose required. Regardless of the reason(s) for these risks, such findings indicate that safety is a valid concern for a subset of patients treated with ESAs. Because we cannot yet identify which patients would be included in this subset, and accordingly exclude them from the specifications for the Hemoglobin Less Than 10g/dL measure, we have concluded that

it would not be appropriate to continue to incentivize ESRD providers and facilities to achieve hemoglobin levels above 10g/dL in all patients. In addition we believe that this change is reflective of the FDA modified dosing recommendation for erythropoiesis stimulating agents (<http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>). We have discussed with the FDA our proposal to retire the Hemoglobin Greater Than 10 g/dL measure starting in PY 2013. Since this measure encourages providers to keep hemoglobin above 10 g/dL in all patients, the FDA agrees that removing this measure is consistent with the new labeling for erythropoiesis stimulating agents approved by the FDA. The previous labeling recommendations to maintain hemoglobin levels between 10 and 12 g/dL are no longer appropriate and have been removed from the drug label. We, therefore, propose to retire the Hemoglobin Less Than 10g/dL measure from the ESRD QIP measure set, beginning with the PY 2013 program.

We propose to maintain the Hemoglobin Greater Than 12g/dL measure as a measure of anemia management because studies have been unable to establish that higher hemoglobin levels are clinically beneficial. In addition, the studies continue to show that targeting hemoglobin levels above this level through the use of ESAs can contribute to adverse patient outcomes.¹ This measure, consistent with the requirement under section

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).

1881(h)(2)(A)(i) of the Act, also continues to reflect the labeling approved by the FDA for anemia management. The FDA has stated that using ESAs to target a hemoglobin level of greater than 11g/dL increases the risk of serious adverse cardiovascular events and has not been shown to provide additional patient benefit. The Hemoglobin Greater Than 12g/dL measure focuses on achieved hemoglobin levels, not simply hemoglobin level targets, and these levels also reflect patient factors such as underlying causes of anemia and sensitivity to treatment. Since these factors can vary over time in an unpredictable fashion, even within an individual patient, we believe that the current anemia measure allows for these unanticipated excursions of the *achieved* hemoglobin while continuing to highlight that higher hemoglobin targets can result in adverse patient outcomes. We plan to revisit this measure with the input of stakeholders and will replace or update the measure for future years of the ESRD QIP if deemed appropriate. We seek public input on the continued inclusion of the Hemoglobin Greater Than 12g/dL measure in the PY 2013 ESRD QIP.

We are also proposing to retain the URR Hemodialysis Adequacy measure, which assesses the percentage of Medicare patients with an average URR > 65 percent for PY 2013. Section 1881(h)(2)(A)(i) states that the measures specified under the ESRD QIP for a payment year shall include measures on dialysis

adequacy. For the reasons stated in the CY 2011 ESRD PPS final rule (75 FR 49182) we believe that URR hemodialysis adequacy continues to be an appropriate and accurate measure of hemodialysis adequacy, although we note that we are proposing below to adopt an alternative measure of dialysis adequacy for the PY 2014 ESRD QIP.

Therefore, for the PY 2013 ESRD QIP, we propose to continue to use the following two measures previously adopted for the PY 2012 ESRD QIP:

- Hemoglobin Greater Than 12g/dL Measure.
- URR Hemodialysis Adequacy Measure.

We also propose to continue to use the specifications for these measures that we finalized for the PY 2012 ESRD QIP. Consistent with the PY 2012 ESRD, we are also proposing to require providers/facilities to have at least 11 cases that meet the reporting criteria for a measure in order to be scored on the measure. As we noted in the 2012 ESRD QIP final rule (76 FR 639), we believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skews a small provider/facility's performance score. Additionally, eleven cases is a statistically valid threshold that will give us confidence that a provider or facility's total

performance score is an accurate reflection of the quality of care it furnishes.

We seek public comments on our proposed selection of these two measures for the PY 2013 ESRD QIP.

c. Proposed Performance Period 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. We selected all of CY 2010 as the performance period for the PY 2012 ESRD QIP because we believe that it best balanced the need to collect and analyze sufficient data, allowed sufficient time to calculate total performance scores and prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012, and allowed providers and facilities time to preview their performance scores and inquire about their scores prior to finalizing their scores and making performance data public (76 FR 631).

In determining what performance period to propose to select for the PY 2013 ESRD QIP, we carefully considered the impact of selecting all or part of CY 2011 as well as including part of CY 2012. We determined that using less than a 12-month period could reduce the validity of provider/facility performance data and that using data from multiple calendar years (and still making payments on time) would necessitate using data from

multiple data sets collected over two different payment periods, and, therefore, would not provide sufficient time to compile the data files to make accurate provider/facility payments beginning with January 1, 2013 services. 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 a year's worth of data will provide us with enough data to accurately and fairly determine whether a provider/facility has met or exceeded the proposed performance standards with respect to the proposed measures. For these reasons, we propose to select all of CY 2011 as the performance period for the PY 2013 ESRD QIP. We seek public comments on this proposal.

d. Proposed Performance Standards for the PY 2013 ESRD QIP

For the PY 2012 ESRD QIP, we established the performance standard for the measures using the special rule under section 1881(h)(4)(E) of the Act (76 FR 629). We selected as the performance standard for PY 2012 the lesser of (1) the performance of a provider or facility on each measure during 2007 (the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii) of the Act, referred to as the base utilization year), or (2) the national performance rate (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) for each measure in a period determined by the Secretary. With respect to the second prong of this standard, the period we selected for the PY 2012 ESRD QIP was calendar year 2008 because data from that year was, at that time, the most recent publicly available data prior to the beginning of the performance period. As reported on the Dialysis Facility Compare website in November 2009, the 2008 national performance rates for the anemia management measures and the URR hemodialysis adequacy measure were:

- For the Hemoglobin Less Than 10g/dL measure (which is based on the national performance percentage of Medicare patients who have an average hemoglobin value less than 10g/dL): 2 percent.
- For the Hemoglobin More Than 12g/dL measure (which is based on the national performance percentage of Medicare patients who have an average hemoglobin value greater than 12g/dL): 26 percent.
- For the URR Hemodialysis Adequacy Measure (which is based on the national percentage of Medicare patients who have an average URR level of at least 65 percent): 96 percent.

In considering what performance standards to select for the PY 2013 ESRD QIP, we took into account the fact that we had selected a one year period for the PY 2012 ESRD QIP and that for

the reasons discussed above, we would be proposing to select the next one year performance period for the PY 2013 ESRD QIP. We determined 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. We also noted that due to operational issues, it was not feasible for us to establish performance standards prior to the beginning of the proposed performance period, as required in order to establish performance standards under section 1881(h)(4)(A) of the Act. For these reasons, we propose to continue using the performance standard under section 1881(h)(4)(E) of the Act for the PY 2013 QIP. Under this proposed 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. With respect to the second prong, we propose to select CY 2009 because that is the most recent year-long period for which data is publicly available prior to the beginning of the proposed performance period. As reported on the Dialysis Facility Compare website, the 2009 national performance rates for the Hemoglobin Greater Than 12g/dL measure

and the URR Hemodialysis Adequacy measure are:

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

We seek public comments about the proposed selection of this performance standard for the PY 2013 ESRD QIP.

e. Proposed Methodology for Calculating the Total Performance Score 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 will calculate the performance of each provider and facility on each of the three measures by assigning 0-10 points based on how well the provider/facility

performed on the measure during the CY 2010 performance period. For example, if a provider or facility meets or exceeds the performance standard for one measure, then it will receive 10 points for that measure. Providers or facilities that do not meet or exceed the performance standard for a measure will receive fewer than 10 points for that measure, with the exact number of points corresponding to how far below the performance standard the provider/facility's actual performance falls. Two points will be subtracted for every one percentage point the provider's/facility's performance falls below the performance standard (76 FR 632). 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 propose to adopt the same methodology for scoring provider/facility performance on each of the proposed measures that we adopted for the PY 2012 ESRD QIP. As discussed in the 2012 ESRD QIP final rule (76 FR 633), 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. Under this methodology, we would 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 or

exceeds the performance standard for a measure, then it would receive 10 points for that 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 during 2011, the proposed performance period, falls below the performance standard.

For the PY 2012 ESRD QIP, we also finalized a weighting methodology that weighted the Hemoglobin Less Than 10g/dL measure at 50 percent of the total performance score, with the remaining 50 percent of the total performance score divided equally between the Hemoglobin Greater Than 12g/dL measure (25 percent) and the URR Hemodialysis Adequacy Measure (25 percent) (76 FR 633).

For the PY 2013 ESRD QIP, we are proposing to weight the total performance score for each provider/facility such that the proposed Hemoglobin Greater Than 12g/dL measure makes up 50 percent of the score and the proposed URR Hemodialysis Adequacy measure makes up 50 percent of the score. To be consistent with the scoring methodology that we finalized for the PY 2012 ESRD QIP, we propose award up to 30 points to a provider/facility based on its performance on the proposed measures. However, because we are only proposing to adopt two measures for the PY 2013 ESRD QIP measure set, we propose to calculate a provider's/facility's total performance score by multiplying

each measure score (0-10 points) by 1.5, and adding both measure scores together to result in a 0-30 point range.

We seek public comments about the proposed scoring and weighting methodologies for the PY 2013 ESRD QIP.

f. Proposed Payment Reductions for the PY 2013 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 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.

We implemented a sliding scale of payment reductions for the PY 2012 ESRD QIP, 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 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 propose 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. 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 5 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 5. 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 |

Table 6. Finalized PY 2012 Payment Reduction Scale

| Total Performance Score | 2012 Percent of Payment Reduction |
|--------------------------------|--|
| 30-26 Points | 0.0 Percent |
| 21-25 | 0.5 Percent |

| | |
|-------|-------------|
| 16-20 | 1.0 Percent |
| 11-15 | 1.5 Percent |
| 0-10 | 2.0 Percent |

We seek public comments on this proposal.

2. Proposed PY 2014 ESRD QIP

a. Overview of the Proposed PY 2014 ESRD QIP

This proposed rule also proposes to implement requirements that will apply to the PY 2014 ESRD QIP. In general, we propose to calculate individual total performance scores ranging from 0-100 points for providers and facilities based on eight measures that we propose to adopt for the PY 2014 ESRD QIP. We propose to continue using the Hemoglobin Greater Than 12g/dL measure that we are proposing to use for the PY 2013 ESRD QIP, and to adopt four additional clinical measures: Kt/V Dialysis Adequacy measure; Vascular Access Type measure; Vascular Access Infections measure; and Standardized Hospitalization Ratio (SHR) Admissions measure. We also propose to adopt three additional measures that would be scored differently from the proposed clinical measures. These proposed measures are the National Health Safety Network (NHSN) Dialysis Event reporting measure, the Patient Experience of Care reporting measure (using the In-Center Hemodialysis Consumer Assessment of Healthcare Advisors (ICH CAHPS) survey tool), and the Mineral Metabolism reporting measure. Providers/facilities that do not meet or exceed a

certain total performance score would receive a payment reduction ranging from 0.5 percent to 2.0 percent.

b. Proposed Performance Measures for the PY 2014 ESRD QIP

For the PY 2014 ESRD QIP, we propose to continue using the Hemoglobin Greater Than 12g/dL measure, adopt seven new measures (Kt/V Dialysis Adequacy, Vascular Access Type, Vascular Access Infections, SHR Admissions, NHSN Dialysis Event reporting, Patient Experience of Care reporting, and Mineral Metabolism reporting) and to retire the URR Hemodialysis Adequacy measure. We strongly believe that the eight proposed measures individually and collectively provide information useful for assessing provider/facility quality, for informing patient decision-making, and for furthering CMS and HHS priorities for quality improvement activities.

We note that we are proposing for the first time 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 National Quality Forum (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. Proposed Anemia Management Measure (Hemoglobin Greater Than 12g/dL)

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 propose to retain the Hemoglobin Greater Than 12g/dL measure that we adopted for the PY 2012 ESRD QIP and that we are proposing to retain for the PY 2013 ESRD QIP. We are making this proposal for the same reasons (discussed above) we proposed to retain this measure for the PY 2013 ESRD QIP measure set.

We also propose to continue to use the specifications for this measure that we finalized for the PY 2012 ESRD QIP and which we have proposed for the PY 2013 ESRD QIP. We also propose to continue requiring that providers/facilities have at least 11 cases that meet the reporting criteria in order to be scored on the measure. As noted above, we believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons

unrelated to the quality of care, skew a small provider/facility's performance score. Also, eleven cases is a statistically valid threshold that will give us confidence that a provider or facility's total performance score is an accurate reflection of the quality of care it furnishes. As a result, this threshold will help preserve beneficiary access to care at much needed small providers/facilities in rural and/or under-served areas.

Technical details on the methodology used to calculate the Hemoglobin Greater Than 12g/dL measure are available on the Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center Web site: www.dialysisreports.org/pdf/esrd/public/DFRGuide.pdf.

We seek public comment on the use of the Hemoglobin Greater Than 12g/dl measure in the PY 2014 ESRD QIP.

ii. Proposed Kt/V Dialysis Adequacy Measure

For the PY 2014 ESRD QIP, we are proposing to retire the URR Hemodialysis Adequacy measure we adopted for the PY 2012 ESRD QIP and proposed to retain for the PY 2013 ESRD QIP. In its place, we are proposing to adopt a Kt/V measure of dialysis adequacy (K = dialyzer clearance, t = dialysis time, and V = volume of distribution) for the PY 2014 ESRD QIP. We note that we have asked all providers/facilities to report the Kt/V value and the date of the value on all ESRD claims since July 1, 2010

(see Change Request (CR) 6782).

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, this 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 National Quality Forum (#0250 and #0321). 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 (home and in-center patients), we would measure the percentage of adult (≥ 18 years old) Medicare patients who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a Kt/V of at least 1.2 during the proposed performance period. For peritoneal dialysis patients, we would measure the percentage of adult (≥ 18 years old) Medicare patients whose average delivered peritoneal dialysis dose was a weekly Kt/V urea of at least 1.7 (dialytic + residual) during the proposed performance period. At this time,

the measure specifications exclude pediatric patients because there is not a consensus on what an adequate Kt/V level should be in this patient population.

In light of the fact that the renal community has advocated the use of this measure, it is based on two NQF endorsed measures of Kt/V dialysis adequacy, and our belief that Kt/V is an accurate measure of dialysis adequacy, we propose to adopt the Kt/V Dialysis Adequacy measure for the PY 2014 ESRD QIP. We also propose to require that providers/facilities have at least 11 cases that can be reported under the measure specifications to be scored on this measure. As stated above, we believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skew a small provider/facility's performance score. Technical details on the proposed methodology we would use to calculate this measure are available at:

http://www.arborresearch.org/ESRD_QMS.aspx

We seek public comments on the retirement of the URR Hemodialysis Adequacy measure and the proposed adoption of the Kt/V Dialysis Adequacy measure for the PY 2014 ESRD QIP. We also seek public comments on the exclusion of pediatric patients from this proposed measure.

iii. Proposed Vascular Access Type 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.

Arteriovenous fistulas (AV fistulas) 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,^{2,3} we propose to adopt a Vascular Access Type measure, which is based on two measures that are endorsed by the NQF. These measures assess 1. 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 2. the percentage of provider's/facility's hemodialysis patients who have an intravenous catheter in place for 90 days or longer prior to the last hemodialysis session (NQF #0256).

While catheter reduction and increased use of arteriovenous fistula are both important steps to improve patient care, we recognize that these two events are tightly interrelated and do

²http://www.kidney.org/professionals/kdofi/guideline_uphd_pd_va/va_guide2.htm

³<http://www.fistulafirst.org/AboutAVFistulaFirst/History.aspx>

not want to penalize providers/facilities twice for related outcomes. We are therefore proposing 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 are proposing to calculate two measure rates for the measure, based on a provider/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. We seek public comment on the proposed combination of these two measures into one overall score for the Vascular Access Type measure versus separating the measures into two separate measures which would then contribute separate scores to the overall Total Performance Score equally weighted with the other clinical measures.

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 believe that assessing the type of vascular access used in hemodialysis patients is important because clinical evidence, as noted previously, has shown that proper vascular access reduces the risk of adverse outcomes such as infections. In determining how to best measure vascular access type for purposes of the ESRD QIP, we considered proposing to adopt the two NQF-endorsed measures noted above (#0256 and #0257). However, under the NQF-endorsed specifications for each of these measures, data must be collected from all hemodialysis patients. We currently collect this data via claims forms for Medicare patients only. We believe that expanding this data collection to all patients would be overly burdensome for ESRD providers/facilities and would not allow us to collect this data in time for the PY 2014 program. For these reasons, we are proposing to limit the patient population to which this proposed measure applies to the Medicare hemodialysis patient population, and to collect the data via Medicare claims. Accordingly, we are proposing to adopt this measure under section 1881(h)(2)(B)(ii) of the Act.

We note that since July 1, 2010, we have asked dialysis

providers/facilities to submit vascular access type data on ESRD claims (Change Request 6782). We also note that hemodialysis patients with acute renal failure, peritoneal dialysis patients, and patients under 18 years of age would be excluded from this proposed measure. Medicare patients with acute renal failure receive treatment for a relatively short period of time as kidney function is usually restored after an acute episode, thus making a fistula unnecessary; those on peritoneal dialysis require access through the peritoneal cavity; and the access considerations are different for those in the pediatric population. We also believe 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.⁴

Finally, we propose to require that providers/facilities have at least 11 cases that meet the reporting criteria for this proposed measure to be scored on it. As stated above, we believe that this minimum threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skew a small provider/facility's performance score. Technical details on the methodology we propose to use to calculate this measure are available at:

⁴ See <http://www.fistulafirst.org/> for further information regarding this initiative.

http://www.arborresearch.org/ESRD_QMS.aspx

We seek public comment on the proposed adoption of this measure for the PY 2014 ESRD QIP.

iv. Proposed Vascular Access Infections Measure

Infections are one of the leading causes of hospitalizations and death among hemodialysis patients.⁵ The reduction of healthcare-associated infections (HAI), which are infections that may have been contracted in process of receiving care, is a key priority area for the Department of Health and Human Services. We have engaged in national efforts such as the National Patient Safety Initiative and the Partnership for Patients to reduce the number of preventable infections across healthcare settings, and have worked with dialysis providers/facilities as part of this effort. Use of effective infection control measures have proven successful in reducing the risk of life-threatening infections.

We propose 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 note that since July 1, 2010, we have asked dialysis providers/facilities to code all Medicare claims for dialysis access-related infections using this modifier (Change Request 6782). Pediatric patients (patients <

⁵ http://www.cdc.gov/media/releases/2011/p0301_vitalsigns.html

18 years of age) would be excluded from this measure because pediatric access considerations are greatly different than those of the adult patient population. Peritoneal dialysis patients would also be excluded from the calculation of the measure because there is no consensus on how to best measure dialysis access-related infection rates from catheters in these patients. We plan, however, to convene an expert panel for the purpose of trying to determine how to best address this issue in the pediatric and peritoneal dialysis patient populations.

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. While the proposed Vascular Access Infections measure is not NQF endorsed, we believe that the incidence of

dialysis access-related infections is a significant patient safety concern. We are not aware of any measures endorsed by a consensus entity for vascular access infections for the ESRD population, and, at this time, the proposed Vascular Access Infections measure is also the only measure for which we have the necessary data to measure provider/facility performance. Thus, we are proposing to adopt this measure in order to promote patient safety in this area.

Technical details on the methodology used to calculate this measure are available at:

http://www.arborresearch.org/ESRD_QMS.aspx

We seek public comments on our proposal to adopt this measure in the PY 2014 ESRD QIP.

v. Proposed Standardized Hospitalization Ratio - Admissions Measure

Hospitalizations are an important indicator of patient quality of life and morbidity. According to 2009 data provided by the United States Renal Disease Data System, dialysis patients are hospitalized, on average, twice a year. The proposed Standardized Hospitalization Ratio-Admissions (SHR-Admissions) measure is a risk-adjusted measure of hospitalizations for Medicare dialysis patients. The data needed to calculate the proposed SHR-Admissions measure has been regularly reported to Dialysis Facility Reports (DFR) since 1995

(previously known as Unit-Specific Reports) and has been used by providers/facilities and ESRD Networks for quality improvement activities. These reports contain critical information on topics such as patient characteristics, treatment patterns, hospitalizations, mortality, and provider/facility characteristics.

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) 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. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for hospital admissions applicable to the ESRD population. We are unaware of any other measures for hospital admissions that have been approved by

voluntary consensus standards bodies and/or endorsed by NQF for ESRD patients. Therefore, we are proposing to adopt this SHR-Admissions measure as it is directly applicable to the Medicare ESRD population. This measure is undergoing NQF review for endorsement, and we intend to revisit this measure in the future if this review results in substantive changes to this measure.

While we recognize that this is an "all-cause" measure, meaning that hospitalizations related to other medical conditions outside of ESRD are included in the measure, our review of the data listing the most frequent 100 in-patient diagnoses for ESRD patients demonstrate that a clear majority, estimated at 90 percent or greater, of admitting diagnoses are related to ESRD. The use of a subset of diagnoses was considered when the measure was reviewed by a Technical Expert Panel in 2007 convened by us, in part, to discuss this issue, but the panel concluded that use of specific diagnoses were more prone to poor inter-rater variation and variation in diagnosis coding, and for this reason, recommended that the measure be calculated using all admissions, regardless of the cause.

The proposed SHR-Admissions measure is claims-based and describes, as a ratio, the number of ESRD Medicare patient actual admissions versus expected hospitalizations adjusted for the provider's/facility's Medicare patient case mix. For inclusion in this measure, patients must have received services

from the provider/facility for 60 days or more, and the provider/facility must have at least 5 patient years at risk (meaning the provider/facility must have at least 5 years of patient data aggregated across all patients at the facility during the performance period, for example, 10 patients with 6 months of data each, or 5 patients with 12 months of data each) to receive an SHR score. Technical details on the methodology we are proposing to use to calculate this measure, including the adjustment for patient mix, are available at:

http://www.arborresearch.org/ESRD_QMS.aspx

We seek public comments on our proposal to adopt this measure for the PY 2014 ESRD QIP.

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

Healthcare-associated infections (HAI) are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including at 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 National Healthcare Safety Network (NHSN) as a way to track and facilitate action for reducing HAIs.

The NHSN is currently a voluntary, 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 healthcare-associated infections. Accordingly, we have developed a measure that would assess whether providers/facilities enroll and report dialysis event data to the NHSN.

By measuring only whether providers/facilities report dialysis event data to the NHSN, we believe that we can allow providers/facilities time to become familiar with the NHSN reporting process. We intend in the future to propose to adopt a measure that would score providers/facilities based on actual dialysis events reported to the NHSN.

Specifically, we are proposing that providers/facilities:

- (1) enroll in the NHSN and complete any training required by the CDC; and
- (2) submit three or more consecutive months of dialysis event data to the NHSN.

Under this proposal,

providers/facilities would be able submit data to the NHSN until the end of the month following the month for which it collected data. For example, if a provider/facility chose to submit data for October 2012, it would have until November 30, 2012 to submit that data. Information regarding NHSN enrollment and training can be accessed at:

<http://www.cdc.gov/nhsn/enroll.html>. Section 1881(h)(2)(B)(i) of the Act requires that unless the exception set forth in section 1881(h)(2)(B)(ii) applies of 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). 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 a measure calculated using NHSN dialysis event data results is currently under review by the NQF, we are not aware that any measure similar to the reporting measure we are proposing to adopt has been endorsed or adopted by any consensus

building entity. As we explained above, we are proposing to adopt a limited reporting measure because we believe it is important to incentivize providers/facilities to report so that providers/facilities will have a process for such reporting should we consider measuring providers/facilities on the incidence of these dialysis events in future years.

Accordingly, we are proposing to adopt this measure under the exception authority in section 1881(h)(2)(B)(ii) of the Act. We note 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.

We seek public comments on our proposal to adopt the NHSN Dialysis Event reporting measure for the PY 2014 ESRD QIP.

vii. Proposed 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 provider/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 propose 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 their quality of hemodialysis care.

The ICH CAHPS Survey was developed by the Agency for Healthcare Research and Quality (AHRQ) to assess the experience of hemodialysis patients receiving in-center dialysis. The areas evaluated by the ICH CAHPS Survey include:

- Nephrologists' communication and caring.
- Quality of dialysis center care and operations.
- Providing information to patients.
- Rating of kidney doctors.
- Rating of dialysis center staff.
- Rating of dialysis center.

The results of this survey have been used since January 2006 by many providers/facilities as well as ESRD Networks for improving the care and services furnished to beneficiaries receiving hemodialysis. We have also required that providers/facilities include patient experience of care or satisfaction as a component of their quality assessment and performance improvement program as part of the conditions for coverage since 2008. While we did not specifically require use of the standardized ICH CAHPS tool, we strongly encouraged

providers/facilities to use it to assess patient experience of care (73 FR 20415).

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 the ICH CAHPS Survey itself has been endorsed by the NQF (#0258), the measure we are proposing to adopt, which assesses the extent to which providers/facilities use the survey, has not, and we are not aware that such a measure has been endorsed or adopted by any consensus building organization. However, as explained above, we believe it is important to incentivize providers/facilities to administer the survey. Therefore, we are proposing to adopt this measure under the exception in section 1881(h)(2)(B)(ii) of the Act, and we

note that we intend to propose to adopt in the future a measure that would be calculated using the actual ICH CAHPS survey results.

Specifically, we propose to measure whether a provider/facility has attested that it successfully administered the ICH CAHPS survey during the proposed performance period for the PY 2014 program.

We propose that providers/facilities would be required to submit this attestation through CROWNWeb, which will be implemented nationally in 2012, by January 30, 2013 at 11:59p.m. EST. We seek comments on the feasibility of this electronic submission through CROWNWeb and further request comments on whether providers/facilities should be allowed to elect to submit these attestations in paper format.

As noted above, we are only proposing to measure whether a provider/facility administers the survey, and are not proposing to measure a provider's/facility's actual performance based on the survey results. We expect to adopt the ICH CAHPS survey itself as a measure for the ESRD QIP in future rulemaking. For purposes of reporting this proposed measure for the ESRD QIP, we will consider the ICH CAHPS survey to have been administered if the provider/facility administered it in accordance with the current specifications endorsed 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

We seek public comments on our proposal to adopt the Patient Experience of Care Survey reporting measure for the PY 2014 ESRD QIP.

viii. Proposed 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 (calcium and phosphorus) are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced chronic kidney disease. 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.⁶

⁶ 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.)

The Kidney Disease: Improving Global Outcomes (KDIGO) 2009 guideline⁷ 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. The guideline also recommends that therapy to correct for abnormal levels be administered based on the health needs of the individual patient. Accordingly, 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 note that there is currently no NQF endorsed measure dealing with the achievement of specific target phosphorus levels.

The KDIGO recommendation regarding serum calcium levels for dialysis patients is also to maintain serum calcium in the normal range. We note that the NQF is currently considering whether to endorse the following mineral metabolism measure:

- The percentage of patients in a dialysis facility with a 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

Go to [www.qualityforum.org/Projects/e-g/End Stage Renal Disease 2010/End Stage Renal Disease 2010.aspx](http://www.qualityforum.org/Projects/e-g/End_Stage_Renal_Disease_2010/End_Stage_Renal_Disease_2010.aspx)

7 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.)

to find more information regarding the National Voluntary Consensus Standards for ESRD.

Despite the current lack of consensus on specific target ranges for both phosphorus and calcium levels in dialysis patients, we believe there is consensus that monthly monitoring of calcium and phosphorus is important for early detection of abnormalities. We also note that the NQF has endorsed phosphorus and calcium monitoring measures (NQF #0261 and NQF #0255) and, in 2008, we adopted serum calcium and serum phosphorus monitoring as CPM measures (http://www.arborresearch.org/ESRD_QMS.aspx).

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, 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 have developed 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 propose to adopt it under section 1881(h)(2)(B)(ii) of the Act. This proposed measure will assess whether providers/facilities monitor a patient's phosphorus and calcium levels on a monthly basis throughout the portion of the proposed performance period during which the patient was treated. Although we will not be collecting actual serum calcium and serum phosphorus level data, or data regarding how these levels are being managed, we believe that routine monitoring of these levels is extremely important for the purpose of detecting abnormal states of calcium and phosphorous levels in this population, which this proposed measure will help address.

We propose that providers/facilities would be required to submit an attestation that they have conducted the appropriate monitoring through CROWNWeb, which will be implemented nationally in 2012. We further propose that this reporting must be electronically submitted by January 30, 2013 at 11:59p.m. EST. We seek comments on the feasibility of this electronic submission through CROWNWeb and further request comments on whether providers/facilities should be allowed to elect to submit these attestations in paper format.

We seek public comment on our proposal to adopt the Mineral Metabolism reporting measure for the PY 2014 ESRD QIP.

We also note 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. Those measurement data will be collected via CROWNWeb under the authority of the Conditions for Coverage ESRD Final Rule (73 FR 20370) published in the **Federal Register** on April 15, 2008. We seek public comment on the clinical evidence that would support the establishment of specific target levels for serum phosphorus for purposes of developing one or more future ESRD QIP measures. We also seek public comment on the above calcium measure that has been submitted to the NQF for endorsement.

c. Proposed 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 QIP, we examined what performance period would be most appropriate for the PY 2014 ESRD QIP. We believe that a 12-month performance period is most appropriate for the ESRD QIP at this point in the program. 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 propose to select all of CY 2012 as the performance period for the PY 2014 ESRD QIP.

We seek public comments about the proposed selection of CY 2012 as the performance period for the PY 2014 QIP. We also seek public comments on the use of shorter performance periods in future years of the ESRD QIP.

d. Proposed Performance Standards for the PY 2014 ESRD QIP

For the PY 2014 ESRD QIP, we are proposing to establish performance standards under section 1881(h)(4)(A) of the Act because it is feasible to establish them prior to the beginning of CY 2012, the proposed start of the performance period. This section generally provides that 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, these performance standards 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 three of the proposed clinical measures (Hemoglobin Greater Than 12g/dL, Kt/V Dialysis Adequacy, and Vascular Access Infections), we propose 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 propose 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. Additionally, we propose to set the improvement performance standard as the national performance rate on each measure during the same proposed baseline period because we believe that it is important to encourage the utmost improvement in quality and care. We believe that selecting the national performance rate as the

performance standard for both the improvement and achievement performance standards (collectively, the performance standards) represents a meaningful and achievable standard of provider/facility performance because it represents how well providers/facilities are actually performing on each measure during a previous baseline period while still allowing significant room for improvement. 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 (discussed below). We expect that the national performance rate on each measure will increase in future years of the ESRD QIP because it will reflect overall improved levels of performance.

To ensure that these proposed performance standards are based on a full calendar year of performance data that is as close as possible to the proposed performance period, we propose to use a baseline period from July 1, 2010 to June 30, 2011. This proposed baseline period will enable us to calculate national performance rate values for these proposed clinical measures before the beginning of the performance period, and we intend to specify those values in the final rule.

With respect to the proposed Vascular Access Type measure, we are proposing to set performance standards using the same methodology and baseline period that we are proposing to use for

the three proposed clinical measures discussed above, however we would set performance standards for each of the subcomponent measures rather than for the overall combined measure. We seek public comment on this methodology for setting the performance standards for this measure.

With respect to the proposed SHR-Admissions measure, we also propose to establish the performance standards as the national performance rate during a proposed baseline period. However, we propose to establish CY 2010 as the baseline period. Because this measure would be calculated using hospital claims, we have determined that we need additional time to calculate and finalize the performance standards in order to specify the precise values in the final rule.

We specify example performance standards, generally using data from July 1, 2010 through November 30, 2010 for the proposed Hemoglobin Greater Than 12g/dL, Kt/V Dialysis Adequacy, Vascular Access Type, and Vascular Access Infections measures, and CY 2009 for the proposed SHR-Admissions measure in the Table 7, below. We note that because the proposed Vascular Access Type measure subcomponents would only include patients who have been on a catheter for 90-days, we are only able to provide example performance standards from October 1, 2010 through November 30, 2010 for the catheter subcomponent of the Vascular Access Type measure.

Table 7. Example Achievement and Improvement Performance Standards for the PY 2014 ESRD QIP

| Proposed Measure | Example Achievement/Improvement Performance Standard |
|---|---|
| Hemoglobin Greater Than 12 g/dL Measure | 15% |
| Dialysis Adequacy Measure (Kt/V) | 94% |
| Vascular Access Type Measure | XX |
| %Fistula | 55% |
| %Catheter | 12% |
| Vascular Access Infections Measure ¹ | 0.2 |
| SHR-Admissions Measure ² | 1.0 |

¹ Measured as hemodialysis access-related bacteremia rate per 1000 hemodialysis days

² Measured as ratio of observed hospitalizations to hospitalizations expected based on facility patient case mix

We propose to establish the achievement performance standard for the proposed NHSN Dialysis Event reporting measure as the successful completion by providers/facilities of: (1) 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 (2) submission to the NHSN of at least 3-consecutive months of dialysis event data gathered during the performance period.

We propose to establish the achievement performance standard for the proposed Patient Experience of Care reporting

measure as an attestation by the provider/facility at the end of the performance period that it successfully administered the ICH CHAPS survey during the proposed performance period.

We propose to establish the achievement performance standard for the proposed Mineral Metabolism reporting measure as whether the provider/facility 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 proposed 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 have 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 seek public comments on the proposed performance standards for all of the proposed PY 2014 ESRD QIP measures and the proposed baseline periods that we would use to establish the performance standards for the five proposed clinical performance measures.

We also note 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 are proposing 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. We believe that this approach best balances the goal of incentivizing providers/facilities to provide quality care across all of the measures with recognizing the higher quality of care provided by those providers/facilities that exceed the performance standards on certain measures. We seek comment on this proposed approach to scoring providers/facilities.

Additionally, 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. 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. We welcome comments on this proposed approach.

e. Proposed 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. Section 1881(h)(3)(B) of the Act requires the Secretary to calculate separate performance scores for each measure.

The final rule entitled, "Medicare Programs; Hospital Inpatient Value-Based Purchasing Program," appeared in the **Federal Register** on May 6, 2011 (76 FR 26490). In this final rule, we stated our view that value-based purchasing represents an important step in revamping how care and services are paid for, 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 first year of the ESRD QIP (PY 2012), we finalized a scoring methodology that provides a straightforward approach for assessing provider/facility performance intended for use with a very limited number of measures, and we are proposing to continue using this methodology for the PY 2013 ESRD QIP. We have recognized that this straightforward approach might not be appropriate as we adopt for the program new measures for which there could be wider variability in performance (75 FR 49222). For the PY 2014 ESRD QIP, we propose to adopt a new performance scoring methodology to replace the methodology we are using for the PY 2012 ESRD QIP and that we have proposed to use 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 FY 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 also believe that this scoring methodology more closely aligns with the scoring methodology we have adopted for the Hospital Inpatient Value-Based Purchasing Program, and that it can readily accommodate the adoption of new ESRD QIP measures in the future. 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. The proposed performance scoring methodology is based on the methodology developed for the Hospital Value-Based Purchasing (VBP) program (76 FR 26513 through 26526). It is important to note that, while we have attempted to align the two scoring methodologies as much as possible, the ESRD QIP and the Hospital VBP program present distinct statutory and programmatic requirements that necessitate differences between the two scoring methodologies.

i. 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 five proposed clinical measures would be determined based on the higher of (1) an achievement score or (2) an improvement score. In determining the achievement score, we propose that providers/facilities would receive points along an achievement

range, defined as a scale that runs from the achievement threshold to the benchmark. We are proposing 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 above to set as the national performance rate on the measure during the baseline period). We believe that setting the achievement threshold at one standard deviation below the national performance rate will enable us to reserve greatest penalty to those providers/facilities whose performance is substantially below the national performance rate. Performance at this level represents a significant deviation in care from the performance standard (performance worse than about 84% of providers/facilities based on a normal distribution), while at the same time, accounting for the degree of variance across provider/facility performance levels. We also believe that it 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 are proposing to define the benchmark as provider/facility performance at 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. This approach is consistent with the approach adopted in the Hospital Inpatient Value-Based Purchasing Program (76 FR 26515).

In determining an improvement score for the five proposed clinical measures, we propose 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 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 to its performance on the measure during the baseline period.

Under this proposed methodology, we propose to establish the benchmarks and achievement thresholds for three of the proposed clinical measures (Hemoglobin Less Than 12g/dL, Kt/V Dialysis Adequacy, and Vascular Access Infections), using national data from a one-year baseline period from July 2010 to June 2011 (discussed above in section II.B.2.d of this proposed rule). For the proposed Vascular Access Type measure, we propose to establish a separate benchmark and achievement threshold for each of the two subcomponent measures using national data from the proposed July 1, 2010 to June 30, 2011 baseline period. For the proposed SHR-Admissions measure, we propose to establish the benchmark and achievement threshold

using national data from CY 2010 as the baseline period.

In view of our desire to adopt a scoring methodology that will allow us to distinguish between providers and facilities that do not meet or exceed the performance standards established with respect to an individual measure, we are proposing to set the achievement threshold for the 2014 ESRD QIP at one standard deviation below the national performance rate of provider/facility performance during the baseline period.

Setting the achievement threshold in this manner complies with the ESRD QIP statutory requirements, and enables us to provide discrete scores to providers/facilities based on how far their performance is below or above the performance standards. This proposed methodology will incentivize providers/facilities to continuously improve their performance, and will not penalize a provider/facility whose total performance score is equal to or above the performance standards for all measures.

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

For four of the proposed clinical measures (Hemoglobin Greater Than 12g/dL, Kt/V Dialysis Adequacy, Vascular Access Infections, and SHR-Admissions), we propose to award between 0 and 10 points for achievement based on where a facility's/provider's performance falls relative to the proposed achievement threshold (which we propose above to define as one

standard deviation below the national performance rate on a given proposed measure during the baseline period) and the proposed benchmark (which we propose to define above as performance at the mean of the top decile of national facility/provider performance during the baseline period), according to the following formula:

[9* ((Provider's performance period score - achievement threshold) / (benchmark - achievement threshold))] +.5, where the provider performance period score falls in the range from the achievement threshold to the benchmark.

All achievement points would be rounded to the nearest integer (for example, an achievement score of 4.5 would be rounded up to 5). If a provider's/facility's score was:

- Equal to or greater than the benchmark, the provider/facility would receive 10 points for achievement
- Equal to or greater than the achievement threshold (but below the benchmark), the provider/facility would receive a score of 1 to 9 points based on a linear scale established for the achievement range (which distributes 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.)

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

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

Similar to the performance scoring model finalized in the Hospital VPB Program final rule (76 FR 26516 through 26526), we propose that providers/facilities would earn between 0 and 9 points on each of the four proposed clinical measures (Hemoglobin Greater Than 12/dL, Kt/V Dialysis Adequacy, Vascular Access Infections, SHR-Admissions) based on how much their performance on the measure during the performance period improved from their performance on the measure during the proposed baseline period. A unique improvement range for each measure would be established for each provider/facility which we propose to define as the distance between the provider's/facility's baseline period score and the benchmark for the measure (the mean of the top decile), according to the following formula:

$$[10 * ((\text{Provider performance period score} - \text{provider baseline period score}) / (\text{Benchmark} - \text{provider$$

baseline period score))] - .5, where the provider performance score falls in the range from the provider's baseline period score to the benchmark.

All improvement points would be rounded up to the nearest integer. If a provider's/facility's score on the measure during the performance period was:

- Greater than its baseline period score but below the benchmark (within the improvement range), the provider/facility would receive a score of 0 to 9 points based on the linear scale that defines the improvement range.
- Equal to or lower than its baseline period score on the measure, the provider/facility would receive 0 points for improvement.

iv. Calculating the Proposed Vascular Access Type Measure Score

We propose to calculate the Vascular Access Type measure score by first calculating the measure rate according to measure specifications for each of the two measure subcomponents. Those two rates would then be converted into separate achievement and improvement scores for each subcomponent using achievement and improvement ranges specific to each subcomponent measure as proposed. The higher of the achievement or improvement score for each measure component would then be averaged to produce one overall score for the Vascular Access Type 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 vascular access type measures.

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

We propose to adopt a different scoring methodology for the proposed NHSN Dialysis Event reporting measure, Patient Experience of Care Survey Usage reporting measure, and Mineral Metabolism reporting measure.

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

- Providers/facilities that enrolled or were previously enrolled and continue to be enrolled in the NHSN during the performance period, completed the required training, and successfully reported at least 3-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 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 the proposed performance period would receive 0 points.

We propose 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, while providers/facilities that did not provide such an attestation would receive 0 points.

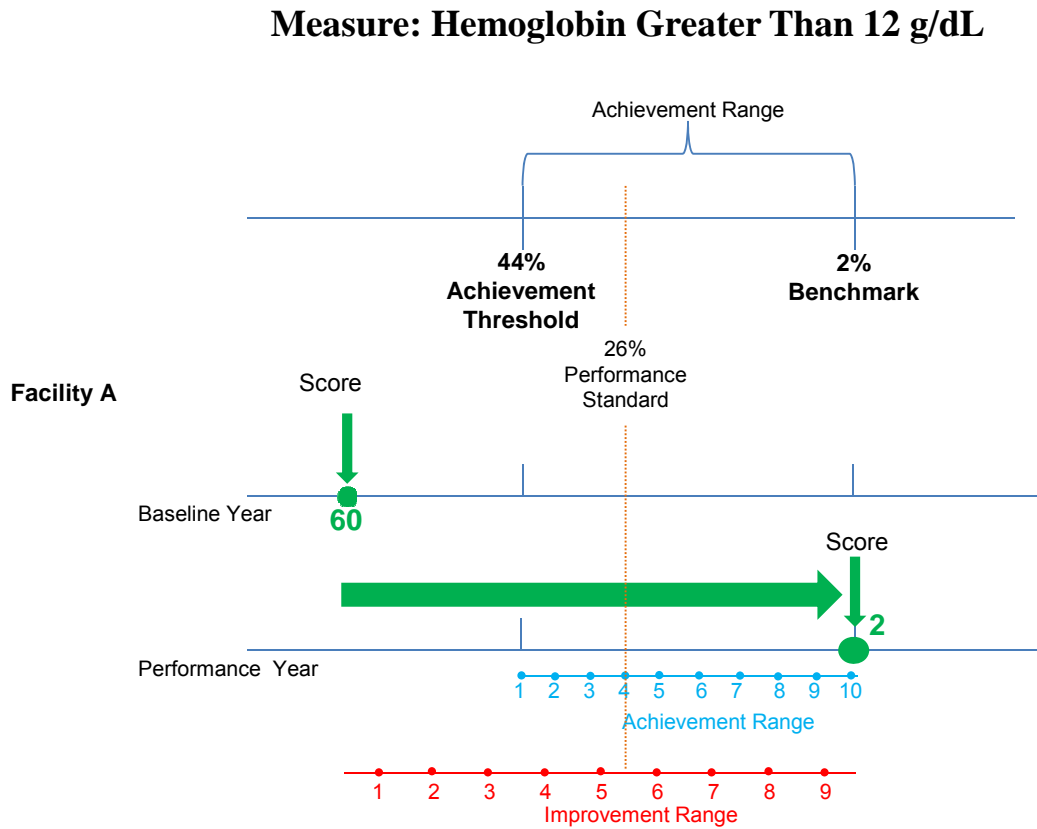
We propose to assign providers/facilities that measured the serum calcium and serum phosphorus levels of all adult Medicare patients treated by the provider/facility at least once within the month throughout the duration of the proposed performance period a score of 10 points, while providers/facilities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

vi. Examples to Illustrate Proposed 2014 ESRD QIP Performance Scoring Model As Applied to Clinical Measures

Three examples are presented to illustrate how the proposed

performance scoring model would be applied in the context of the PY 2014 ESRD QIP using previous data from 2008. Figure 1 shows Facility A's performance on the proposed Hemoglobin Greater Than 12g/dL measure. The example benchmark calculated for this measure in this case is 2 percent (mean of the top decile during the baseline period), while the example achievement threshold is 44 percent (one standard deviation below the national performance rate during the baseline period). Facility A's performance rate of 2 percent during the performance period meets 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

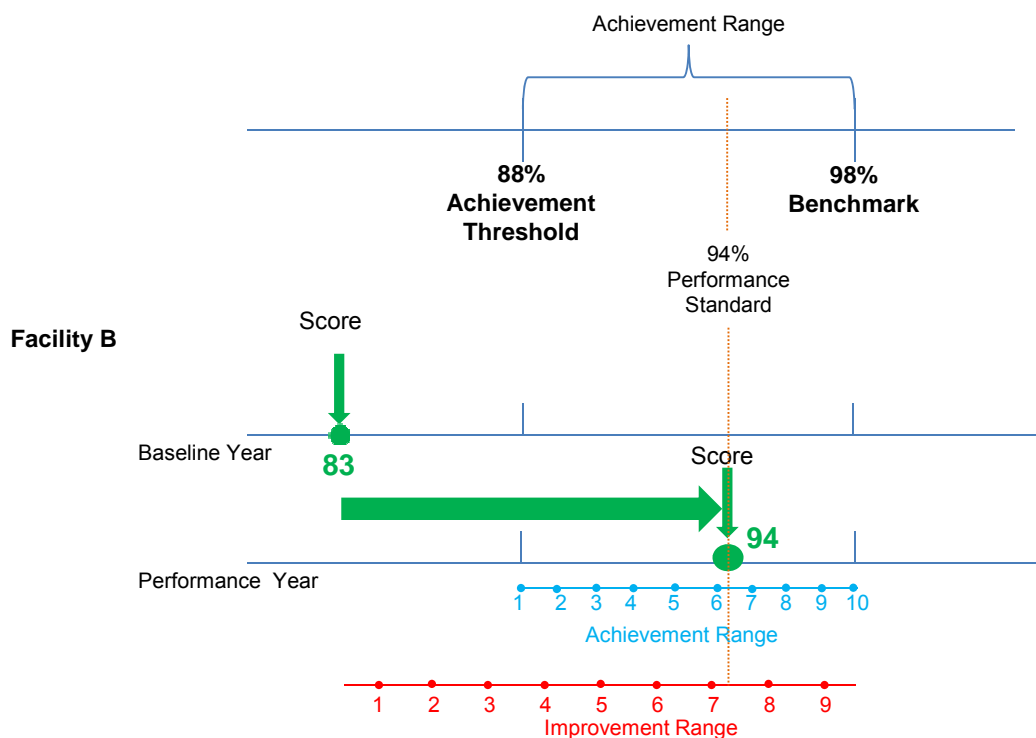


Facility A Earns: 10 points for achievement
 Facility A Score: Maximum of achievement or improvement = 10 points on this measure

Figure 2 shows the scoring for another facility, Facility B. As illustrated below, the facility's performance on the Kt/V Dialysis Adequacy measure went from 83 percent in the baseline period to 94 percent during the performance period.

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

Measure: Kt/V Dialysis Adequacy



Facility B Earns: **6 points for achievement**
7 points for improvement

Facility B Score: Maximum of achievement or improvement
= 7 points on this measure

Applying the achievement scale, Facility B would earn 6 points for achievement, calculated as follows:

$$9 * [(94 - 88) / (98 - 88)] + .5 = 5.4 + .5 = 5.9,$$

which is rounded to 6 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. Applying the improvement scale, based on Facility B's period-to-period improvement, from 83% percent to 94% percent, Facility B would earn 7 improvement points, calculated as follows:

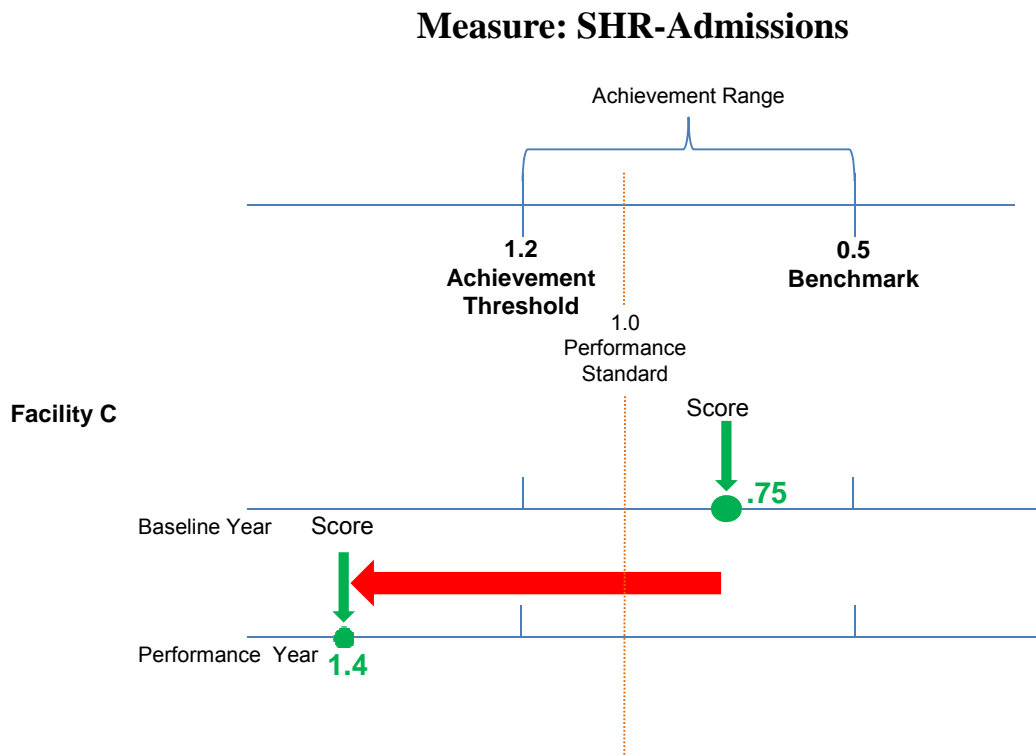
$$10 * [(94 - 83) / (98 - 83)] - .5 = 7.3 - .5 = 6.8,$$

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 3 below, Facility C's performance on the proposed SHR measure drops from .75 in the baseline period to 1.4 in the performance period, a decline of .65. We note that a lower performance score on this proposed measure indicates better performance because it indicates that a provider/facility had fewer than expected hospital admissions.

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



Facility C Earns: 0 points for achievement
0 points for improvement

Facility C Score: Maximum of achievement or improvement
= 0 points on this measure

Because Facility C's performance during the performance period falls below the achievement threshold of 1.2, it would receive no 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 SHR Measure.

vii. Proposed 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 Departmental quality improvement priorities. We believe that weighting the five proposed 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 propose to assign equal weight to the five proposed clinical performance measures: Hemoglobin Greater Than 12g/dL measure, Kt/V Dialysis Adequacy measure, Vascular Access

Type measure, Vascular Access Infections measure, and SHR-Admissions measure; with those equal weights adding up to 90 percent of the total performance score. We believe that while the proposed reporting measures are valuable, the five proposed clinical measures measure actual patient outcomes and therefore, justify a proposed combined weight of 90 percent. We propose that the remaining 10 percent of the total performance score would be comprised of the three proposed reporting measures, with each measure weighted equally. We believe it is of utmost importance to incentivize providers/facilities to improve clinical care, and, therefore, we believe it is necessary to heavily weight these measures. We recognize, however, 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 11 cases with respect to one or more of the proposed clinical measures. As we stated above, we are proposing that this minimum number of cases must be reported with respect to each proposed clinical measure in order for the provider/facility to receive a score on that measure. We also note that we finalized a policy for the PY 2012 ESRD QIP that providers/facilities that reported less than 11 cases meeting

the reporting criteria for each of the measures would not receive a total performance score (76 FR 639). Now that we are proposing to adopt additional measures, we believe it is appropriate to propose 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 propose to only calculate its achievement score, since 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 are proposing that the combined weight of the clinical performance 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 11 cases or more would be included in determining this score, with each such measure being weighting equally. We believe that this approach achieves that goal of including as many providers/facilities as possible, while ensuring the reliability of the measure scores.

Similarly, we propose 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 eight proposed measures, we propose to calculate the provider/facility total performance score using the following formula:

$$\begin{aligned} \text{Total Performance Score} = & [(.1800 * \text{Hemoglobin Greater} \\ & \text{Than 12g/dL Measure}) + (.1800 * \text{Kt/V Dialysis Adequacy} \\ & \text{Measure}) + (.1800 * \text{Vascular Access Type Measure}) + \\ & (.1800 * \text{Vascular Access Infections Measure}) + (.1800 \\ & * \text{SHR-Admissions})] + [(.0333 * \text{NHSN Dialysis Event} \\ & \text{Reporting Measure}) + (.0333 * \text{Patient Experience} \\ & \text{Survey Reporting Measure}) + (.0333 * \text{Mineral} \\ & \text{Metabolism Reporting Measure})] * 10. \end{aligned}$$

The Total Performance Score would 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 Vascular Access Type and Vascular Access Infections measures, the provider's/facility's total performance score would be calculated as follows:

$$\begin{aligned} \text{Total Performance Score} = & [(.3000 * \text{Hemoglobin Greater} \\ & \text{Than 12g/dL Measure}) + (.3000 * \text{Kt/V Dialysis Adequacy} \\ & \text{Measure}) + (.3000 * \text{SHR}) + (.0333 * \text{NHSN Reporting} \\ & \text{Measure}) + (.0333 * \text{Patient Experience Survey} \\ & \text{Reporting Measure}) + (.0333 * \text{Mineral Metabolism} \end{aligned}$$

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)).

viii. Example of Applying the Proposed PY 2014 ESRD QIP Performance Scoring Model and Calculating the Total Performance Score

To illustrate the application of the proposed 2014 ESRD QIP performance scoring model, we offer the following example:

For the performance period, Facility D reports and receives raw scores on the measures as set forth in columns 5 and 6 of Table 8 below. For this example, we calculated sample benchmarks and achievement thresholds using 2009 National Facility Values data as the baseline period, except for the proposed SHR measure, for which we used 2008 National Facility Values. Columns 7 and 8 of Table 8 below display the individual measure scores (on achievement and improvement), while column 9 displays the earned points for each measure. Finally, row 9 displays the total performance score Facility D would receive after applying the proposed performance scoring and weighting methodology.

Table 8. Example of Calculation of Provider/Facility Total Performance Score based on Proposed 2014 ESRD QIP Scoring Methodology

| Quality Measure | Measure Description/Definition | Achievement Threshold (one standard deviation from the national performance rate) * | Benchmark (mean of the top decile) * | Provider/Facility Baseline Score | Provider/Facility Performance Score | Achievement Points | Improvement Points | Earned Points (higher of achievement and improvement) |
|---|--|---|--------------------------------------|----------------------------------|-------------------------------------|--------------------|--------------------|---|
| Hemoglobin greater than 12 g/dL measure | % of patients with hemoglobin greater than 12 g/dL | 44% | 2% | 22.0% | 14.0% | 7 | 4 | 7 |
| Dialysis Adequacy Measure (Kt/V) | % of hemodialysis (HD) patients with Kt/V ≥ 1.2 | 85% | 100% | 80.0% | 95.0% | 7 | 8 | 8 |
| Vascular Access Type Measure | Average of the two sub-measures | | | | | | | 3 |
| (Fistula) | % of patients receiving treatment with fistulae | 40% | 73% | 25.0% | 40.0% | 0 | 3 | 3 |
| (Catheter) | % of patients receiving treatment with catheter | 38% | 11% | 29% | 30% | 3 | 0 | 3 |
| Vascular Access Infections Measure | Overall access-related bacteremia: rate of access-related bacteremia among adult chronic HD patients (Express as: rate per 1000 HD patient days) | 3.1 | 0.0 | 0.5 | 1.1 | 6 | 0 | 6 |
| SHR-Admissions Measure | Standardized Hospitalization Ratio | 1.35 | 0.58 | 1.32 | 1.54 | 0 | 0 | 0 |
| NHSN Dialysis Event Reporting Measure | Enroll and report at least 3 months of dialysis event data | N/A | N/A | N/A | 10 | N/A | N/A | 10 |
| Patient Experience of Care Survey Usage Reporting | Providers/facilities must attest that they successfully fielded survey during the performance period | N/A | N/A | N/A | 10 | N/A | N/A | 10 |

| | | | | | | | | |
|---|--|-----|-----|-----|---|-----|-----|-------|
| Measure | | | | | | | | |
| Mineral Metabolism Reporting measure | Measure serum calcium and serum phosphorus levels of Medicare patients | N/A | N/A | N/A | 10 | N/A | N/A | 10 |
| | | | | | Provider/Facility Total Performance Score: | | | 53.19 |
| *Achievement Thresholds and Benchmarks are based on 2009 National Facility Values (except for the SHR-Admissions Measure, which is based on 2008 National Facility Values). | | | | | | | | |

We solicit public comment on the proposed performance scoring methodology.

f. Proposed 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 implemented a sliding scale of payment reductions for the PY 2012 ESRD QIP, (76 FR 634) and are proposing a similar scale for the 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 this proposed approach, a provider/facility would not be required to meet or exceed the performance standards with respect to each of the eight proposed 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 or greater than the minimum total performance score it would receive if it had met the performance standards for each proposed measure, or, in the case of the Vascular Access Type measure, for the two subcomponent measures. Because we are proposing to establish the performance standards, achievement thresholds, and benchmarks for each of the proposed clinical measures based on provider/facility performance during the respective proposed baseline period that applies to the measure, we will not know what each of those values will be until those baseline periods have concluded. However, because we have proposed to assign 10 points to each provider/facility that meets the achievement performance standard on each of the three reporting measures, we know how performance on these measures will factor into this minimum total performance score. We estimate at this time 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 will specify the exact number in the final rule. We propose 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 receiving the largest reductions, we propose 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 propose 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 believe 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. We will review this data to ensure that all providers/facilities will be sufficiently incentivized to provide high quality care. If we determine that the proposed approach for selecting the minimum total performance score is not rigorous enough we may finalize a higher minimum total performance score or a

scalable approach to the scoring methodology. As stated above, the specific total performance score that a provider/facility would be required to achieve to avoid a payment reduction will be specified in the final rule.

We seek public comments on the proposed payment reductions for the PY 2014 ESRD QIP.

3. Proposed 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 has an opportunity to review the information to be made public with respect to that provider/facility prior to its 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 propose no change in the implementation of these statutory provisions (section 1881(h)(6)(A) through section 1881(h)(6)(A)(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.

We seek public comments on the proposed public reporting requirements for the PY 2013 and PY 2014 ESRD QIP.

4. 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 are considering the adoption of measures on pediatric anemia (for example, iron targets), and fluid management for future years.

We also seek public comment on the inclusion of iron management measures, serum calcium management measures, and serum phosphorus management measures for future years of the QIP. Specifically, we seek 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 Clinical Practice Measures set. The full specifications for these measures may be accessed at: http://www.arborresearch.org/ESRD_QMS.aspx.

5. Proposed 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 concerns 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 are proposing that we would post a notice of the updates we intend to make to the measure(s) in the **Federal Register**. We would specify in the Notice a time period during which we would accept

comments from the public. We would consider these comments and post a Notice in the **Federal Register** finalizing any updates that we make to the measure(s). 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.

We request comment on this proposed procedure for updating ESRD QIP measures in accordance with section 1886(h)(2)(C) of the Act.

III. Ambulance Fee Schedule

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

1. 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 Medicare and Medicaid Extenders Act of 2010 (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.

Accordingly, we are proposing 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.

2. 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. The statute originally 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. Thus, we are proposing 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.

3. 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 originally 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 PFS 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(1)(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.

Accordingly, we are proposing 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.

B. Technical Correction

In addition, we are making a technical correction to §414.610(c)(1). 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 was inadvertently left out of this regulation. Specifically, the following sentence was inadvertently omitted from revised §414.610(c)(1): "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)(1)(i). We did not intend to delete this language in making the CY 2011 formatting changes. Thus, we are proposing to revise §414.610(c)(1) to reinstate this sentence which was inadvertently deleted in the CY 2011 physician fee schedule final rule.

IV. Durable Medical Equipment and Supplies

A. Background for Durable Medical Equipment 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 DME furnished on or after January 1, 1989. 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 propose a rule regarding how long equipment must withstand repeated use to be considered durable medical equipment.

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 (P.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 Benefits 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, 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 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

Section 1861(n) of the Act defines DME to include items such as iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home whether furnished on a rental basis or purchased. The regulation at §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.

CMS program instructions at section 110.1 of chapter 15, Medicare Benefits Policy Manual further clarify that an item can be considered durable if it can withstand repeated use, in other words, the type of item that could normally be rented. Section 1834(a)(7)(C) of the Act sets forth the provisions for the establishment of RUL for certain items of DME, payment for replacement of items and the length of RUL. However, the RUL is not specifically set forth as a minimum lifetime standard. Computation of the

RUL is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

The regulation and program instructions do not lend any 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 the forefront in light of the recent technology and engineering in the field of medical devices and equipment. Establishing a minimum lifetime criteria 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, 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 website, 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. Provisions of the Proposed Regulations

We are proposing changes to the definition of DME at 42 CFR §414.202 in order to clarify the meaning of the term "durable" and reflect our current interpretation of the statute. Specifically, we propose to establish a 3-year minimum lifetime requirement that equipment must meet in order to be considered DME. Section 1861(n) of the Act provides examples of items such as wheelchairs, power operated vehicles, hospital beds, ventilators, and oxygen equipment to illustrate the DME benefit. The citation of these examples in the statutory language for many years indicates that the DME benefit was intended to be limited to medical items designed to be durable. Although the ability to pay on a purchase basis for certain items was added to the statute, the addition of this flexibility to the program did not fundamentally alter the types of items included in the DME benefit category or the requirement that the equipment must be durable.

Section 1861(n) of the Act states that items may be included under the DME benefit whether furnished on a rental basis or purchased. The regulation at §414.202 and

program instructions at Section 110.1 of Chapter 15 of the Medicare Benefits Policy Manual specify that an item is considered durable if it can withstand repeated use, that is, the type of item that could normally be rented. This excludes items that are of a disposable or single use nature. Based upon the statute and current regulations, equipment could be eliminated from the DME benefit category if it could not withstand repeated use or be reused by successive patients or the same patient. Although the capacity for reuse is in itself a logical 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 estimates⁸. Furthermore, economics dictionaries⁹, various encyclopedias¹⁰, and economics textbooks¹¹ define durable

⁸The 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>

⁹The 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.

¹⁰Encyclopedia of Business, Britannica Encyclopedia and Gale Encyclopedia.

¹¹A Lexicon of Economics by Kenyon A. Knopf.

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)¹², 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 propose a 3-year minimum lifetime standard for items to meet the durability criterion for DME.

A minimum lifetime standard would 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 would need to be met in order for the equipment to be considered DME. In addition, the revised regulation would provide clear guidance to CMS and other stakeholders for making consistent informal benefit category determinations and national coverage determinations for DME. It would assist manufacturers in designing and developing new medical equipment to have a better understanding of how long a period of time an item

¹²<http://resna.org/>

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 minimum period of durability 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 minimum lifetime requirement for DME. Although the proposed 3-year lifetime would be a requirement for determining whether an item is 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.

1. Application of the 3-year lifetime standard to items currently covered as DME and to supplies and accessories of covered DME

The 3-year minimum lifetime requirement would be prospective only and would not apply to items classified as DME before the proposed rule would be implemented. We expect that a vast majority of the categories of items that are currently classified as DME function for 3 or more years. In addition, the proposed regulation would allow for continued coverage of attendant supplies that are necessary for the effective use of DME. Such supplies include drugs and biologicals which must be inserted

directly into the equipment for the effective use of DME. Finally, we do not propose to apply the 3-year lifetime requirement to accessories used with DME.

2. Application of the 3-year minimum lifetime criteria 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 lifetime standard 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 minimum lifetime requirement. Although we are not proposing to change our policy with regard to these types of systems at this point, we are seeking public comments on this topic. Specifically, we are soliciting public comments on various ways we might consider applying the 3-year rule to multi-component devices consisting of both durable and non-durable components. Various options might

include the following:

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

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.

B. Requirements in Regulation Text

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

As discussed in section I.C.5 of this proposed 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 prior to November 1st of each year. 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 this proposed rule, for CY 2012, we estimate 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 proposed rule, using 2009 claims our contractor, UM-KECC, identified 939 ESRD facilities as providing treatments below the low-volume threshold of 4,000 treatments in 2009. Of these 939 facilities, we estimated that 358 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 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 proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed 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. Proposed Display of Certificates for PY 2013 and PY 2014 ESRD QIP

Section II.B of this proposed rule discusses a disclosure requirement for both the PY 2013 and the PY 2014 ESRD QIP. As stated earlier in this proposed 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 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 are proposing to issue a PY 2013 and PY 2014 QIP certificate to providers and facilities via a generally accessible electronic file format. We propose that each provider and facility would be required to prominently display the applicable QIP certificate in patient areas. In addition, we propose that each provider and facility will take the necessary measures to ensure the security of the certificate in the patient areas. Finally, we propose 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 2012 ESRD QIP.

The burden associated with the aforementioned requirements is the time and effort necessary for providers and facilities to print the applicable 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 5,227 providers and facilities will receive a QIP certificate in PY 2013 and PY 2014 and will be required to display it. We also estimate that it

will take each provider or facility 10 minutes per year to print, prominently display and secure the QIP certificate, for a total estimated annual burden of 871 hours at a cost of \$30,000. We estimate that approximately one-third of ESRD patients will ask a question about the QIP certificate. We further estimate that it will take each provider/facility approximately 5 minutes to answer each patient question about the applicable QIP certificate, or 1.65 hours per provider or facility each year. The total estimated annual burden associated with this requirement is 8,625 hours. The total estimated annual burden for both displaying the QIP certificates and answering patient questions about the certificates is 9,496 hours (for each of PY 2013 and PY 2014). While the total estimated annual burden associated with both of these requirements as discussed is 9,496 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 proposed 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 \$300,000.

2. Proposed NHSN Reporting Requirement for the PY 2014
ESRD QIP

As stated above in section II.B.2.b.vi of this proposed rule, we propose to include reporting dialysis events to the National Healthcare Safety Network (NHSN) as a reporting measure for the PY 2014 ESRD QIP.

Specifically, we would require 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 estimate that approximately 5,227 providers and facilities will enroll in the NHSN and submit the necessary data. We also estimate that it will 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 250,896 hours. Based on the Bureau of Labor Statistics we estimate the average inflation adjusted salary to be \$34.63 per hour. Thus,

average cost for each provider/facility would be \$1,662.24 (48 hours times \$34.63 per hour). Across all 5,227 providers/facilities, this would equal \$8.7 million. 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 10 minutes to collect and submit data on these events and the estimated burden for submitting 3 months of data will be 20,947 hours. If the dialysis events were distributed evenly across all 5,227 providers/facilities, that would result in an additional 4 hour burden (\$138.78) for each provider/facility. The total estimated annual burden for enrolling in the NHSN, conducting the required training, and submitting 3 consecutive months of data is 271,843 hours. We estimate that the total cost for all ESRD providers/facilities to comply with the proposed collection of information requirements associated with NHSN reporting requirement each year would be less than \$9.5 million, with the total average cost per provider/facility approximately \$1,801.02.

3. Proposed Patient Experience Survey Usage Requirement for the PY 2014 ESRD QIP

As stated above in section B.A.2. of this proposed rule, we propose 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 5,227 providers and facilities will administer the ICH CAHPS survey and submit an attestation to that effect. 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 84,068 hours which is valued at \$2.9 million, or \$556.97 per provider/facility. We estimate that administering the survey would take 45 minutes per patient (to account for variability in education levels) and 200 surveys per year which equals 154 hours or \$2,707.32 per facility-year to administer the ICH CAHPS survey for an estimated annual burden of 804,958 hours which is valued at \$14.1 million. As discussed in section A. of this proposed 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 would be approximately \$3,264.29, or \$17.1 million across all ESRD providers/facilities.

4. Proposed Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP

As stated above in section B.A.2. of this proposed rule, we propose 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 5,227 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 94,086 hours which is valued at \$3.3 million, or \$623 per provider/facility.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at

<http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage>.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-1577-P]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed 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 proposed rule. We solicit comment on the Regulatory Impact Analysis provided.

2. Statement of Need

This rule proposes a number of routine updates for renal dialysis services in CY 2012, implementing the second year of the transition, and making several policy and

technical changes to the CY 2011 ESRD PPS final rule as well as proposed revisions to the regulations. This includes proposed 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 proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2012.

In addition, this rule implements 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 proposed rule would revise the ambulance fee schedule regulations to conform with the requirements of section 106 of the Medicare and Medicaid Extenders Act of 2010 Pub. L. 111-309 (MMEA). Finally, this proposed rule revises the definition of durable medical equipment. The revision adds a 3-year minimum lifetime criterion 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.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately \$200 million in payments to ESRD facilities in CY 2012. Furthermore, as a result of implementing the QIP for Medicare outpatient ESRD dialysis providers and facilities, we estimate aggregate payment reductions in payment years 2013 and 2014 would be \$47.2 million and \$14 million, respectively. However, given the lack of data for several measures, the actual impact of the proposed 2014 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 proposed rule (Display of Certificates for the 2013 ESRD QIP) are estimated to be \$300,000 for all ESRD facilities in 2013. The additional estimated aggregate costs associated with the collection of information requirements described in sections III.1. (Display of Certificates for the 2013 and 2014 ESRD QIP), III.2 (NHSN Reporting Requirement for the 2014 ESRD QIP), III.3 (CAHPS Survey Requirement for the 2014 ESRD QIP) and III.4 (Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP) in this proposed 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).

Finally, the fiscal impact of the proposed 3-year minimum lifetime standard 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.

However, we would expect that this proposed rule would have a small, if any, savings impact on the program.

B. Detailed Economic Analysis

1. CY 2012 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

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 ESRD PPS 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.

We used the June 2010 update of CY 2009 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2009 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.C.7 of this proposed 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 2009 amounts as 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 where ASP data was available. We updated the last available quarter of actual ASP data for the top twelve drugs (the second quarter of 2011) thru 2012 by using the quarterly growth in the

Producer Price Index for Drugs (PPI), consistent with the method for addressing price growth in the ESRDB market basket. This resulted in 1.5 percent, 1.0 percent, 1.7 percent, 1.2 percent, 1.2 percent and 0.2 percent increase, respectively, for the third quarter of 2011 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 9 below shows the updates used for the drugs.

We updated payments for laboratory tests paid through the laboratory fee schedule to 2011 and 2012 using the statutory required update of the CPI-U increase with any legislative adjustments. For this proposed rule, the growth from 2009 to 2011 is -3.6 percent and the growth from 2009 to 2012 is -5.1 percent.

Table 9: Price Increases from 2009 to 2011 and 2009 to 2012 of Separately Billable Part B Drugs.

| Drugs and Biologicals | Price Update 2009 to 2011 | Price Update 2009 to 2012 |
|------------------------------|--------------------------------------|--------------------------------------|
| EPO | 3.9% | 9.1% |
| Paricalcitol | -16.2% | -14.6% |
| Sodium_ferric_glut | 5.1% | 9.6% |
| Iron_sucrose | -6.0% | -1.6% |
| Levocarnitine | 1.4% | 15.5% |
| Doxercalciferol | 8.0% | 15.7% |
| Calcitriol | -6.4% | -2.0% |
| Iron_dextran | -4.3% | 0.5% |
| Vancomycin | 1.6% | 7.2% |
| Alteplase | 15.9% | 21.6% |
| Aranesp | 3.0% | 8.6% |
| Daptomycin | 16.6% | 22.5% |

Other Injectibles 0.8% 5.5%

Table 10 shows the impact of the proposed estimated CY 2012 ESRD payments compared to estimated payments to ESRD facilities in CY 2011.

Table 10 Impact of Proposed Changes in Payment to ESRD facilities for CY 2012 ESRD proposed rule. [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 | 5,304 | 38.4 | 0.2% | 0.0% | 2.1% |
| Type | | | | | |
| Freestanding | 4,759 | 34.8 | 0.3% | 0.0% | 2.1% |
| Hospital based | 545 | 3.6 | -0.1% | -0.3% | 1.7% |
| Ownership Type | | | | | |
| Large dialysis organization | 3,396 | 24.8 | 0.3% | 0.0% | 2.2% |
| Regional chain | 848 | 6.4 | 0.1% | -0.1% | 1.8% |
| Independent | 624 | 4.3 | 0.0% | 0.0% | 2.0% |
| Hospital based ¹ | 430 | 2.8 | -0.1% | -0.4% | 1.7% |

| | | | | | |
|---|-------|------|------|-------|------|
| Unknown | 6 | 0.0 | 0.2% | 0.2% | 2.1% |
| Geographic Location | | | | | |
| Urban | 4,117 | 31.9 | 0.2% | 0.0% | 2.0% |
| Rural | 1,187 | 6.4 | 0.3% | -0.1% | 2.1% |
| Census Region | | | | | |
| East North Central | 875 | 5.9 | 0.2% | -0.2% | 1.9% |
| East South Central | 415 | 2.9 | 0.4% | -0.2% | 2.0% |
| Middle Atlantic | 584 | 4.7 | 0.1% | 0.0% | 2.1% |
| Mountain | 321 | 1.7 | 0.1% | 0.1% | 2.1% |
| New England | 163 | 1.3 | 0.2% | 0.1% | 2.1% |
| Pacific | 620 | 5.0 | 0.1% | 0.2% | 2.2% |
| South Atlantic | 1,180 | 8.7 | 0.3% | -0.3% | 1.9% |
| West North Central | 389 | 2.1 | 0.2% | 0.2% | 2.2% |
| West South Central | 718 | 5.5 | 0.3% | 0.3% | 2.4% |
| Puerto Rico and Virgin Islands | 39 | 0.4 | 0.2% | -2.5% | 0.0% |
| Facility Size | | | | | |
| Less than 4,000 treatments ² | 939 | 2.0 | 0.2% | -0.1% | 2.1% |
| 4,000 to 9,999 treatments | 2,101 | 10.9 | 0.3% | -0.1% | 2.0% |
| 10,000 or more treatments | 2,214 | 25.4 | 0.2% | 0.0% | 2.1% |
| Unknown | 50 | 0.2 | 0.1% | -0.4% | 1.8% |
| Percentage of Pediatric Patients | | | | | |
| Less than 2% | 5,192 | 37.8 | 0.2% | 0.0% | 2.1% |
| Between 2% and 19% | 55 | 0.5 | 0.1% | -0.3% | 1.8% |
| Between 20% and 49% | 7 | 0.0 | 0.0% | 0.2% | 1.8% |
| More than 50% | 50 | 0.0 | 0.0% | -0.3% | 1.3% |

¹ Includes hospital based facilities not reported to be part of a large dialysis organization or part of regional chain ownership.

² Of the 939 Facilities with less than 4,000 treatments, only 358 qualify for the low-volume adjustment. The low-volume adjustment was not applied to pediatric patients. The estimated impact to these Low volume Facilities is a 2.4% increase in payments.

³ Includes the effect of the ESRDB Market Basket minus productivity adjustment, which results in an increase of 1.8% 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 from 14.7% to 14.4% 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 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.

Column A of 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 proposed changes in outlier payment policy and the proposed change for the BSA national average described in section I.C.10 and section I.C.9, respectively, of this proposed rule, are shown in column C. For CY 2012, the impact on all facilities of our proposed changes in outlier payment policy and the proposed BSA national average would be a 0.2 percent increase in estimated payments. The estimated impact of our proposed changes in outlier payment policy and the BSA national average ranges from -0.1 percent decrease to a 0.4 percent increase. Most ESRD facilities are anticipated to have a positive effect on the estimated CY 2012 payments as a result of the proposed outlier and BSA national average changes.

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 2.5 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 proposed 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 0.3 percent increase due to changes in the wage index.

Column E reflects the overall impact (that is the effects of the proposed outlier and BSA national average changes, the proposed 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). It is expected that overall ESRD facilities will experience a 2.1 percent increase in estimated payments in 2012. Puerto Rico is expected to receive no increase in their estimated payments in CY 2012 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 1.3 percent to 2.4 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 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 proposed 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 \$8.3 billion. This estimate is based on various price update factors discussed in section VII of this proposed rule. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 4.2 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 that have

chosen the ESRD PPS transition. As a result of the projected 2.1 percent overall increase in the proposed ESRD PPS payment amounts in CY 2012, we estimate that there will be an increase in beneficiary co-insurance payments of 2.1 percent in CY 2012, which translates to approximately \$40 million.

e. Alternatives Considered

In developing this proposed rule, we considered eliminating all laboratory tests from the outlier policy, but instead we are proposing to eliminate only the Automated Multi-Channel Chemistry (AMCC) panel tests. We believe this proposed approach would continue to recognize expensive laboratory tests in the outlier policy while reducing the burden associated with the 50 percent rule (see section I.C.10 of this proposed 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 portions of the blended payment during the transition, such as applying the wage index budget-neutrality adjustment factor to the ESRD PPS wage index values, but instead we proposed applying 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 PPSs (see section I.C.c of this proposed rule for additional information on how we propose to apply the wage budget-neutrality adjustment factor).

2. End-Stage Renal Disease Quality Incentive Program (QIP)

a. Effects of the Proposed 2013 and 2014 ESRD QIP

This proposed 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 a 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 proposing to determine a provider/facility's performance score is described in section IV.A.3 (Methodology for Calculating the Total Performance Score for the 2013 ESRD QIP) and section IV.A.2.e (Methodology for Calculating the Total Performance Score for the PY 2014 ESRD QIP) of this proposed rule. Any reductions in ESRD payment would begin on January 1, 2013

for services furnished on or after January 1, 2013 for the 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 2014 ESRD QIP.

As a result, based on the QIP outlined in this proposed rule, we estimate that approximately 38.8 percent or 2,059 of total ESRD dialysis facilities would likely receive a payment reduction for PY 2013. In PY 2014, we estimate that approximately 13.8 percent or 737 of total ESRD facilities would likely receive some type of payment reduction.

The QIP impact assessment assumes an initial count of 5,430 dialysis facilities with paid Medicare dialysis claims in 2009. The PPS analysis, presented earlier, excludes 126 facilities for PPS-specific reasons thereby narrowing the final analytic sample to 5,304. Specifically, facilities excluded include those they do not have information on the PPS phase-in election. Most of these facilities closed during 2009 or 2010. In addition, they exclude a relatively small number of facilities that were either located in certain US territories (Guam, American Samoa, Marianna Islands) where a different payment approach has been used (they have not been paid under the Composite Rate system) or that represented facilities with no

payments reported on the very small number of claims they submitted. As a result, Table 11 shows the overall estimated distribution of payment reductions resulting from the PY 2013 ESRD QIP. Table 12 shows the overall estimated distribution of payment reductions resulting from the PY 2014 ESRD QIP.

Table 11. Estimated Distribution of CY 2013 ESRD QIP Payment Reductions.

| Payment Reduction | Number of Facilities | Percent of Facilities |
|-------------------|----------------------|-----------------------|
| 0.0% | 3,245 | 61.2% |
| 1.0% | 741 | 14.0% |
| 1.5% | 755 | 14.2% |
| 2.0% | 563 | 10.6% |

Table 12. Estimated Distribution of CY 2014 ESRD QIP Payment Reductions.

| Payment Reduction | Number of Facilities | Percent of Facilities |
|-------------------|----------------------|-----------------------|
| 0.0% | 4,567 | 86.1% |
| 1.0% | 434 | 8.2% |
| 1.5% | 211 | 4.0% |
| 2.0% | 92 | 1.7% |

¹CY 2014 QIP Scores estimated using the measures Hemoglobin > 12 g/dl, Urea Reduction Ratio ≥ 65% as a proxy for the Kt/V measure, and Standard Hospitalization Ratio.

To estimate the total payment reductions in 2013 and 2014 resulting from the proposed rule for each facility, we multiplied the number of patients treated at each facility receiving a reduction times an average of three treatments per week. We then multiplied this product by a base rate of \$229.63 per dialysis treatment (before an adjustor is

applied) to arrive at a total ESRD payment for each facility:

((Number of patients treated at each facility X 3 treatments per week) X base rate).

Finally, we applied the estimated payment reduction percentage expected under the QIP, yielding a total payment reduction amount for each facility:

(Total ESRD payment X estimated payment reduction percentage).

For payment consequence year 2013, totaling all of the payment reductions for each of the 2,059 facilities expected to receive a reduction leads to a total payment reduction of approximately \$47.2 million. Further, we estimate that the total costs associated with the collection of information requirements described in section III.1, of this proposed rule (Display of Certificates for the 2013 ESRD QIP) would be less than \$300,000 for all ESRD facilities in 2013.

For payment consequence year 2014, totaling all of the payment reductions for each of the 737 facilities expected to receive a reduction leads to a total payment reduction of approximately \$14 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 2013 and 2014 ESRD QIP), III.2 (NHSN Reporting Requirement for the 2014 ESRD QIP), III.3 (Patient Experience Survey Usage Reporting Requirement for the 2014 ESRD QIP) and III.4 (Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP) of this proposed rule would be less than \$24 million for all ESRD facilities.

As a result, we estimate that ESRD facilities will experience an aggregate impact of \$47.5 million for 2013 and \$38 million payment reduction for 2014.

Table 13 below shows the estimated impact of the proposed QIP payment reductions to all ESRD facilities for payment consequence year 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).

Table 13. Impact of Proposed QIP Payment Reductions to ESRD Facilities for CY 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 | 5,304 | 38.4 | 4,709 | 2,059 | -0.57% |
| Facility Type: | | | | | |
| Freestanding | 4,759 | 34.8 | 4,334 | 1,874 | -0.57% |
| Hospital-based | 545 | 3.6 | 375 | 185 | -0.57% |

| | 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) |
|---|----------------------|--|-------------------------------------|--|---|
| Ownership Type: | | | | | |
| Large Dialysis | 3,396 | 24.8 | 3,145 | 1,326 | -0.56% |
| Regional Chain | 848 | 6.4 | 755 | 348 | -0.62% |
| Independent | 624 | 4.3 | 519 | 250 | -0.60% |
| Hospital-based (non-chain) | 430 | 2.8 | 288 | 135 | -0.52% |
| Unknown | 6 | 0 | 2 | 0 | 0.00% |
| Facility Size: | | | | | |
| Large Entities | 4,302 | 31.7 | 3,953 | 1,700 | -0.57% |
| Small Entities ¹ | 1,054 | 7.1 | 807 | 385 | -0.57% |
| Unknown | 6 | 0 | 0 | 0 | - |
| Urban/Rural Status: | | | | | |
| Urban | 4,117 | 31.9 | 3,630 | 1,581 | -0.56% |
| Rural | 1,187 | 6.4 | 1,079 | 478 | -0.60% |
| Census Region: | | | | | |
| Northeast | 746 | 6.1 | 671 | 284 | -0.58% |
| Midwest | 1,258 | 8 | 1,075 | 479 | -0.57% |
| South | 2,311 | 17.1 | 2,123 | 980 | -0.61% |
| West | 939 | 6.8 | 806 | 303 | -0.46% |
| US Territories ² | 39 | 0.4 | 34 | 13 | -0.52% |
| Unknown | 11 | 0 | 0 | 0 | - |
| Census Division: | | | | | |
| East North Central | 875 | 5.9 | 730 | 330 | -0.56% |
| East South Central | 415 | 2.9 | 384 | 189 | -0.69% |
| Middle Atlantic | 584 | 4.7 | 526 | 232 | -0.61% |
| Mountain | 321 | 1.7 | 276 | 87 | -0.40% |
| New England | 163 | 1.3 | 145 | 52 | -0.50% |
| Pacific | 620 | 5 | 530 | 216 | -0.49% |
| South Atlantic | 1,180 | 8.7 | 1,088 | 514 | -0.62% |
| West North Central | 389 | 2.1 | 345 | 149 | -0.61% |
| West South Central | 718 | 5.5 | 651 | 277 | -0.56% |
| US Territories ² | 39 | 0.4 | 34 | 13 | -0.52% |
| Facility Size (# of total treatments): | | | | | |
| Less than 4,000 treatments | 939 | 2 | 514 | 171 | -0.29% |
| 4,000-9,999 treatments | 2,101 | 10.9 | 2,006 | 846 | -0.60% |

| | 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) |
|--|----------------------|--|-------------------------------------|--|---|
| Over 10,000 treatments | 2,214 | 25.4 | 2,177 | 1,038 | -0.66% |
| Unknown | 50 | 0.2 | 12 | 4 | -0.19% |
| 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 2014 ESRD QIP we lacked performance data on the Vascular Access Type Measure (Fistula), Dialysis Adequacy Measure (Kt/V), the Vascular Access Type Measure (Catheter), and the Vascular Access Infections Measure to conduct an analysis at this time and we have omitted those measures from these estimates. Rather, we conducted a simulation using the latest available performance data on the Hemoglobin Greater Than 12g/dL measure, the Dialysis Adequacy (URR) measure (as a proxy for the Dialysis Adequacy Measure (Kt/V)), and the SHR measure to estimate the impact of this proposed rule as accurately as possible. These simulated analyses were performed using 2009 claims data as the performance year and 2008 claims data as the baseline year for the Hemoglobin Greater Than 12g/dL measure and the Dialysis Adequacy Measure (URR); SHR performance data was extracted from the 2010 DFR data set using 2008 as the performance year and 2007 as the baseline year.

Using these conditions, we calculated estimated national achievement threshold and benchmark values for the Hemoglobin Greater than 12g/dL, Dialysis Adequacy (URR), and SHR measures using all facilities present in the data set. Equal weighting was applied in calculating total performance scores. Given the lack of data for several measures, the actual impact of the proposed 2014 QIP may vary significantly from the values provided here.

Using the above assumptions, Table 14 below shows the estimated impact of the proposed QIP payment reductions to all ESRD facilities for payment consequence year 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 14. Impact of Proposed QIP Payment Reductions to ESRD Facilities for CY 2014

| | <i>Number of Facilities</i> | <i>Number of Medicare Treatments 2009 (in millions)</i> | <i>Number of Facilities with QIP Score</i> | <i>Number of Facilities Expected to Receive a Payment Reduction</i> | <i>Payment Reduction (percent change in total ESRD payments)</i> |
|------------------------|-----------------------------|---|--|---|--|
| All Facilities | 5,304 | 38.4 | 4,238 | 737 | -0.17% |
| Facility Type: | | | | | |
| Freestanding | 4,759 | 34.8 | 4,077 | 712 | -0.18% |
| Hospital-based | 545 | 3.6 | 161 | 25 | -0.06% |
| Ownership Type: | | | | | |
| Large Dialysis | 3,396 | 24.8 | 2,981 | 497 | -0.18% |
| Regional Chain | 848 | 6.4 | 671 | 108 | -0.16% |

| | <i>Number of Facilities</i> | <i>Number of Medicare Treatments 2009 (in millions)</i> | <i>Number of Facilities with QIP Score</i> | <i>Number of Facilities Expected to Receive a Payment Reduction</i> | <i>Payment Reduction (percent change in total ESRD payments)</i> |
|--|-----------------------------|---|--|---|--|
| Independent | 624 | 4.3 | 477 | 115 | -0.24% |
| Hospital-based (non-chain) | 430 | 2.8 | 109 | 17 | -0.05% |
| Unknown | 6 | 0 | 0 | 0 | 0.00% |
| Facility Size: | | | | | |
| Large Entities | 4,302 | 31.7 | 3,696 | 616 | -0.18% |
| Small Entities ¹ | 1,054 | 7.1 | 586 | 132 | -0.16% |
| Unknown | 6 | 0 | 0 | 0 | - |
| Urban/Rural Status: | | | | | |
| Urban | 4,117 | 31.9 | 3,289 | 587 | -0.18% |
| Rural | 1,187 | 6.4 | 949 | 150 | -0.16% |
| Census Region: | | | | | |
| Northeast | 746 | 6.1 | 579 | 116 | -0.19% |
| Midwest | 1,262 | 8 | 937 | 189 | -0.19% |
| South | 2,312 | 17.1 | 1,994 | 329 | -0.18% |
| West | 939 | 6.8 | 703 | 94 | -0.12% |
| US Territories ² | 39 | 0.4 | 25 | 9 | -0.28% |
| Unknown | 6 | 0 | 0 | 0 | - |
| Census Division: | | | | | |
| East North Central | 875 | 5.9 | 643 | 128 | -0.18% |
| East South Central | 415 | 2.9 | 364 | 64 | -0.19% |
| Middle Atlantic | 584 | 4.7 | 447 | 98 | -0.21% |
| Mountain | 321 | 1.7 | 230 | 26 | -0.10% |
| New England | 163 | 1.3 | 132 | 18 | -0.12% |
| Pacific | 620 | 5 | 473 | 68 | -0.14% |
| South Atlantic | 1,180 | 8.7 | 1,014 | 175 | -0.18% |
| West North Central | 389 | 2.1 | 294 | 61 | -0.20% |
| West South Central | 718 | 5.5 | 616 | 90 | -0.16% |
| US Territories ² | 39 | 0.4 | 25 | 9 | -0.28% |
| Facility Size (# of total treatments): | | | | | |
| Less than 4,000 treatments | 939 | 2 | 384 | 63 | -0.09% |
| 4,000-9,999 treatments | 2,101 | 10.9 | 1,822 | 332 | -0.20% |
| Over 10,000 treatments | 2,214 | 25.4 | 2,023 | 338 | -0.18% |
| Unknown | 50 | 0.2 | 9 | 4 | -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. | | | | | |

| | <i>Number of Facilities</i> | <i>Number of Medicare Treatments 2009 (in millions)</i> | <i>Number of Facilities with QIP Score</i> | <i>Number of Facilities Expected to Receive a Payment Reduction</i> | <i>Payment Reduction (percent change in total ESRD payments)</i> |
|--|-----------------------------|---|--|---|--|
| ³ CY 2014 QIP Scores estimated using the measures Hemoglobin > 12 g/dl, Urea Reduction Ratio ≥ 65%, and Standard Hospitalization Ratio. | | | | | |

b. Alternatives Considered for 2013 and 2014 ESRD QIP

In developing the proposed 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 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 that the QIP strives for. 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 11g/dL. We have decided to retire the Hemoglobin Less Than 10g/dL measure from the program, and are requesting the public's comments on this proposal.

As stated previously for the PY 2014 ESRD QIP, we propose to implement a QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning 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 proposed 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 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. 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.

In proposing the scoring methodology for the 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 2014 ESRD QIP, we aim to design a scoring methodology that is straightforward and transparent to providers/facilities, patients, and other stakeholders. We believe that all scoring methodologies for Medicare Value-Based Purchasing programs should be aligned as appropriate given their specific statutory requirements.

3. Ambulance Fee Schedule

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

As discussed in section V. of this proposed 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 V, we are proposing to amend 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 as the 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 proposed 3-year minimum lifetime standard for DME is likely to be minimal because we believe that this standard is consistent with our current interpretation of durability 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 minimum lifetime standard. However, even absent the rule, it is likely that new products which do not meet the 3-year lifetime standard would not qualify as DME based upon our current interpretation of durability for DME. It is possible that with the clarification of the 3-year minimum lifetime standard, we would be limiting 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 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 would expect that this proposed rule would have a small, if any, savings impact on the program.

C. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 15 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

| TABLE 15: Accounting Statement: Classification of Estimated Transfers and Costs ESRD PPS for CY 2012 | |
|---|--|
| Category | Transfers |
| Annualized Monetized Transfers | \$160 million |
| From Whom to Whom | Federal Government to ESRD providers |
| Category | Costs |
| Increased Beneficiary Co-insurance Payments | \$40 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 | \$11.7 million |
| Annualized Monetized ESRD Provider Costs at the 7% Discount Rate | \$11.9 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 RUL not estimated |
| From Whom to Whom | Federal Government to DME suppliers |

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 seventeen 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 utilized to estimate payments to ESRD facilities in this RFA and RIA do not identify which dialysis facilities are part of an large dialysis organizations (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 proposed 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 15. Using the definitions in this ownership category, we consider the 624 facilities that are independent and the 430 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 proposed in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 1.7 percent increase in payments for CY 2012. An independent facility (as defined by ownership type) is estimated to receive a 2.0 percent increase in payments for 2012.

Based on the proposed 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 15 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 proposed 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 15 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 proposed rule will not have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

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 603 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 proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 174 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 174 rural hospital-based dialysis facilities will experience an estimated 1.8 percent increase in payments. As a result, this proposed 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 proposed 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 proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would 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 proposed rule. 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 website 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, the Center for Medicare & Medicaid Services proposes to amend 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 had 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) To receive the low-volume adjustment an ESRD facility must provide an attestation statement, prior to November 1st of each 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.

* * * * *

4. Section 413.237 is amended by adding 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

5. The authority citation for part 414 continues to

read as follows:

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

Subpart D-Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

6. 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) Has an expected life of at least 3 years (This expected life requirement applies to items classified as DME after **[EFFECTIVE DATE OF FINAL RULE]**).
- (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 H - Fee Schedule for Ambulance Services

7. 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.

* * * * *

(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.*

* * * * *

(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.

* * * * *

(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.

CMS-1577-P

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

Dated: June 16, 2011

Donald M. Berwick,
Administrator,
Centers for Medicare &
Medicaid Services.

Approved: June 20, 2011

Kathleen Sebelius,
Secretary,
Department of Health and
Human Services.

BILLING CODE 4120-01-P

