

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 417

[CMS-1352-P]

RIN 0938-AR13

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers

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

ACTION: Proposed rule.

SUMMARY: This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013. This rule also proposes to set forth requirements for the ESRD quality incentive program (QIP), including for payment year (PY) 2015 and beyond. This proposed rule will implement changes to bad debt reimbursement for all Medicare providers, suppliers, and other entities eligible to receive bad debt. (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. E.S.T. on August 31, 2012.

ADDRESSES: In commenting, please refer to file code CMS 1352 P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1352-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1352-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786 9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously 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:

Michelle Cruse or Terri Deutsch, (410) 786-4533, for issues related to ESRD. Heidi Oumarou, (410) 786-7942, for issues related to the ESRD market basket.

Teresa Casey, (410) 786-7215, for issues related to the QIP.

Kellie Shannon, (410) 786-0416 for information regarding Medicare bad debt.

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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they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: <http://www.cms.gov/ESRDPayment/PAY/list.asp>. Readers who experience any problems accessing any of the Addenda to the proposed and final rules of the ESRD PPS that are posted on the CMS Web site identified above should contact Michelle Cruse at 410-786-7540.

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- 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
- CCN CMS Certification Number
- 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
 CY Calendar Year
 DFC Dialysis Facility Compare
 DFR Dialysis Facility Report
 DME Durable Medical Equipment
 ESA Erythropoiesis Stimulating Agent
 ESRD End-Stage Renal Disease
 ESRDB End-Stage Renal Disease Bundled
 FDA Food and Drug Administration
 FI/MAC Fiscal Intermediary/Medicare
 Administrative Contractor
 FY Fiscal Year
 GDP Gross Domestic Product
 HAI Healthcare-Associated Infections
 HCPCS Healthcare Common Procedure
 Coding System
 HD Hemodialysis
 HHD Home Hemodialysis
 ICD-9-CM International Classification of
 Diseases, 9th Edition, Clinical
 Modifications
 ICH CAHPS In-Center Hemodialysis
 Consumer Assessment of Healthcare
 Providers and Systems
 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
 PSR Performance Score Report
 PY Payment Year
 QIP Quality Incentive Program
 REMIS Renal Management Information
 System
 RFA Regulatory Flexibility Act
 RUL Reasonable Useful Lifetime
 SBA Small Business Administration
 SIMS Standard Information Management
 System
 SHR Standardized Hospitalization Ratio
 SSA Social Security Administration
 The Act Social Security Act
 The Affordable Care Act The Patient
 Protection and Affordable Care Act
 URR Urea Reduction Ratio
 VBP Value Based Purchasing

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013. 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) (Pub. L. 110-275), Centers for Medicare & Medicaid Services (CMS) implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011. The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

Also, section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111-148), established that beginning CY 2012, and each subsequent year, the Secretary shall reduce the market basket increase factor by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, the application of the productivity adjustment may result in the increase factor being less than 0.0 percent for a year.

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

This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP), including payment year (PY) 2015. The program is authorized under section 153(c) of MIPPA, which added section 1881(h) to the Social Security Act (the Act). The ESRD QIP is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet performance standards established by CMS.

3. Reductions to Bad Debt Payments for All Medicare Providers

This proposed rule would also implement the changes to the limitations on payments for bad debt reimbursement set forth in section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112-96) by revising 42 CFR 413.89, Bad debts, charity, and courtesy allowances.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the composite and ESRD PPS base rate for CY 2013:* For CY 2013, we propose an ESRD PPS base rate of \$240.88. This amount reflects the application of the ESRD bundled (ESRDB) market basket reduced by the productivity adjustment, or 2.5 percent, and the wage index budget-neutrality adjustment factor of 1.000826 to the CY 2012 ESRD PPS base rate of \$234.81. The proposed base rate is applicable to both the ESRD PPS portion of the blended payment under the transition and payments under the full PPS. For CY 2013, we propose a composite rate portion of the ESRD PPS blended payment of \$145.49. This amount reflects the CY 2012 composite rate of \$141.94, increased by the ESRDB market basket reduced by the productivity adjustment.

- *Update to the composite rate drug add-on for CY 2013:* We are not proposing any changes to the methodology used to compute the drug add-on for CY 2013; we are only updating the data used to calculate the drug add-on for CY 2013. Using 6 years of ASP drug expenditure data, and other data, we estimate a 3.0 percent decrease in aggregate drug expenditures and a 4.6 percent increase in enrollment. Using these estimates, we project a 7.3 percent decrease in per patient growth of drug expenditures for CY 2013. Thus, we are projecting that the combined growth in per patient utilization and pricing for CY 2013 would result in a decrease to the drug add-on equal to 1.0 percentage points. We are, however, proposing to apply a zero update to the drug add-on adjustment and maintain the \$20.33 per treatment drug add-on amount for CY 2013. Because the market basket minus productivity that is applied to the composite rate increases the composite rate, the add-on adjustment of 14.3 percent is reduced to 14.0 percent to maintain the drug add-on at \$20.33.

- *Market basket and productivity adjustment:* Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts and the composite rate portion of the transition blended payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by a multi-factor productivity (MFP) adjustment. The proposed CY 2013 ESRDB market basket increase factor is 3.2 percent. The current forecast of the proposed CY 2013 MFP adjustment is 0.7 percent. The resulting proposed CY 2013 MFP-adjusted ESRDB market basket update is equal to 2.5 percent.

- *The transition budget-neutrality adjustment factor:* For CY 2013, we are proposing to apply the transition budget neutrality adjustment methodology established in CY 2011. This results in a 0 percent adjustment. Therefore, for CY 2013 we propose a 0 percent reduction to be applied to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS for renal dialysis services furnished January 1, 2013 through December 31, 2013.

- *Updates to the wage index and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data to account for differing wage levels in areas in which ESRD facilities are located. In CY 2013, we are not proposing any changes to the application of the wage index budget-neutrality adjustment factor and will continue to apply the budget-neutrality adjustment to the pre-floor, pre-reclassified wage index values for the composite rate portion of the blended payment and to the base rate for the ESRD PPS. Over the past several years, we have been gradually decreasing the wage index floor by 0.05 in an effort to gradually phase out the floor and in CY 2013 will continue to do so. Therefore, in CY 2013, we are reducing the wage index floor from 0.55 to 0.50. We also applied the wage index budget-neutrality adjustment factor to the wage index floor of 0.500 which results in an adjusted wage index floor of 0.501 (0.500 × 1.001538) for CY 2013.

- *Update to the outlier policy:* We are updating the outlier services fixed dollar loss amounts and Medicare Allowable Payments (MAPs) for CY 2013 using 2011 data. Based on the use of more current data, the fixed-dollar loss amount for pediatric patients would decrease from \$71.64 to \$50.15 and the MAP amount would decrease from \$45.44 to \$43.63 as compared to CY 2012 values. For adult patients, the fixed-dollar loss amount drops from \$141.21 to \$113.35 and the MAP amount drops from \$78.00 to \$61.06. Because of the decline in utilization associated with the implementation of the expanded bundle, the 1 percent target for outlier payments was not achieved in CY 2011. Use of 2011 data to recalibrate the thresholds, reflecting lower utilization of EPO and other outlier services, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2013. We believe this update to the outlier MAP and fixed dollar loss amounts for CY 2013 will increase payments for ESRD beneficiaries requiring higher resource

utilization in accordance with a 1 percent outlier policy.

- *Policy reiteration (composite rate drugs and AY modifier):* Under the composite and basic case-mix adjusted composite rate payment systems, certain drugs were included in the composite rate and were not eligible for separate payment. Our analyses of claims show that ESRD facilities are continuing to report composite rate drugs. In this proposed rule, we are reiterating that any item or service included in the composite rate should not be identified on ESRD claims.

- An AY modifier can be appended to claims for drugs and laboratory tests that are not ESRD-related to allow for separate payment. Our analyses of claims show that there are ESRD facilities and laboratories that are appending the AY modifier to drugs and laboratory tests that we believe are ESRD-related, resulting in separate payment. In this proposed rule, we are reiterating the purpose of the AY modifier and emphasizing that we are continuing our monitoring efforts. We are also indicating that we may consider eliminating the AY modifier in future rulemaking.

2. ESRD QIP

This proposed rule proposes to implement new requirements for the ESRD QIP. It proposes to continue some of the previous ESRD QIP measures, add new measures, and expand the scope of some of the existing measures to cover the measure topics as follows:

- To evaluate anemia management:
 - Hemoglobin Greater Than 12 g/dL, a clinical measure.
 - Anemia Management, a reporting measure.*
- To evaluate dialysis adequacy:
 - A clinical Kt/V measure for adult hemodialysis patients.*
 - A clinical Kt/V measure for adult peritoneal dialysis patients.*
 - A clinical Kt/V measure for pediatric hemodialysis patients.*
- To determine whether patients are treated using the most beneficial type of vascular access:
 - Vascular Access Type, a clinical measure topic comprised of an arteriovenous fistula and catheter measure.
- To address effective bone mineral metabolism management:
 - Hypercalcemia, a clinical measure.*
 - Mineral Metabolism, a reporting measure.
- To address safety:
 - NHSN Dialysis Event reporting measure.
- To assess patient and caregiver experience:

- ICH CAHPS survey reporting measure.

* Denotes that this measure is new to the ESRD QIP.

It also proposes to establish CY 2013 as the performance period for the PY 2015 ESRD QIP, establish performance standards for each measure, and adopt scoring and payment reduction methodologies that are similar to those finalized for the PY 2014 ESRD QIP.

3. Reductions to Bad Debt Payments for all Medicare Providers

This rule would also implement the statutory changes to the limitations on payments for bad debt reimbursement by revising 42 CFR 413.89, Bad debts, charity, and courtesy allowances. We are also proposing to move 42 CFR 413.178(a) to 42 CFR 413.89(h)(3), and to move 42 CFR 413.178(d)(2) to 42 CFR 413.89(i)(2) and to remove 42 CFR 413.178(b), (c) and (d)(1), as they are duplicated and discussed at 42 CFR 413.89. Additionally, we are making a technical correction to the cross reference in 42 CFR 417.536(f)(1) to Medicare bad debt reimbursement policy.

C. Summary of Costs and Benefits

In section VII of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section VII.B.1.a of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2013 as compared to estimated payments in CY 2012. The overall impact of the CY 2013 changes is projected to be a 3.1 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.7 percent increase in payments compared with freestanding facilities with an estimated 3.0 percent increase. Urban facilities are expected to receive an estimated payment increase of 3.1 percent compared to an estimated 3.0 percent increase for rural facilities. We expect a 2.4 percent decrease in estimated payments as a result of wage index adjustments for Puerto Rico and the Virgin Islands. However, this is offset by the impact of the outlier policy, resulting in an estimated 0.4 percent increase in payment. The estimated 3.1 percent overall payment increase would result in a \$250 million cost to Medicare and a \$70 million cost to beneficiaries. In 2013, a 2.5 percent market basket increase would result in a \$200 million

cost to Medicare and a \$50 million cost to beneficiaries. The outlier fixed dollar loss and MAP adjustments in CY 2013 would result in a \$30 million cost to Medicare and a \$10 million cost to beneficiaries.

2. Impacts for ESRD QIP

The overall economic impact of the proposed ESRD QIP is an estimated \$20.9 million for PY 2015. We expect the total payment reductions to be approximately \$8.5 million, and the costs associated with the collection of information requirements for certain measures to be approximately \$12.4 million.

The estimated payment reduction will continue to incentivize facilities to provide higher quality care to beneficiaries. The reporting measures that result in costs associated with the collection of information are critical to better understanding the quality of care beneficiaries receive, particularly a patient's experience of care, and will be used to incentivize improvements in the quality of care provided.

3. Impacts of Bad Debt Provisions

We are codifying the provisions of section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 that requires reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement; these provisions are specifically prescribed by statute and thus, are self-implementing. There will be a \$10.9 billion savings to the program over 10 years resulting from these self-implementing reductions in bad debt reimbursement.

II. Calendar Year (CY) 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On August 12, 2010, we published in the **Federal Register** a final rule (75 FR 49030 through 49214) titled, "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 services beginning January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA.

On November 10, 2011, we published in the **Federal Register**, a final rule (76 FR 70228 through 70316) titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System

and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (hereinafter referred to as the CY 2012 ESRD PPS final rule). In that final rule, for the ESRD PPS, we made a number of routine updates for CY 2012, implemented the second year of the transition to the ESRD PPS, made several policy changes and clarifications, and made technical changes with regard to the CY 2011 ESRD PPS final rule. In that rule, we finalized the following:

- A composite rate of \$141.94 per treatment for renal dialysis services that is used in the composite rate portion of the ESRD PPS payment for ESRD facilities receiving blended payments during the transition. The \$141.94 reflected the addition of the CY 2011 Part D per treatment amount (\$.49) for oral ESRD drugs with an injectable equivalent to the CY 2011 composite rate of \$138.53, and the application of the ESRD Bundled (ESRDB) market basket update of 3.0 percent minus a multifactor productivity adjustment of 0.9 percent, that is, a 2.1 percent increase.

- A zero update to the drug add-on adjustment and maintaining the \$20.33 per treatment drug add-on amount for the composite rate portion of the ESRD PPS blended payment. This results in a 14.3 percent drug add-on adjustment to the composite rate portion of the ESRD PPS blended payment.

- An ESRD PPS base rate of \$234.81 per treatment for renal dialysis services. The ESRD PPS base rate applies to the ESRD PPS portion of the blended payments during the transition and to the ESRD PPS payments. This amount reflected the CY 2012 ESRDB market basket update of 3.0 percent minus a multifactor productivity adjustment of 0.9 percent, that is, a 2.1 percent increase. This amount also reflected the application of the wage index budget-neutrality adjustment of 1.001520.

- A zero percent transition budget-neutrality adjustment factor for claims for renal dialysis services furnished from April 1, 2011 through December 31, 2011 and for CY 2012.

- The labor-related share of 41.737 percent for the CY 2012 ESRD PPS payment and the labor-related share of 53.711 percent for the CYs 2012 and 2013 ESRD composite rate portion of the blended payment for those ESRD facilities receiving a blended payment during the transition.

- The methodology for CY 2012 and subsequent years for computing the wage index budget-neutrality

adjustment factors. For CY 2012, the wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment is 1.002830, and is applied to the wage index values. The wage index budget-neutrality adjustment factor for the ESRD PPS portion of the blended payment and for the ESRD PPS is 1.001520, and is applied to the ESRD PPS base rate.

- A 0.05 reduction to the wage index floor for CYs 2012 and 2013 which resulted in a wage index floor of 0.550 and 0.500, respectively. For CY 2012, the wage index floor under the composite rate portion of the blended payment is 0.552 after the wage index budget-neutrality adjustment factor is applied to 0.550. The wage index floor under the ESRD PPS is 0.550.

- The methodologies used for CY 2012 and subsequent years of computing a wage index value for areas without hospital data for urban and rural geographic areas and for Puerto Rico.

- Using the ESRDB market basket forecasts for the ESRD PPS transition payment updates.

- The methodology for calculating and applying the multifactor productivity adjustment to the ESRDB market basket.

- An annual deadline of November 1st for ESRD facilities to submit an attestation if they believe that they are eligible for the low-volume payment adjustment.

- Changes to 42 CFR 413.232(b)(1) and (b)(2) to indicate that in the absence of an ESRD facility's final settled 12-consecutive month cost report, a fiscal intermediary (FI) or A/B Medicare Administrative Contractor (MAC) can review the ESRD facility's as-filed 12-consecutive month cost report when determining if an ESRD facility meets the low-volume criteria.

- Eliminating the restriction on vancomycin to allow ESRD facilities to receive separate payment by appending the AY modifier on the claim for vancomycin when the diagnosis reported on the claim indicates the drug was used to treat a non-ESRD related condition.

- Incorporating the Part B drug overfill policy into our outlier policy and for purposes of the composite rate portion of the blended payment during the transition, that is, ESRD facilities may only report units and charges for drugs and biologicals actually purchased.

- Using a body surface area (BSA) national average of 1.87, which is the latest national average as the reference point for the computation of the BSA

adjustment for both the composite rate portion of the ESRD PPS blended payment and for the ESRD PPS. We will also review the BSA national average on the CY 2012 claims and every 5 years thereafter.

- Changes to the outlier provision which included: (1) Eliminating the issuance of a specific list of eligible outlier service drugs, (2) including antibiotics furnished in the home to treat catheter site infections or peritonitis associated with peritoneal dialysis as an eligible outlier service, (3) excluding thrombolytic drugs and biologicals from the outlier policy, (4) including testosterone and anabolic steroids that are used for anemia management as an eligible outlier service, and (5) excluding the laboratory tests that comprise the Automated Multi-Channel Chemistry panel from the definition of outlier services and revising § 413.237 to indicate this change. Finally, in the CY 2012 ESRD PPS final rule (76 FR 70228), we clarified the following:

- For the low-volume payment adjustment, (1) “payment year” was defined as the period of time that we use for determining payment to ESRD facilities, which is a calendar year; (2) “eligibility” years was defined as the 3 years preceding the payment year and are based on cost reporting years; (3) for the cost reporting years, ESRD facilities must report costs for 12-consecutive months; (4) in the absence of a final-settled cost report, an FI or A/B MAC can review the ESRD facility’s as-filed cost report when verifying eligibility; and (5) if the FI or A/B MAC finds that the ESRD facility did not meet low-volume eligibility based on the final settled cost report, they should discontinue application of the low-volume adjustment and recoup the inappropriate payments.

- The ICD–9–CM diagnosis codes that are eligible for the co-morbidity payment adjustments 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.

- Laboratory tests that are performed for Medicare ESRD beneficiaries in an emergency room or emergency department as part of the general work-up of the patient necessary for diagnosis are not considered to be renal dialysis services.

B. Routine Updates and Proposed Policy Changes to the CY 2013 ESRD PPS

1. Composite Rate Portion of the ESRD PPS Blended Payment

Section 1881(b)(14)(E)(i) of the Act requires a 4-year transition under the ESRD PPS. This proposed rule would implement the third year of the transition period for those ESRD facilities going through the transition rather than electing to receive payment based on 100 percent of the payment amount under the ESRD PPS. For CY 2013, under 42 CFR § 413.239(a)(3), facilities that go through the transition will receive a blended rate equal to the sum of 75 percent of the full ESRD PPS amount and 25 percent of the basic case-mix adjusted composite payment amount. Accordingly, as a result of the transition period under the ESRD PPS, we continue to update the composite rate portion of the blended payment during the 4-year transition, (that is, CY 2011 through 2013), 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 includes 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 II.B.1.a of this proposed rule and the wage index is discussed in section II.B.5 of this proposed rule. For CY 2013, we are also proposing to update the second part of the transition budget-neutrality adjustment to reflect updated data. The transition budget-neutrality adjustment 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 II.B.4 of this proposed rule.

As discussed in section II.B.3 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 and, for CY 2012 and each subsequent year, the ESRDB market basket shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In sections II.B.3.b and II.B.3.c of this proposed rule, we describe the basis for the proposed CY 2013 ESRDB market basket increase of 3.2 percent, and the productivity offset of 0.7 percent,

yielding a proposed forecasted rate of increase in the base rate of 2.5 percent.

For CY 2013, the composite rate portion of the ESRD PPS blended payment would be \$145.49. The \$145.49 reflects the CY 2012 composite rate of \$141.94 increased by the ESRDB market basket reduced by the productivity adjustment (3.2 percent minus 0.7 percent) of 2.5 percent.

a. 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 4-year transition under the ESRD PPS. Under § 413.239, ESRD facilities were permitted to make a one-time election by November 1, 2010, to be excluded from the transition and receive full payment under the ESRD PPS. Section 413.239(a)(3) provides for ESRD facilities that elected to receive payment under the transition to be paid a blended amount that will consist of 25 percent of the basic case-mix adjusted composite payment system and 75 percent of the ESRD PPS payment in CY 2013. Thus, during the ESRD PPS transition, we must continue to update the composite rate portion of the blended payment amount which includes an update to the drug add-on.

As required under section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system includes services in the composite rate and an add-on to the composite rate to account for the difference between pre-MMA payments for separately billed drugs and the revised drug pricing specified in the statute. In this proposed rule, we are not proposing any changes to the drug add-on methodology in CY 2013, but are merely updating the data used in computing the drug add-on as described below.

i. Estimating Growth in Expenditures for Drugs and Biologicals in CY 2013

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 6 years of drug expenditure data based on ASP pricing, for CY 2013, 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 2013, we looked at the average annual growth in total drug expenditures between 2006 and 2011. First, we estimated the total drug expenditures for all ESRD facilities in CY 2011. We used the final CY 2006 through CY 2010 ESRD claims data and the latest available CY 2011 ESRD facility claims, updated through December 31, 2011 (that is, claims with dates of service from January 1 through December 31, 2011, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2011). For the CY 2013 PPS final rule, we intend to use additional updated CY 2011 claims with dates of service for the same timeframe. This updated CY 2011 data file will include claims received, processed, paid, and passed to the National Claims History File as of June 30, 2012. While the CY 2011 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 2013, based on analysis of the 2010 claims, we inflated the CY 2011 drug expenditures to estimate the June 30, 2012 update of the 2011 claims file. We used the relationship between the December 2010 and the June 2011 versions of 2010 claims to estimate the more complete 2011 claims that will be available in June 2012 and applied that ratio to the 2011 claims data from the December 2011 claims file. The net adjustment to the CY 2011 claims data is an increase of 9.7 percent to the 2011 expenditure data. This adjustment allows us to more accurately compare the 2010 and 2011 drug expenditure data to estimate per patient growth.

Using the completed full-year 2011 drug expenditure figure, we calculated the average annual change in drug expenditures from 2006 through 2011. This average annual change showed a decrease of 3.0 percent in drug expenditures from 2006 through 2011. We used this 3.0 percent decrease to project drug expenditures for both 2012 and 2013.

ii. Estimating per Patient Growth

Once we had the projected growth in drug expenditures from 2012 to 2013, we calculated per patient growth between CYs 2012 and 2013 by

removing the estimated growth in enrollment data between CYs 2012 and 2013. We estimate a 4.6 percent growth in fee for service Medicare dialysis beneficiary enrollment between CYs 2012 and 2013. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change of a 3 percent decrease between 2012 and 2013 (0.97) by enrollment growth of 4.6 percent (1.046) for the same timeframe. The result is a per-patient growth factor equal to 0.927 ($0.97/1.046 = 0.927$). Thus, we are projecting a 7.3 percent decrease ($-7.3\% = - .073 = 0.927 - 1$) in per patient growth in drug expenditures between 2012 and 2013.

iii. Applying the Proposed Growth Update to the Drug Add-On Adjustment

In the CY 2012 ESRD PPS proposed and final rules, we provided an incorrect citation to the CY 2006 PFS final rule with comment in the discussion of the application of the projected growth update percentages. The correct citation to this discussion in the CY 2006 PFS final rule with comment is 70 FR 70166 and 70167. In that rule, we applied the projected growth percentage to the total amount of drug add-on dollars established for CY 2005 to establish a dollar amount for the CY 2006 growth. 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 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 a 14.7 percent adjustment to the composite rate for CY 2006.

Subsequent to the publication of the CY 2006 PFS final rule with comment, the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171) was enacted on February 8, 2006. Section 5106 of the DRA amended section 1881(b)(12) of the Act to require the Secretary to increase the amount of the composite rate component of the basic case-mix adjusted system for dialysis services furnished on or after January 1, 2006 by 1.6 percent above the amount of the composite rate for such services furnished on December 31, 2005. We issued Change Request (CR) 4291, Transmittal 849, entitled, "Update to the ESRD Composite Payment Rates" on February 10, 2006 to instruct contractors to implement this change. We stated in CR 4291 that because the drug add-on adjustment is determined as a percentage of the composite rate, it was

necessary to adjust the drug add-on percentage to account for the 1.6 percent increase in the composite payment rate. Therefore, the total drug add-on adjustment to the composite payment rate for 2006 was 14.5 percent instead of 14.7 percent.

In the CY 2007 PFS final rule with comment period (71 FR 69683 and 69684), 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 CYs 2009, 2010, and 2011 PFS final rule with comment period (73 FR 69755 through 69757, 74 FR 61923, 75 FR 73485, respectively) and the CY 2012 ESRD PPS final rule (76 FR 70239), 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 2013, we are again proposing no update to the per treatment drug add-on amount of \$20.33 established in CY 2008.

iv. Proposed Update to the Drug Add-On Adjustment for CY 2013

As discussed above, we estimate a 3.0 percent decrease in drug expenditures between CYs 2012 and CY 2013. Combining this decrease with a 4.6 percent increase in enrollment, as described above, we are projecting a 7.3 percent decrease in per patient growth of drug expenditures between CYs 2012 and CY 2013. Therefore, we are projecting that the combined growth in per patient utilization and pricing for CY 2013 would result in a decrease to the drug add-on equal to 1.0 percentage points (out of the 14.3 percent add-on for 2012). This figure is derived by applying the 7.3 percent decrease to the CY 2012 drug add-on of \$20.33. This would result in a revised drug add-on of \$18.85, which is 13.0 percent of the proposed CY 2013 base composite rate of \$145.49. If we were to apply no decrease to the drug add-on of \$20.33, this would result in a 14.0 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. Therefore, we propose to apply a zero update and maintain the \$20.33 per treatment drug add-on amount for CY 2013. 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 14.3 percent drug add-on adjustment to the composite rate in effect for CY 2012. As discussed in section II.B.3.a. 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 (proposed forecast of 2.5 percent in 2013 effective January 1, 2013), resulting in a proposed decrease to the CY 2013 drug add-on adjustment from 14.3 to 14.0 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 2013 composite rate is higher than the CY 2012 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 2013 of 14.0 percent.

2. ESRD PPS Base Rate

In the CY 2012 ESRD PPS final rule (76 FR 70231), we discussed the development of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at § 413.220 and § 413.230. We explained that the CY 2011 ESRD PPS final rule (75 FR 49071 through 49082) provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget-neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. 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. We further explained that in accordance with § 413.230, the ESRD PPS base rate is adjusted for the patient-specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, as well as any outlier payment or training payments (if applicable). For CY 2012, the ESRD PPS base rate was \$234.81 (76 FR 70231).

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, for this proposed rule, we applied the 2.5 percent increase to the CY 2012 ESRD PPS base rate of \$234.81, which results in a CY 2013 ESRD PPS base rate of \$240.68 ($\$234.81 \times 1.025 = \240.68). The proposed CY 2013 ESRD PPS base rate is applicable to both the ESRD PPS portion of the blended payment under the transition and payments under the full ESRD PPS.

In addition, as discussed in section II.B.5.c. of this proposed rule, for CY 2013 we are applying the wage index budget-neutrality adjustment factor of 1.000826 to the CY 2013 ESRD PPS base rate (that is, \$240.68), yielding a proposed CY 2013 ESRD PPS wage-index budget-neutrality adjusted base rate of \$240.88 ($\$240.68 \times 1.000826 = \240.88).

3. ESRD Bundled Market Basket

a. Overview and Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment described may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. 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 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 CYs 2011 through 2013; though beginning in CY 2012, such market basket increase factor will be reduced by the productivity adjustment. Therefore, 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 2013

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

For this proposed rule, we are proposing to use the same methodology described in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162) to compute the CY 2013 ESRDB market basket increase factor and labor-related share based on the best available data (76 FR 40503). Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Insight (IGI), Inc.’s forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Using this methodology and the IGI forecast for the first quarter of 2012 of the CY 2008-based ESRDB market basket (with historical data through the fourth quarter of 2011), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2013 ESRDB market basket increase factor is 3.2 percent. For the CY 2013 ESRD payment update, we will continue to use a labor-related share of 41.737 percent for the ESRD PPS payment and the ESRD PPS portion of the blended payment, which was finalized in the CY 2011 ESRD final rule (75 FR 49161). We will also continue to use a labor-related share of 53.711 percent for the ESRD composite rate portion of the blended payment for all years of the transition. This labor-related share was developed from the labor-related components of the 1997 ESRD composite rate market basket that was finalized in the CY 2006 Physician Fee Schedule (PFS) final rule (70 FR 70168), and is consistent with the mix of labor-related services paid under the composite rate, as well as the method finalized in the CY 2011 ESRD PPS final rule (75 FR 49116).

c. Proposed Productivity Adjustment

The ESRDB market basket must be annually adjusted by changes in economy-wide productivity. Specifically, under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). The 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 and final methodology for calculating and applying the MFP adjustment to the ESRD payment update is similar to the methodology used in other payment systems, as required by section 3401 of the Affordable Care Act.

The projection of MFP is currently produced by IGI. The details regarding the methodology for forecasting MFP and how it is applied to the market basket was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70234). Using this method and the IGI forecast for the first quarter of 2012 of the 10-year moving average of MFP, the proposed CY 2013 MFP factor is 0.7 percent.

d. Calculation of the ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2013

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts and the composite rate portion of the transition blended payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by a productivity adjustment. We are proposing to follow the same methodology for calculating the ESRDB market basket updates adjusted for MFP that was finalized in the CY 2012 ESRD PPS final rule (76 FR 70234).

Thus, in accordance with section 1881(b)(14)(F)(i) of the Act, the proposed market basket increase factor for CY 2013 for the ESRDB market basket is based on the 1st quarter 2012

forecast of the CY 2008-based ESRDB market basket update, which is estimated to be 3.2 percent. This market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2013) of 0.7 percent, which is based on IGI's 1st quarter 2012 forecast. The resulting proposed MFP-adjusted ESRDB market basket update for CY 2013 is equal to 2.5 percent, or 3.2 percent less 0.7 percentage point. If more recent data is subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we will use such data, if appropriate, to determine the CY 2013 market basket update and MFP adjustment in the CY 2013 ESRD PPS final rule.

4. Transition Budget-Neutrality Adjustment for CY 2013

Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide a 4-year phase-in of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, with payments under the ESRD PPS fully implemented for renal dialysis services furnished on or after January 1, 2014. We use the term "transition" rather than "phase-in" to be consistent with other Medicare payment systems.

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

In the CY 2012 ESRD PPS final rule (76 FR 70235), we discussed the methodology used to develop the transition budget-neutrality adjustment factor. We explained that there were two parts that comprised the adjustment. For the first part, we created a one-time payment adjustment to the composite rate portion of the blended payment during the transition to account for the

per treatment costs of ESRD drugs with an injectable equivalent that were paid under Part D. We finalized the one-time addition of the CY 2011 Part D per treatment amount of \$0.49 to the composite rate (76 FR 70231). For the second part, we computed a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition, equal to the estimated total amount of payments that would otherwise occur without such a transition. We finalized in the CY 2011 ESRD PPS final rule a transition budget-neutrality adjustment of 3.1 percent based on estimates of ESRD facilities that would elect to be excluded from the transition. On April 6, 2011, we published an interim final rule (76 FR 18930) in which we revised the transition budget-neutrality adjustment from 3.1 to 0.0 percent for treatments furnished from April 1, 2011 through December 31, 2011. For CY 2012, we did not make any changes to our methodology for computing the second part of the transition budget-neutrality adjustment. In the CY 2012 ESRD PPS final rule (76 FR 70236), we finalized a zero percent reduction to all payments made to ESRD facilities for CY 2012 (that is, the zero percent adjustment was applied to both the blended payments under the transition and payments made under the 100 percent ESRD PPS).

Given that the transition budget-neutrality adjustment required under section 1881(b)(14)(E)(iii) of the Act applies in each year of the transition, we must update the transition budget-neutrality adjustment for CY 2013, the third year of the transition. As discussed in detail below, and in accordance with section 1881(b)(14)(E)(iii) of the Act, an adjustment is made to payments so that estimated total payments under the transition equal estimated total payment amounts without such a transition. In this proposed rule, we are not proposing for CY 2013 to change the methodology used to calculate either part of the transition budget-neutrality adjustment factor. We are, however, proposing to use updated data. The first part, which was addressed and finalized in the CY 2012 ESRD PPS final rule, is the Part D payment amount added to the composite rate. Therefore, this amount is updated annually by the ESRDB market basket reduced by the productivity adjustment. The second part is updated as described below.

For CY 2013, we started with 2011 utilization data from claims, as 2011 is the latest complete year of claims data available. For this proposed rule, we used the December claims file. We updated the CY 2011 utilization data to

CYs 2012 and 2013 payments by using the price growth factors for CYs 2012 and 2013, as discussed in the impact analysis in section VII.B.1.a. of this proposed rule. We then took the estimated payments under the full CY 2013 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 2013 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 reduction factor for CY 2013. Therefore, for CY 2013, 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, 2013 through December 31, 2013. We solicit comments on the proposed second part of CY 2013 transition budget-neutrality adjustment.

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

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic wage index, such as the index referred to in section 1881(b)(12)(D) of the Act. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized the wage index policy that is used under the ESRD PPS. Under the ESRD PPS, we have adopted the same method and source of wage index values used previously to compute the wage index values for the basic case-mix adjusted composite payment system. Specifically, we finalized our policies to continue to utilize the methodology established under the composite payment system for updating the wage index values using the OMB's CBSA-based geographic area designations to define urban and rural areas and corresponding wage index value values; the gradual reduction of the wage index floor during the transition; and the policies for areas

with no hospital data. For CY 2013, we are not proposing any changes to the methodology finalized in the CY 2012 final rule and will update the wage index values using the FY 2013 IPPS pre-floor, pre-reclassified hospital wage data.

In the CY 2012 ESRD PPS final rule (76 FR 70242), we explained that we would continue to use the labor-related share of 53.711 finalized in the 2005 PFS final rule (70 FR 70168) for the composite rate portion of the blended payment during the transition and continue to use a labor-related share of 41.737 for the ESRD PPS payment for CY 2012. We also discussed that 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 urban and rural definitions and corresponding wage index values. Additional discussion on the labor-share can be found in section II.B.3.b. of this proposed rule. For CY 2013, we are not proposing to change the labor-related shares as finalized in the CY 2012 rule and as discussed in section II.B.3.b of this proposed rule.

In the CY 2012 ESRD PPS final rule (76 FR 70240), we discussed that 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, for CY 2013 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.

a. Reduction to the ESRD Wage Index Floor

In the CY 2012 ESRD PPS final rule (76 FR 70239 through 70241), we finalized that we will continue to reduce the wage index floor by 0.05 for each of the remaining years of the transition. That is, we finalized the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.550 and 0.500, respectively. The wage index floor value is used in lieu of wage index values below the floor. In CY 2013, the wage index floor only applies to areas located in Puerto Rico because those are the only areas that have wage index values below the wage index floor value of 0.500 in CY 2013. The wage index floor is applied to both the composite rate

portion of the blend and to the ESRD PPS. In this proposed rule, we are not proposing any changes to the wage index floor methodology or reduction.

Consequently for CY 2013, we will continue to reduce the wage index floor by 0.05 which will reduce the wage index value from 0.550 to 0.500. The ESRD wage index floor value of 0.500 would be applied to areas that are below the wage index floor.

In the CY 2012 ESRD PPS final rule (76 FR 70241), we explained that continuing to artificially adjust the wage index values after the transition by substituting a wage index floor is not an appropriate method to address low wages in certain geographic locations. Therefore, we would no longer apply a wage index floor beginning January 1, 2014 because the wage index floor would be lower than areas with low wage index values.

b. Policies for Areas With No Wage Data

In the CY 2012 ESRD PPS final rule (76 FR 70241), we explained that we adopted the CBSA designations for the basic case-mix adjusted composite rate payment system and for the ESRD PPS. We also discussed and finalized the methodologies we use to calculate wage index values for ESRD facilities that are located in urban and rural areas where there are no hospital data. That is, for urban areas with no hospital data we compute the average wage index value of all urban areas within the State and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. For rural Puerto Rico, we use the wage index floor as the wage index value, since all rural Puerto Rico areas are subject to the floor.

We further explained that for rural Massachusetts, we determined that the borders of Dukes and Nantucket Counties are contiguous with Barnstable and Bristol counties. Under the methodology, the values for these counties are averaged to establish the wage index value for rural Massachusetts. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized that for CY 2012 and subsequent years, we will continue to follow these methodologies for computing a wage index value for areas without hospital data for urban and rural geographic areas and for Puerto Rico.

Subsequent to the issuance of the CY 2012 ESRD PPS final rule, we determined that for CY 2012 there was a rural hospital with wage data to base

an area wage index on for rural Massachusetts. We note that the wage index value for rural Massachusetts was correctly identified on the wage index table for CY 2012 based on the wage data for that rural hospital.

Consequently, in this proposed rule we are correcting the statement in the CY 2012 final rule that “For rural Massachusetts, we determined that the borders of Dukes and Nantucket Counties are contiguous with Barnstable and Bristol counties. Under the methodology, the values for these counties are averaged to establish the wage index value for rural Massachusetts” (76 FR 70241).

Therefore, for CY 2012 and subsequent years, the area wage index value for rural Massachusetts is based on wage index data of the rural hospital.

For CY 2013, we will continue to use the statewide urban average based on the average of all urban areas within the state for urban areas without hospital data. We note that Yuba City, California now has hospital data to calculate a wage index. Therefore, the methodology for computing a wage index for urban areas without hospital data no longer applies to that area. The only urban area without wage index data is Hineville-Fort Stewart, GA.

c. Proposed Wage Index Budget-Neutrality Adjustment

In the CY 2012 ESRD PPS final rule (76 FR 70241 and 70242), we explained that we have broad discretion under section 1881(b)(14)(D)(iv)(II) of the Act to develop a geographic wage index. We explained that in addition to being given broad discretion, the section cites the wage index under the basic case-mix adjusted composite payment system as an example. We have previously interpreted the statutory requirement in section 1881(b)(12)(D) of the Act for the geographic adjustment for the basic case-mix adjusted composite payment system as requiring that the geographic adjustment be made in a budget-neutral manner.

In the CY 2012 ESRD PPS final rule (76 FR 70241 and 70242), we finalized the policy to apply the wage index in a budget-neutral manner under the ESRD PPS using a wage index budget-neutrality adjustment factor. We further explained that in the first year of the ESRD PPS, 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. In the CY 2012 ESRD PPS final rule (76 FR 70242), we finalized that for CY 2012 and CY

2013 we will apply the wage index budget-neutrality adjustment to the wage index values for the composite rate portion of the blended payment and that for CY 2012 and subsequent years we will apply the wage index budget-neutrality adjustment to the ESRD PPS base rate for purposes of the ESRD PPS portion of the blended payment during the transition and the ESRD PPS payment. We are not proposing any changes to the wage index budget-neutrality adjustment methodology for CY 2013.

In the CY 2012 ESRD PPS final rule (76 FR 70242), we also finalized the methodology for computing the wage index budget-neutrality adjustment factor for CY 2012 and subsequent years. For CY 2013, we are not proposing any changes to the methodology. Consequently, for CY 2013 wage index budget-neutrality adjustment factors, we use the fiscal year (FY) 2013 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2011 outpatient claims (paid and processed as of December 31, 2011), and geographic location information for each facility which may be found through Dialysis Facility Compare. Dialysis Facility Compare can be found at the Dialysis Facility Compare Web page on the CMS Web site at <http://www.cms.hhs.gov/DialysisFacilityCompare/>. The FY 2013 hospital wage index data for each urban and rural locale by CBSA may also be accessed on the CMS Web site at <http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp>. The wage index data are located in the section entitled, “FY 2013 Proposed Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA”.

To compute the CY 2013 wage index budget-neutrality adjustment factor for this proposed rule, using treatment counts from the 2011 claims and facility-specific CY 2012 payment rates, we computed the estimated total dollar amount that each ESRD facility would have received in CY 2012. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2013. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the final ESRD wage index for CY 2013. The total of these payments becomes the new CY 2013 amount of wage-adjusted expenditures for all ESRD facilities.

After comparing these two dollar amounts (target amount divided by the new CY 2013 amount), we calculated two wage index budget-neutrality

adjustment factors that, when multiplied by the applicable CY 2013 estimated payments, would result in aggregate payments to ESRD facilities that would remain budget-neutral when compared to the target amount of expenditures. The first factor was applied to the ESRD PPS base rate. The second factor would be applied to the wage index values for the composite rate portion of the blended payment. Therefore, we are proposing for CY 2013, a wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment of 1.001538, 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 a wage index budget-neutrality adjustment factor of 1.000826 would be applied to the ESRD PPS base rate.

Because we apply the wage index budget-neutrality adjustment factor to the wage index values to ensure budget-neutrality under the composite rate portion of the blended payment, we also apply the wage index budget-neutrality adjustment factor to the wage index floor. Therefore, for the composite rate portion of the blended payment, for CY 2013, we would apply the wage index budget-neutrality adjustment factor to the wage index floor of 0.500 which results in an adjusted wage index floor of 0.501 (1.001538 × 0.500). Under the ESRD PPS, the wage index floor for CY 2013 is 0.500 because the wage index budget-neutrality adjustment factor is applied to the base rate.

d. ESRD PPS Wage Index Tables

The CY 2013 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 Web site at <http://www.cms.gov/ESRDPayment/PAY/list.asp>. The wage index tables list two separate columns of wage index values. One column represents the wage index values for the composite rate portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied. 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 we have finalized for CY 2012 and subsequent years, that we will apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

6. Proposed Drug Policy Changes

a. Daptomycin

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. This policy also applies to any drug or biological that may be developed in the future.

Subsequent to the publication of the CY 2011 ESRD PPS final rule, we received numerous comments indicating that vancomycin is indicated in the treatment of both ESRD and non-ESRD conditions, such as skin infections. In the CY 2012 ESRD PPS final rule (75 FR 70243), we eliminated 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. We also stipulated that in accordance with ICD-9 guidelines as described in the CY 2011 ESRD PPS final rule (75 FR 49107), an ESRD facility must report the diagnosis code for which vancomycin is indicated. We also reiterated that treatment of any skin infection that is related to renal dialysis access management would be considered a renal dialysis service paid under the ESRD PPS, and that no separate payment would be made. Finally, in response to comments, we stated that we would consider removing the system edit for daptomycin in future rulemaking.

After consultation with our medical experts, we are proposing to eliminate the restriction on daptomycin to allow ESRD facilities to receive separate payment by placing the AY modifier on the claim for daptomycin when furnished to treat non-ESRD related conditions for CY 2013 and subsequent years. In accordance with ICD-9-CM coding guidelines, the ESRD facility would also be required to report the diagnosis code for which the daptomycin is indicated. We solicit public comments on our proposal to eliminate the restriction on daptomycin to allow ESRD facilities to receive separate payment for these drugs when furnished to treat non-ESRD related conditions. We will continue to monitor the use of anti-infectives furnished by

ESRD facilities including those that are identified as non-ESRD related.

b. Alteplase and Other Thrombolytics

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 discussion on the outlier policy is in section II.B.7. of this proposed rule.

In the CY 2012 ESRD PPS final rule (76 FR 70246), we explained that subsequent to the publication of the CY 2011 ESRD PPS final rule, our clinical review of the 2007 ESRD claims used to develop the ESRD PPS revealed that dialysis facilities routinely used alteplase and other thrombolytic drugs for access management purposes. We explained that under the Medicare Benefit Policy Manual, Pub. 100-02, chapter 11, section 30.4.1, drugs used as a substitute for any of the listed items, or used to accomplish the same effect were covered under the composite rate. We further explained that because heparin is a composite rate drug and could be used for access management, any drug or biological used for the same purpose may not be separately paid. Section 413.237(a)(1) provides the definition of ESRD outlier services. Specifically, § 413.237(a)(1)(i) includes "ESRD related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B."

Because outlier payments are restricted under § 413.237(a) to those items or services that were or would have been considered separately billable prior to January 1, 2011, in the CY 2012 ESRD PPS final rule (76 FR 70249), we excluded thrombolytic drugs from the outlier policy and we recomputed the outlier MAP amounts to reflect this change. However, for CY 2012 we did not propose to exclude separate payment of thrombolytic drugs under the composite rate portion of the blended payment.

For CY 2013, we are proposing that thrombolytic drugs would not be considered eligible for separate payment under the composite rate portion of the blended payment for those ESRD facilities that are receiving a blended payment under the transition. We believe that this proposal is consistent

with the changes we made to our outlier policy regarding excluding thrombolytic drugs from outlier eligibility as discussed above. We solicit comment on our proposal to exclude thrombolytic drugs from separate payment under the composite rate portion of the blended payment during the transition.

c. Part B Drug Pricing

In the CY 2011 ESRD PPS proposed rule (74 FR 49991), with respect to estimating the imputed MAP amounts of ESRD outlier services that are separately billable under Part B, we proposed to use Average Sales Price (ASP) data for Part B ESRD-related drugs (which is updated quarterly). We did not make any changes to this proposed methodology in the CY 2011 final rule. In the CY 2012 ESRD PPS final rule (76 FR 70243), we explained that ESRD facilities receiving blended payments under the transition would receive payments based on ASP for separately billable ESRD drugs and biologicals for the composite rate portion of the blend. In the CY 2012 ESRD PPS final rule (76 FR 70244), we stated that under the outlier policy, we use the ASP methodology.

We are proposing for CY 2013 and subsequent years to continue to use the ASP methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute our outlier MAP amounts, the drug add-on, and any other policy that requires the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS and for the composite rate portion of the blended payment during the transition. We also would use this methodology for payment analyses that CMS may perform. We are seeking comment on our proposal to apply the ASP methodology or any modifications to the ASP for these purposes, as updated from time to time in the PFS rule or in updating the ASP pricing.

7. 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. Our regulations at 42 CFR 413.237(a)(1) provides that ESRD outlier services include: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that

were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) 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 (iv) 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.

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).

Drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services were specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010 rescinded and replaced by Transmittal 2094, dated November 17, 2010. With respect to the outlier policy, Transmittal 2094 identified additional drugs and laboratory tests that may be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011 which was issued to correct the subject on the Transmittal page and made no other changes.

In the CY 2012 ESRD PPS final rule (76 FR 70246), we finalized 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. We stated in that rule, however, that we planned to use separate guidance 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 also plan to identify, through our monitoring efforts, items and services that are incorrectly being identified as eligible outlier services. Any updates to the list of renal dialysis items and services that qualify as outlier services will be made through administrative issuances, if necessary.

Our regulations at 42 CFR 413.237(a)(2) through (a)(6), and (b) specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. In accordance with § 413.237(c) of the regulations, 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).

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 and 49139), the predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments. The average outlier services MAP amount per treatment for CY 2011 was based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. For CY 2012, the outlier services MAP amounts and fixed dollar loss amounts were based on 2010 data (76 FR 70250). That is, for CYs 2011 and 2012, the MAP and fixed dollar loss amounts were computed based on pre-ESRD PPS claims data and utilization.

a. Impact of Proposed Changes to the Outlier Policy

For CY 2013, we are not proposing any changes to the methodology used to compute the MAP or fixed dollar loss amounts. Rather, in this proposed rule, we are updating the outlier services MAP amounts and fixed dollar loss amounts to reflect the utilization of outlier services reported on the 2011 claims using the December 2011 claims file. That is, for CY 2013, the MAP and fixed dollar loss amounts are based on ESRD PPS claims and utilization. The impact of this update is shown in Table 1 which compares the outlier services MAP amounts and fixed dollar loss amounts used for the outlier policy in CY 2012 with the updated estimates for this proposed rule. The estimates for the proposed outlier CY 2013 outlier policy, which are included in Column III of Table 1, were inflation adjusted to reflect projected 2013 prices for outlier services.

TABLE 1—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Outlier policy for CY 2012 (based on 2010 data price inflated to 2012)*		Column II Updated outlier estimates based on 2011 data price inflated to 2012*		Column III Proposed outlier policy for CY 2013 (based on 2011 data price inflated to 2013)*	
	Age <18	Age >=18	Age <18	Age >=18	Age <18	Age >=18
Average outlier services MAP amount per treatment ¹ ...	\$46.26	\$81.73	\$40.20	\$60.58	\$41.49	\$62.95
Adjustments:						
Standardization for outlier services ²	1.0024	0.9738	1.0731	0.9898	1.0731	0.9898
MIPPA reduction	0.98	0.98	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount ³	\$45.44	\$78.00	\$42.27	\$58.76	\$43.63	\$61.06
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold ⁴	\$71.64	\$141.21	\$46.70	\$105.96	\$50.15	\$113.35

TABLE 1—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY—Continued

	Column I Outlier policy for CY 2012 (based on 2010 data price inflated to 2012)*		Column II Updated outlier estimates based on 2011 data price inflated to 2012*		Column III Proposed outlier policy for CY 2013 (based on 2011 data price inflated to 2013)*	
	Age <18	Age >=18	Age <18	Age >=18	Age <18	Age >=18
Patient months qualifying for outlier payment	5.7%	5.4%	7.6%	5.2%	7.4%	5.1%

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect updated prices for outlier services (that is, 2012 prices in Columns I and II and projected 2013 prices in Column III).

¹ Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts are based on 2011 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in place under the ESA claims monitoring policy were applied.

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

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

⁴ The fixed dollar loss amounts were calculated using 2011 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

As seen in Table 1, the estimated fixed dollar loss amounts that determine the 2013 outlier threshold amounts (Column III) are lower than those used for the 2012 outlier policy (Column I). The main reason for these reductions is the lower utilization of epoetin and other outlier services in the first year of the PPS. This can be seen by comparing the outlier service MAP amounts in Column I (which are based on 2010 data) vs. Column II (which is based on 2011 data).

The fixed dollar loss amounts which are added to the predicted MAP amounts per treatment to determine the outlier thresholds are being updated from \$141.21 to \$113.35 for adult patients and from \$71.64 to \$50.15 for pediatric patients compared with CY 2012 values. We estimate that the percentage of patient months qualifying for outlier payments under the current policy will be 5.1 percent and 7.4 percent for adult and pediatric patients, respectively, based on our use of 2011 data. The pediatric outlier MAP and fixed dollar loss amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of epoetin and other injectable drugs).

b. Outlier Policy Percentage

Section 413.220(b)(4) stipulates that the per treatment base rate is reduced by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. Because of the decline in utilization associated with the implementation of the expanded bundle, the 1 percent target for outlier payments was not achieved in CY 2011. Based on the 2011 claims, outlier payments represented approximately 0.52 percent of total payments. That is, the historical data

previously used to set the outlier thresholds for CY 2011 overestimated the use of outlier services under the expanded ESRD PPS, leading to lower outlier payments than expected. Use of 2011 data to recalibrate the thresholds, reflecting lower utilization of EPO and other outlier services, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2013. We believe this update to the outlier MAP and fixed dollar loss amounts for CY 2013 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier policy.

We note that recalibration of the fixed dollar loss amounts in this proposed rule for CY 2013 outlier payments results in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but raises payments to providers for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would increase for renal dialysis services eligible for outlier services and would remain unchanged for those not eligible.

C. Clarifications Regarding the ESRD PPS

1. Reporting Composite Rate Items and Services

In the CY 2011 ESRD PPS final rule (75 FR 49036), we explained that section 1881(b)(14)(B)(i) of the Act requires that the ESRD PPS payment bundle include composite rate services. The basic case-mix adjusted composite payment system represented a limited PPS for a bundle of routine outpatient maintenance renal dialysis services. We defined composite rate services at § 413.171 as “items and services used in

the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) [of the Act] and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.” In § 413.171 we also defined renal dialysis services as including, “items and services included in the composite rate for renal dialysis services as of December 31, 2010.”

The composite rate included a number of items and services beyond the dialysis treatment itself. In the CY 2011 ESRD PPS final rule (75 FR 49173), we explained that currently services that are billed on the ESRD claim do not provide any detail of the composite rate items and services that are furnished to the patient. As we discussed in the Medicare Claims Processing Manual, Pub. 100–04, chapter 8, sections 50.1 and 50.2., laboratory tests and drugs covered under the facility’s composite rate may not be billed separately. As mentioned above, the composite rate represented the routine items and services provided to Medicare beneficiaries for outpatient maintenance dialysis, therefore was full payment for those items and services. It would not have been appropriate for ESRD facilities to bill for items and services in the composite rate because this would result in duplicate payments made by Medicare.

In the CY 2011 ESRD PPS final rule (75 FR 49048), we also explained that in our analysis of the ESRD claims we identified drugs and biologicals that were included in the composite payment rate but for which ESRD facilities received separate payment in addition to the composite rate payment. Because these composite rate drugs and biologicals were listed separately on the ESRD claims, separate payment was

inadvertently made. We further explained that we excluded those payments from the final ESRD PPS base rate calculation. We also noted that the Medicare Benefit Policy Manual, Pub. 100-02, chapter 11, section 30.4.1 lists the drugs and fluids that were included under the composite payment system as heparin, antiarrhythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, and verapamil. The Medicare Benefit Policy Manual, Pub. 100-02, chapter 11, section 30.4.1 also explicitly states, “* * * drugs used in the dialysis procedure are covered under the facility’s composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate.” The manual further provides that “administration of these items (both the staff time and supplies) is covered under the composite rate and may not be billed separately” (75 FR 49048). In the CY 2012 final rule (76 FR 70243), with regards to antibiotics, we provided for separate payment for vancomycin when furnished to treat non-ESRD related conditions. Also, in section II.B.6.a of this proposed rule, we proposed to provide for separate payment for daptomycin if furnished for non-ESRD-related conditions. We also eliminated the payment distinction for antibiotics furnished in an ESRD facility or in the home used to treat access infections or peritonitis. We finalized that antibiotics furnished in the home to treat access site infections and peritonitis would be eligible for outlier payment (76 FR 70246).

As described at § 413.239, there are ESRD facilities receiving reimbursement under the transition, that is, receiving a blended payment of the basic case-mix adjusted composite rate payment system and the ESRD PPS. If an ESRD facility receives payment under the transition and reports a drug, biological, or laboratory test that was included in the composite rate on the ESRD claim, it could receive separate payment for that item or service within the portion of the blended payment that is based on the basic case-mix adjusted composite payment system.

As mentioned above and defined at § 413.237, ESRD-related drugs, biologicals, and laboratory tests that were or would have been separately payable under the basic case-mix adjusted composite payment system qualify as eligible outlier services. In the

CY 2012 ESRD PPS final rule (76 FR 70246), we finalized the elimination of 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. Therefore, if an ESRD facility reports a drug or biological that was included in the basic case-mix adjusted composite payment system on the ESRD claim, it would inappropriately be applied toward an outlier calculation. This is because all drugs and biologicals with a rate available on the ASP pricing file when the modifier AY is not present are eligible for outlier consideration.

As a result of our monitoring efforts, we continue to see composite rate drugs reported on ESRD claims. Therefore, in this proposed rule we are reiterating that composite rate items and services are not to be reported on the ESRD facility claim. We are instituting measures to ensure that composite rate drugs will be prevented from being applied to the outlier payment. These measures will be discussed through administrative issuances. We are continuing to monitor the reporting of composite rate items and services on ESRD claims and plan to take actions to recoup inappropriate and duplicative payments. If the inclusion of composite rate items and services such as laboratory tests, drugs and supplies on claims will be required, we will discuss this requirement in future rulemaking.

2. ESRD Facility Responsibilities for ESRD-Related Drugs and Biologicals

It has come to our attention that some ESRD facilities are requiring ESRD beneficiaries to purchase renal dialysis drugs and are informing beneficiaries not to use their Part D plan for their purchases.

Section 1866(a)(1)(A) of the Act as codified in regulations at 42 CFR 489.21 prohibits providers from billing beneficiaries for services for which the beneficiary would have been entitled to have payment made under Medicare if the provider appropriately filed claims. Furthermore, section 1881(b)(2)(A) of the Act states that payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services except for the beneficiary co-insurance and deductible amounts.

In the CY 2011 ESRD PPS final rule (75 FR 49045), we explained that the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient. We stated that we had incorporated payments under the basic case-mix adjusted composite rate payment system as well as payments for separately billable items and services

into the ESRD PPS base rate. As a result, we believe the ESRD PPS payments are sufficient and reflect the average cost of providing care to the average patient with ESRD and therefore, we expect that, on average, high cost patients would be offset by low cost patients. In the CY 2011 ESRD PPS final rule (75 FR 49045), we also explained that we had provided for higher acuity patients with patient case-mix adjusters and outlier payments for high-cost patients. We further cited 42 CFR § 494.90 of the ESRD Conditions for Coverage which requires the development of an individualized patient plan of care to address patient needs and concluded that we believe ESRD facilities should make medical decisions based on patient needs and not solely on a financial basis.

In the CY 2011 ESRD PPS final rule (75 FR 49050), we stipulated that any drug or biological (that is injectable, oral or other forms of administration) furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism would be considered renal dialysis services under the ESRD PPS. Any drug or biological used as a substitute for a drug or biological that was included in the ESRD PPS bundled base rate would also be a renal dialysis service and would not be eligible for separate payment. Antiemetics, anti-infectives, antipruritics, anxiolytic, excess fluid management, fluid and electrolyte management and pain management could be used for dialysis purposes and therefore, considered ESRD related. We indicated that we presumed these drugs and biologicals in whatever form they are furnished to be renal dialysis services unless indicated that they are used for non-ESRD related conditions. Drugs and biologicals paid under Part D that are furnished by an ESRD facility for ESRD-related purposes, would be considered renal dialysis services (75 FR 49050 and 49051).

We are reiterating in this proposed rule that ESRD facilities are responsible for furnishing renal dialysis items and services that are required to meet patient needs. This would include oral or other forms of administration of injectable drugs and biologicals that are furnished for ESRD-related conditions. We would also expect that ESRD facilities would not restrict access to necessary drugs for financial purposes, requiring patients to purchase medically necessary drugs and biologicals. We expect that ESRD facilities would furnish drugs and biologicals that had been considered medically necessary

prior to the implementation of the ESRD PPS and not exclude them because the ESRD facility is now financially responsible for these drugs and biologicals. Because of the reasons cited above, ESRD facilities may not require, induce or coerce beneficiaries to purchase any renal dialysis item or service.

3. Use of AY Modifiers

In response to comments received, in the CY 2011 ESRD PPS final rule, we stated that we had developed a mechanism to be used by ESRD facilities to identify and be paid separately for non-ESRD-related drugs and biologicals (75 FR 49052 and 75 FR 49168). We provided this mechanism in order to support a Medicare beneficiary's need for the furnishing of non-ESRD-related items and services (that is, predominantly drugs and laboratory tests) during a dialysis treatment to mitigate the need for the beneficiary to receive additional injections or health care visits. We further stated that in the event that supplies or equipment are not ESRD-related, ESRD facilities would be required to place a modifier for those supplies and equipment signifying that they were used for services that are not ESRD-related and eligible for separate payment (75 FR 49168). Change Request 7064, Transmittal 2033, entitled "End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services, issued on August 20, 2010, re-issued November 17, 2010 under Transmittal 2094, and re-issued January 14, 2011 under Transmittal 2134, provided instructions in the use of the modifier. In that Change Request, we indicated that the claim lines for laboratory tests and drugs provided to a beneficiary for reasons other than the treatment of ESRD, must be submitted with the AY modifier to allow for separate payment outside of the ESRD PPS. In the CY 2012 final rule, we provided for the use of the AY modifier with vancomycin, if used for non-ESRD-related conditions with the requirement that the ESRD facilities include the diagnosis code of the condition (76 FR 70243). In this proposed rule, in section II.B.6.a, we are also proposing the use of the AY modifier with daptomycin for non-ESRD related conditions. ESRD facilities will also be required to indicate the ICD-9-CM code on the claim that reflects the condition requiring the use of daptomycin.

Our monitoring activities have identified that there are ESRD facilities and clinical laboratories that are appending the AY modifier for items

that we believe are ESRD-related. Additionally, some ESRD facilities and clinical laboratories appear to be appending the AY modifier on many items and services reported on the claims. We are reiterating in this proposed rule that the purpose of the AY modifier is to allow beneficiaries the convenience to receive non-ESRD-related items (that is, drugs and laboratory tests) during their dialysis treatment and to allow the ESRD facility to receive payment for furnishing those items. The AY modifier is also intended to allow separate payment to laboratories in the event an ESRD-related laboratory test was required for non-ESRD conditions. The AY modifier is not intended to be used to receive separate payment for items that are ESRD-related and therefore are included in the ESRD PPS base rate. We are continuing to monitor the use of the AY modifier and intend to take steps to recoup inappropriate payments. In the event that we believe that the AY modifier is not being used for the purpose intended, we may be forced to discontinue the AY modifier and cease to provide separate payment for any non-ESRD-related drug or laboratory test furnished.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2015

A. Background

For over 30 years, monitoring the quality of care provided to end-stage renal disease (ESRD) patients by dialysis providers or facilities (hereinafter referred to collectively as "facility" or "facilities") has been an important component of the Medicare ESRD payment system. The ESRD quality incentive program (QIP) is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS. The ESRD QIP is authorized by section 153(c) of MIPPA, which added section 1881(h) to the Act. CMS established the ESRD QIP for PY 2012, the initial year of the program in which payment reductions are being made, in two rules published in the **Federal Register** on August 12, 2010 and January 5, 2011 (75 FR 49030 and 76 FR 628, respectively). On November 10, 2011, CMS published a rule in the **Federal Register** outlining the PY 2013 and PY 2014 ESRD QIP (76 FR 70228).

Section 1881(h) of the Act requires the Secretary to establish an ESRD QIP by (i) selecting measures; (ii) establishing the performance standards that apply to the individual measures;

(iii) specifying a performance period with respect to a year; (iv) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (v) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score. This proposed rule discusses each of these elements and our proposals for their application to PY 2015 and future years of the ESRD QIP.

B. Considerations in Updating and Expanding Quality Measures Under the ESRD QIP for PY 2015 and Subsequent PYs

1. Value-Based Purchasing (VBP) Overview

Throughout the past decade, Medicare has been transitioning from a program that pays for healthcare based solely on the number of services furnished to a beneficiary to a program that ties portions of payments to providers and suppliers to the quality of services they deliver. By paying for the quality of care, rather than merely the quantity of care, we believe we are strengthening the healthcare system while also advancing the National Quality Strategy and the three part aim which promote (i) better care for the individual thereby (ii) advancing the health of the entire population while also (iii) reducing costs. CMS specifies the domains and specific measures of quality for our value-based purchasing (VBP) programs and we are working to link the aims of the National Quality Strategy with our payment policies on a national scale.

There are currently six domains of measurement for our VBP programs, based on the six priorities of the National Quality Strategy: (i) Care coordination; (ii) population/community health; (iii) efficiency and cost reduction; (iv) safety; (v) patient- and caregiver-centered experience and outcomes; and (vi) clinical care. Together these domains not only encourage better care at the facility level, but also encourage different care settings to interface to comprehensively improve healthcare. Although currently none of the VBP programs measure quality across all of the six domains, we are working to ensure that each program considers measures supporting the six national priorities where feasible. Furthermore, we are working in partnership with facilities, beneficiaries, the National Quality Forum (NQF), the Measures Application Partnership, sister agencies in the Department of Health and Human Services (HHS), and other stakeholders to develop new

measures where gaps exist, refine measures requiring adjustment, and remove measures when appropriate. We are also working with stakeholders to ensure that the ESRD QIP serves the needs of our beneficiaries and also advances the goals of the National Quality Strategy.

We believe that the development of an ESRD QIP that is successful in promoting the delivery of high quality healthcare services in dialysis facilities is paramount. We seek to adopt measures for the ESRD QIP that promote better, safer, and more efficient care. Our measure development and selection activities for the ESRD QIP take into account national priorities, such as those established by the National Priorities Partnership (<http://www.nationalprioritiespartnership.org/>), HHS Strategic Plan (<http://www.hhs.gov/secretary/about/priorities/priorities.html>), the National Strategy for Quality Improvement in Healthcare (<http://www.healthcare.gov/center/reports/quality03212011a.html>), and the HHS National Action Plan to Prevent Healthcare Associated Infections (HAIs) (<http://www.hhs.gov/ash/initiatives/hai/esrd.html>). To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of facilities, purchasers/payers, beneficiaries, and other stakeholders.

2. Brief Overview of Proposed PY 2015 Measures

Thus far, we have adopted measures for the ESRD QIP that fall under three of the six National Quality Strategy measure priority domains:

- *Safety*: National Healthcare Safety Network (NHSN) Dialysis Event reporting;
- *Patient- and Caregiver-Centered Experience*: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting; and
- *Clinical Quality of Care*: (i) Hemoglobin Greater Than 12 g/dL; (ii) Hemodialysis Adequacy (Urea Reduction Ratio (URR)); (iii) Vascular Access Type; (iv) and Mineral Metabolism reporting (76 FR 70228).

For PY 2015, we are proposing to add new measures in the clinical quality of care domain and to expand the scope of the NHSN Dialysis Event reporting measure (safety domain) and the Mineral Metabolism reporting measure (clinical quality of care domain). We believe that the PY 2015 ESRD QIP not only further promotes the health of ESRD patients, but also strengthens the

goals of the National Quality Strategy. To that end, and as proposed and further discussed below, we are proposing to include 11 measures in the PY 2015 ESRD QIP. We also propose to include these measures and measure topics in subsequent payment years. The following measures seek to evaluate facilities on the clinical quality of care which they deliver.

- For purposes of evaluating anemia management:
 - Hemoglobin Greater Than 12 g/dL, a clinical measure.
 - Anemia Management, a reporting measure.*
 - To evaluate dialysis adequacy:
 - A clinical Kt/V measure for adult hemodialysis patients.*
 - A clinical Kt/V measure for adult peritoneal dialysis patients.*
 - A clinical Kt/V measure for pediatric hemodialysis patients.*
 - To determine whether patients are treated using the most beneficial type of vascular access:
 - An arteriovenous fistula measure.
 - A catheter measure.
 - To address effective bone mineral metabolism management:
 - Hypercalcemia, a clinical measure.*
 - Mineral Metabolism, a reporting measure (expansion proposed).
- Additionally, we are proposing to expand a previously adopted reporting measure addressing safety:
- NHSN Dialysis Event reporting measure.

We are also proposing to continue using a previously adopted reporting measure assessing patient- and caregiver-centered experience:

- ICH CAHPS survey reporting measure.

* Indicates that the measure is new to the ESRD QIP.

Although, at this time, we are not proposing to adopt measures that address care coordination, population/community health, or efficiency and cost of care, we are soliciting comments in this proposed rule on potential measures that would fall into each of these areas. We also discuss below the following measures that are under consideration for future adoption: a 30-Day Hospital Readmission measure to address care coordination; an access to care measure to address population/community health; and an efficiency measure. We also discuss below the Standardized Hospitalization Ratio Admissions (SHR) measure and the Standardized Mortality Ratio (SMR) measure that we are considering for program adoption in future years. We welcome further comments on these and

the other potential measures for future program years.

3. PY 2014 Mineral Metabolism Measure

As noted above, in the CY 2012 ESRD PPS final rule, we adopted the Mineral Metabolism reporting measure which requires each facility to attest that it monitored serum calcium and serum phosphorus at least once a month for each Medicare ESRD patient (76 FR 70271). We have since realized, however, that it may be difficult for some facilities to make this attestation if, for example, a patient is seen at the beginning of the month, his or her blood is not drawn, and then he or she is hospitalized or transient for the remainder of the month. While it is our intention to encourage facilities to put systems and processes into place to ensure at least monthly serum calcium and phosphorus monitoring, we believe it is reasonable to give consideration to situations where the monthly blood draw does not happen within the dialysis facility given these scenarios. Therefore, for PY 2014, we propose to change the Mineral Metabolism reporting requirement.

We considered proposing to require facilities to report the required information for less than 100 percent of their patients. Specifically, we considered lowering the threshold to require that a facility attest that it monitored on a monthly basis the serum calcium and serum phosphorus levels for 98 percent of its patients. We ultimately decided that a facility should be required to take and report these values for every patient at least once per month so that each beneficiary receives the highest standard of care. We realize, however, that there are circumstances beyond a facility's control wherein it may not be able to draw a sample for this patient. Therefore, for purposes of scoring the measure, we propose to now require that, in order for a facility to receive 10 points on the PY 2014 Mineral Metabolism measure, it must attest that it monitored on a monthly basis the serum calcium and serum phosphorus levels for every Medicare ESRD patient provided that: (i) The patient is alive for the entirety of the applicable month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a facility must report this information regardless of the number of treatments, provided that a claim is submitted for that patient. Additionally, we propose that if a patient is hospitalized or transient during a claim month, the facility may monitor the serum calcium

and serum phosphorus readings for that patient for the month if a patient has labs drawn by another provider/facility, those labs are evaluated by an accredited laboratory (a laboratory that is accredited by, for example, Joint Commission, College of American Pathologists, AAB (American Association of Bioanalysts), or State or Federal agency), and the dialysis facility reviews the serum calcium and serum phosphorus readings. We believe that these proposals will provide more flexibility for facilities and will also prevent facilities from drawing blood, even when not necessary, each time a patient visits for fear that he or she will fail to come to the facility again during that month. We request comment on this proposal. We also request comment on our consideration to lower the attestation to monthly monitoring of 98 percent of Medicare ESRD patients. We chose 98 percent in order to encourage improvement, and to ensure that we do not undermine the current level of high-reporting (based on the CrownWeb pilot data). We recognize that 100 percent might not be appropriate due to some individual cases that may not fit specified criteria.

Additionally, for purposes of clarification, we note that the PY 2014 attestations for both the Mineral Metabolism and ICH CAHPS measures will become available in CROWNWeb in December. As noted in the CY 2011 ESRD PPS final rule, these attestations must be made before January 31, 2013 (76 FR 70269, 70271).

4. Measures Application Partnership Review

In addition to the considerations discussed above, in selecting measures for the PY 2015 ESRD QIP, we considered input from the multi-stakeholder group, the Measures Application Partnership (<http://www.qualityforum.org.map/>). Section 1890A(a)(1) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the entity with a contract under section 1890(a) of the Act, currently NQF, to convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures for use in certain programs. Section 1890A(a)(2) of the Act requires the Secretary, not later than December 1 of each year, to make available to the public a list of quality and efficiency measures that are under consideration for use in certain programs. Section 1890A(a)(3) of the Act requires the entity with a contract under section 1890(a) of the Act to transmit the input of the multi-stakeholder groups to the Secretary not

later than February 1 of each year, beginning in 2012. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration the input of the multi-stakeholder groups in selecting quality and efficiency measures. The Measures Application Partnership is the public-private partnership comprised of multi-stakeholder groups convened by NQF for the primary purpose of providing input on measures as required by sections 1890A(a)(1) and (3) of the Act. The Measures Application Partnership's input on the quality and efficiency measures under consideration for adoption in CY 2012 was transmitted to the Secretary on February 1, 2012 and is available at (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=69885>). As required by section 1890A(a)(4) of the Act, we considered these recommendations in selecting quality and efficiency measures for the ESRD QIP.

Four proposed measures for the PY 2015 ESRD QIP (that is, three for dialysis adequacy and one for hypercalcemia) were made publicly available in accordance with section 1890A(a)(2) of the Act and were reviewed by the Measures Application Partnership. The Measures Application Partnership gave support to two of the proposed measures, NQF #1454: Proportion of patients with hypercalcemia and NQF #1423: Minimum spKt/V for Pediatric Hemodialysis Patients. The Measures Application Partnership supported the direction of a proposed composite measure comprised of two NQF-endorsed measures, NQF #0249: Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose and NQF #0318: Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum. The Measures Application Partnership recommended that the composite measure comprised of the two NQF dialysis adequacy measures be tested to ensure feasibility. We have taken these comments into consideration for the PY 2015 ESRD QIP. We will further discuss these considerations and our proposals for the PY 2015 ESRD QIP measures in the section below.

C. Proposed Measures for the PY 2015 ESRD QIP and Subsequent PYs of the ESRD QIP

Similar to our other quality reporting and pay for performance programs, we are proposing that once a quality measure is selected and finalized for the ESRD QIP through rulemaking, the

measure would continue to remain part of the program for all future years, unless we remove or replace it through rulemaking or notification. We believe that this will streamline the rulemaking process, provide continuity of quality measurement, and allow ESRD facilities to plan both quality reporting and quality improvement activities. In general, we anticipate considering quality measures for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences. If there is reason to believe that a measure raises potential safety concerns, we are proposing that we would take immediate action to remove the measure from the ESRD QIP and not wait for the annual rulemaking cycle. Such measures would be promptly removed from the measure set, and we would confirm the removal in the next ESRD QIP rulemaking cycle. ESRD facilities and the public would be immediately notified of our decision to remove a measure that raises potential safety concerns through the usual ESRD program communication channels, including memos, email notification, and web postings.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by NQF. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. Under the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and confirming specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews in order to review measures for

continued endorsement in a specific 3-year cycle. Non-NQF-endorsed measures may also go through similar maintenance by their measure stewards; such maintenance includes reviewing and updating measures.

Through the measure maintenance process, measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measures. Examples could be changes to exclusions to the patient population, changes to definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In this proposed rule, we are proposing that if a measure that we have adopted for the ESRD QIP is updated in a manner that we consider to not substantially change the nature of the

measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise our previously adopted measure specifications to clearly identify the updates made by the NQF or other measure steward and either post the updates directly on the CMS Web site or provide links to where the updates can be found. We would also provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to a measure that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate updates to ESRD QIP measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer

the same measure that we originally adopted. We invite public comment on this proposal and on our proposal that once a quality measure is adopted, it is retained for use in the subsequent ESRD QIP payment years unless we remove or replace it as discussed above.

Consistent with these goals and policies, we previously finalized six measures (including one measure with two measure sub-components) (Table 2) for the PY 2014 ESRD QIP (76 FR 70228). We propose to continue to use five of these measures for the PY 2015 ESRD QIP; however, we propose to augment two (NHSN Dialysis Event reporting and Mineral Metabolism reporting) of these five measures used in PY 2014 to continue to promote improvement in the PY 2015 ESRD QIP. We are proposing to remove the PY 2014 URR Dialysis Adequacy measure. In addition, we are proposing to add three new measures of dialysis adequacy, an anemia management reporting measure, and a hypercalcemia clinical measure.

TABLE 2—MEASURES ADOPTED FOR THE PY 2014 ESRD QIP

NQF No.	Measure title	
N/A	Percent of Patients with Hemoglobin Greater Than 12 g/dL*	
N/A	URR Hemodialysis Adequacy	
N/A for composite measure.	Vascular Access Type	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)* (NQF#0257). Hemodialysis Vascular Access- Minimizing use of Catheters as Chronic Dialysis Access* (NQF#0256).
N/A ¹	NHSN Dialysis Event Reporting** Enroll and report 3 months of dialysis event data.	
N/A ²	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Reporting* Facilities are required to attest that they administered the ICH CAHPS survey via a third party during the performance period.	
N/A ³	Mineral Metabolism Reporting. Facilities are required to attest that they have monitored each of their Medicare patient's phosphorus and calcium levels monthly throughout the performance period.**	

¹ We note that an NQF-endorsed bloodstream infection measure (NQF#1460) exists, and data for this measure is collected as part of dialysis event reporting in NHSN. It is our intention to use this measure in future years of the ESRD QIP. We believe that a reporting measure is a necessary step in reaching our goal to use NQF#1460.

² We note that a related measure utilizing the results of this survey has been NQF-endorsed (#0258), and it is our intention to use this measure in future years of the ESRD QIP. We believe that a reporting measure is a necessary step in reaching our goal to use NQF#0258.

³ We note that the NQF has previously endorsed phosphorus and calcium monitoring measures (#0261 and #0255) upon which this measure is based.

* Indicates a measure we are proposing for PY 2015 and future years of the ESRD QIP.

+ Indicates a measure we are proposing to augment for PY 2015 and future years of the ESRD QIP.

Along with the measures that have been previously adopted and which we propose to continue for use in the PY 2015 ESRD QIP as well as subsequent

years of the program, Table 3, below, lists the new measures that are being proposed for the PY 2015 ESRD QIP and subsequent years of the program. Table

4 lists the measures we are considering for future years of the ESRD QIP.

TABLE 3—NEW MEASURES PROPOSED FOR THE ESRD QIP PY 2015 AND FUTURE YEARS OF THE PROGRAM

NQF No.	Measure title
N/A	Anemia Management Reporting.
0249	Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose.
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum.
1423	Minimum spKt/V for Pediatric Hemodialysis Patients.
1454	Proportion of Patients with Hypercalcemia.

TABLE 4—MEASURES UNDER CONSIDERATION FOR FUTURE YEARS OF THE ESRD QIP

NQF No.	Measure title
1463	Standardized Hospitalization Ratio for Admissions (SHR).
0369	Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (SMR).

1. PY 2014 Measures Continuing for PY 2015 and Subsequent Payment Years

We are proposing to continue using two measures and one measure topic adopted in PY 2014 for the PY 2015 ESRD QIP and future years of the program. Proposals for scoring these measures are discussed below. For the reasons stated in the CY 2012 ESRD PPS final rule (76 FR 70262, 70264 through 65, 70269), we propose to continue using: (i) The Hemoglobin Greater than 12 g/dL measure; (ii) the Vascular Access Type measure topic comprised of two measures, (a) the Hemodialysis Vascular Access-Maximizing Placement of AVF (NQF #0257) measure, and (b) the Hemodialysis Vascular Access-Minimizing use of Catheters as Chronic Dialysis Access (NQF #0256) measure; and (iii) the ICH CAHPS survey reporting measure. The technical specifications for these measures can be found at <http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-HGB-2015-NPRM.pdf>; <http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Catheter-2015-NPRM.pdf>; <http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Fistula-2015-NPRM.pdf>; and <http://www.dialysisreports.org/pdf/esrd/public-measures/ICHCAHPS-2015-NPRM.pdf>. We request comment on the proposed continuation of these measures.

2. Expansion of Two PY 2014 Measures for PY 2015 and Subsequent Payment Years

As stated earlier, we believe it is important to continue using measures from one payment year to the next payment year of the program to encourage continued improvements in patient care. Since we believe that continued improvement in patient care is important, we are proposing to

expand the requirements under two reporting measures that we adopted for the PY 2014 ESRD QIP. These proposed expanded requirements would apply to the measures for PY 2015 and future payment years of the ESRD QIP.

a. Proposed Expanded NHSN Dialysis Event Reporting Measure

HAIs are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities. In a national effort to reduce this outcome, HHS agencies, including CMS, are partnering with the Centers for Disease Control and Prevention (CDC) to encourage facilities to report to the NHSN as a way to track and facilitate action intended to reduce HAIs. The NHSN is currently a secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion at the CDC. NHSN has been operational since 2006 and tracks data from acute care hospitals, long-term 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 facilities supports national goals for patient safety, particularly goals for the reduction of HAIs.

For the reasons stated above, we are proposing to retain the NHSN Dialysis Event reporting measure that we adopted for the PY 2014 ESRD QIP (76 FR 70268 through 70269), but with an expanded reporting period. For PY 2014, ESRD QIP facilities were required to: (i) Enroll in the NHSN and complete any training required by the CDC related to reporting dialysis events via the NHSN system; and (ii) submit three or more consecutive months of dialysis

event data to the NHSN. For the PY 2015 ESRD QIP and future payment years, we propose to retain the NHSN measure and expand the reporting period to a full 12 months of dialysis event data. Although we expect most facilities to have enrolled and trained in the NHSN dialysis event system by the end of CY 2012, we note that facilities that have not done so by January 1, 2013 or facilities that receive a CMS certification number (CCN) during 2013 must enroll and complete this training before reporting the data in order to fulfill the requirements of this reporting measure. The information reported to NHSN would be provided by the CDC to CMS for use in the ESRD QIP.

As discussed in more detail below, we are proposing that the performance period for the PY 2015 ESRD QIP would be CY 2013. We propose that facilities must report dialysis event data monthly to the NHSN. We also propose that facilities be granted a “grace period” of one month to report this data. For example, a facility’s dialysis event data for January 2013 must be reported on or before February 28, 2013. The final month of data from the performance period would be reported on or before January 31, 2014. For further information regarding the NHSN’s dialysis event reporting protocols, please see http://www.cdc.gov/nhsn/psc_da_de.html. This link provides general information and links to more detailed, specialized information.

We note that this proposed measure only applies to facilities treating in-center patients. For purposes of the NHSN Dialysis Event reporting measure, we determine whether a facility treats in-center patients by referencing the facility’s information in CMS data sources (that is, SIMS and CROWNWeb). Facilities report the types of patients that they serve in these data sources. If a facility lists in-center

services, we are proposing that the facility would be required to comply with the NHSN dialysis event reporting measure.

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 NQF). Under the exception set forth in 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 so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

An NQF-endorsed bloodstream infection measure (NQF#1460) exists and is collected by the CDC as part of dialysis event reporting in NHSN. This measure assesses the number of hemodialysis patients with positive blood cultures. This measure differs from the dialysis event reporting measure that we adopted for the PY 2014 ESRD QIP and are proposing to expand beginning with the PY 2015 program because it evaluates the number of hemodialysis outpatients with positive blood cultures over a specified time period. By contrast, the proposed NHSN Dialysis Event reporting measure assesses facilities based on whether they enroll and report dialysis event data to the NHSN, not based on what the data reported are. We intend to propose to adopt NQF #1460 once facilities have reported enough data to enable us to compute performance standards, achievement thresholds, improvement thresholds, and benchmarks for the measure.

For the reasons stated in the CY 2012 ESRD PPS final rule (76 FR 70268 through 69), we propose to retain the measure and expand the reporting period for PY 2015 and future years of the program. We request comment on this proposal. The technical specifications for this measure are located at <http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNDialysisReporting-2015-NPRM.pdf>.

b. Proposed Expanded Mineral Metabolism Reporting Measure

Undertreatment of bone mineral metabolism disease can cause severe

consequences for ESRD patients. For PY 2014, it was not yet feasible to adopt a clinical measure evaluating facilities based on their patients' bone mineral metabolism rates because facilities did not report serum phosphorus and serum calcium values during the baseline and performance periods that we finalized with respect to that year. Instead, for PY 2014, we finalized a measure assessing whether facilities routinely monitored the serum calcium and serum phosphorus levels in their patients. For PY 2015, we propose to expand this measure by requiring facilities to report a serum calcium and serum phosphorus level for each qualifying patient each month according to the requirements in CROWNWeb. Facilities would be required to enter these values into CROWNWeb on a monthly basis. Facilities would be granted a "grace period" of one month to enter the data. For example, we would require a facility to report serum calcium and serum phosphorus data for January 2013 on or before February 28, 2013. The final month of data from the performance period would be reported on or before January 31, 2014.

We do not intend for this proposed measure to encourage unnecessary testing or unduly burden a facility. Consequently, for purposes of scoring the measure, we considered proposing to require facilities to report the required information for less than 100 percent of their patients. Specifically, we considered lowering the threshold to reporting 98 percent of patients for a month in order to receive credit for that month. We chose 98 percent in order to encourage improvement, and to ensure that we do not undermine the current level of high-reporting (based on the CrownWeb pilot data). We recognize that 100 percent might not be appropriate due to some individual cases that may not fit specified criteria. We ultimately decided that a facility should be required to take and report these values for every patient at least once per month so that each beneficiary receives the highest standard of care. We realize, however, that there are circumstances beyond a facility's control wherein it may not be able to draw a sample for this patient. Therefore, we are not proposing that the facility itself must draw the serum phosphorus and serum calcium levels. If, for example, a patient is hospitalized or transient during a claim month, the facility may report the serum calcium and serum phosphorus readings for the patient for a month if a patient has labs drawn by another provider/facility and those labs are evaluated by an

accredited laboratory (a laboratories that is accredited by, for example, the Joint Commission, the College of American Pathologists, the AAB (American Association of Bioanalysts), or State or Federal agency), and the dialysis facility obtains the serum calcium and serum phosphorus readings. Additionally, we propose to only consider a patient qualified for this measure (i) if the patient is alive at the end of the month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a claim is submitted for that patient. We believe that these proposals will provide more flexibility for facilities and will also discourage facilities from drawing blood, even when not necessary, for fear that the patient will fail to come to the facility again during that month. We request comment on this proposal. We also request comment on whether facilities should only have to report data for 98 percent of their patients.

Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) 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 NQF). Under the exception set forth in 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 so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

An NQF-endorsed measure assessing hypercalcemia exists (NQF #1454) and we are proposing to adopt this measure for the PY 2015 ESRD QIP and subsequent payment years, as further discussed below. The NQF-endorsed hypercalcemia measure, however, does not score facilities based only on whether or not that facility reported serum calcium values. The Mineral Metabolism reporting measure, unlike the Hypercalcemia measure, would assess only whether facilities report serum calcium and serum phosphorus values. It would not score facilities based on the actual values that they report. We believe it is important to continue to encourage reporting independent of a measure that scores based on the actual values reported because we need such values to monitor

aspects of bone mineral metabolism, for example phosphorus management, independent of hypercalcemia; this information will allow us to develop comprehensive bone mineral metabolism measures for use in future years of the ESRD QIP.

In the CY 2012 ESRD PPS final rule, we discussed the basis for the Mineral Metabolism reporting measure (76 FR 70270 through 71). We stated that “the NQF has previously endorsed phosphorus and calcium monitoring measures (NQF #0261 and NQF #0255) and, in 2008, we adopted serum calcium and serum phosphorus monitoring as Clinical Performance Measures (<http://www.dialysisreports.org/ESRDMeasures.aspx>).” The NQF measures referenced above call for monitoring these serum calcium and serum phosphorus values, but they do not require actual reporting of these values, as is the intent of the Mineral Metabolism reporting measure.

For these reasons, we propose to expand the Mineral Metabolism reporting measure for PY 2015 and subsequent payment years under 1881(h)(2)(B)(ii) of the Act. The technical specifications for this measure can be found at <http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Reporting-2015-NPRM.pdf>. We further note that requiring the reporting of serum calcium and serum phosphorus levels for the PY 2015 ESRD QIP will allow us to develop mineral metabolism measures based on clinical data in the future. We request comment on this proposal to expand the Mineral Metabolism reporting measure.

3. New Measures Proposed for PY 2015 and Subsequent Payment Years of the ESRD QIP

As the program evolves, we believe it is important to continue to evaluate and expand the measures selected for the ESRD QIP. Therefore, for the PY 2015 ESRD QIP and subsequent payment years, we are proposing to adopt five new measures. The proposed new measures include: three measures of dialysis adequacy (together comprising one dialysis adequacy measure topic); one measure of hypercalcemia, and one reporting measure involving hemoglobin and ESA dosages for all patients.

a. Proposed Kt/V Dialysis Adequacy Measure Topic

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of “dialysis adequacy”. For PYs 2012–2014, the ESRD QIP included a hemodialysis adequacy measure evaluating the number of patients with

a URR of at least 65 percent. For the PY 2015 ESRD QIP, and future payment years, we are proposing to remove the URR Hemodialysis Adequacy measure. In its place, we are proposing to adopt three measures of dialysis adequacy (together comprising one dialysis adequacy measure topic) based on Kt/V (K = clearance, t = dialysis time, and V = volume of distribution) for the PY 2015 ESRD QIP and future payment years of the program. Kt/V is a widely accepted measure of dialysis adequacy in the ESRD community because it takes into account the amount of urea removed with excess fluid. Further, while the URR Hemodialysis Adequacy measure only applies to in-center hemodialysis patients, the proposed Kt/V measures will allow us to evaluate dialysis adequacy in adult hemodialysis (HD) patients (in-center and home hemodialysis (HHD)) receiving three treatments weekly, adult peritoneal dialysis (PD) patients, and pediatric HD patients receiving three to four treatments weekly. We are proposing to adopt the following NQF-endorsed Kt/V measures of dialysis adequacy, each one applicable to a different patient population:

(i) NQF #0249: Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose;

(ii) NQF #0318: Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum; and

(iii) NQF #1423: Minimum spKt/V for Pediatric Hemodialysis Patients.

The proposed measures assess whether Medicare dialysis patients (PD, HD, and pediatric hemodialysis) meeting the modality specific Kt/V threshold. Performance on the measures are expressed as a proportion of patient-months meeting the measure threshold.

For the reasons stated above, we are proposing to use Kt/V as the measure of dialysis adequacy for the PY 2015 ESRD QIP and future payment years of the program. Kt/V would be measured for adult HD patients using NQF #0249, adult PD patients using NQF #0318, and pediatric hemodialysis patients using NQF #1423. Additionally, we are proposing to remove the URR Hemodialysis Adequacy measure; we request comments on these proposals. The technical specifications for this measure can be found at <http://www.dialysisreports.org/pdf/esrd/public-measures/PediatricHemodialysisAdequacy-ktv-2015-NPRM.pdf>; <http://www.dialysisreports.org/pdf/esrd/>

www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysisAdequacy-ktv-2015-NPRM.pdf; and <http://www.dialysisreports.org/pdf/esrd/public-measures/HemodialysisAdequacy-ktv-2015-NPRM.pdf>. We request comment on these proposals. The proposed scoring and weighting of the Kt/V Dialysis Adequacy measure topic is discussed below.

b. Hypercalcemia

Section 1881(h)(2)(A)(iii) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Therefore, we believe it is necessary to adopt a clinical measure that encourages proper bone mineral metabolism management.

One indicator of bone mineral metabolism management is hypercalcemia. We are, therefore, proposing to use the NQF-endorsed measure, NQF #1454: Proportion of patients with hypercalcemia, to evaluate ESRD facilities for the PY 2015 and future payment years of the ESRD QIP. This measure assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average. “Uncorrected” means not corrected for serum albumin concentration. Performance on this measure is expressed as a proportion of patient-months for which the 3-month rolling average exceeds the measure threshold. Because the NQF-endorsed measure calls for a 3-month rolling average, we are proposing that the first measure rate for this measure would be calculated using the first 3 months of data collected during the proposed performance period (that is, there would be no measure rate for the first 2 months of the performance period; we would calculate the first measure rate for the performance period using the first 3 months of data and would then calculate a rate each successive month, dropping the oldest month and adding the newest month). Because we are proposing to adopt this measure not only for PY 2015, but also subsequent payment years, we also propose that, beginning with the PY 2016 program, we would measure hypercalcemia beginning in January of the applicable

performance period. This will allow us to have a 3-month rolling average for all months in the performance period. We propose that the 3-month rolling average rate for January would be calculated using the rates from November and December of the previous year as well as January of that year. Likewise, we propose that the rate for February would be calculated using the rates from December, January and February to calculate the 3-month rolling average, and so on. Technical specifications for this measure can be found at <http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Hypercalcemia-2015-NPRM.pdf>. We welcome comments on these proposals.

c. Proposed Anemia Management Reporting Measure

Section 1881(h)(2)(A)(i) requires “measures on anemia management that reflect the labeling approved by the Food and Drug Administration (FDA) for such management.” Although the current FDA-approved label for Erythropoiesis-Stimulating Agents (ESAs) only specifically addresses hemoglobin levels greater than 11 g/dL, previous FDA-approved labels suggested patients on ESAs maintain a hemoglobin level of 10–12 g/dL. As we noted in the CY 2012 ESRD PPS final rule, upon further research, the FDA determined that there is no evidence suggesting a lower target level at which hemoglobin does not cause increased risks of death, serious adverse cardiovascular reactions, and stroke and, therefore, changed its approved label on June 24, 2011 (76 FR 70257).

As a result of the changes in the FDA approved-label and the implementation of the ESRD QIP, we are monitoring trends and indicators of anemia management for the Medicare ESRD population. We have found that the average monthly blood transfusion rate increased from 2.7 percent in 2010 to 3.2 percent in 2011. We are working through our ESRD QIP monitoring and evaluation program to further assess this issue. We believe that it is important that we continue monitoring hemoglobin levels in patients to ensure that anemia is properly treated, and we are proposing to adopt a measure for PY 2015, and future payment years, which requires facilities to report ESA dosage (if applicable) and hemoglobin and/or hematocrit levels for patients on at least one monthly claim. In addition to this measure, proposed below, we plan to continue to monitor the rate of transfusions and may consider the adoption of relevant quality measures through future rulemaking if necessary.

Since January 1, 2012, facilities have been required to report hemoglobin or hematocrit¹ levels for each patient on every claim (CR 7640). Beginning April 1, 2012, if a hemoglobin or hematocrit value is not included in the claim, the claim is returned to the facility (CR 7593). If a hemoglobin or hematocrit value is not available for a patient, a facility can enter a default value of 99.99 on the claim and the claim will not be returned, provided the facility is not billing for an ESA. The default value is not acceptable when the claim includes an ESA, in such a case, the claim will be returned to the provider.

We are concerned that our current policy of paying claims that include a default hemoglobin or hematocrit value of 99.99 could lead to the under-reporting of patients’ hemoglobin or hematocrit levels and ESA dosage by facilities; we are specifically concerned that we will not receive complete and accurate hemoglobin/hematocrit readings for those patients not receiving ESAs because a default value of 99.99 can be reported on claims, and these claims will be paid, if no ESA is administered to the patient. Additionally, we believe that facilities might choose to strategically not report certain patients’ hemoglobin or hematocrit levels on certain claims—those where the patient’s hemoglobin levels are greater than 12 g/dL—in order to make the performance rate of their Hemoglobin Greater Than 12 g/dL measure seem better and reduce the likelihood of a payment reduction under the ESRD QIP.

Because it is possible that facilities could under-report hemoglobin or hematocrit levels, we are proposing to adopt an Anemia Management reporting measure for the PY 2015 ESRD QIP, and future payment years of the program. For this measure, we propose to require facilities to report a hemoglobin or hematocrit value and, as applicable, an ESA dosage for all Medicare patients at least once per month via claims. We propose to consider claims with 99.99 values as not meeting the requirements of this measure (that is, claims reporting 99.99 will be counted as if the hemoglobin or hematocrit value were left blank).

We do not intend for this proposed measure to encourage unnecessary testing or unduly burden a facility. Consequently, for purposes of scoring the measure, we considered proposing to require facilities to report the required information for less than 100

percent of their patients. Specifically, we considered lowering the threshold to reporting 98 percent of patients for a month in order to receive credit for that month. We ultimately decided that a facility should be required to take and report these values for every patient at least once per month so that each beneficiary receives the highest standard of care. We realize, however, that there are circumstances beyond a facility’s control wherein it may not be able to draw a sample for this patient. Therefore, we are not proposing that the facility itself must draw blood for each patient. If, for example, a patient is hospitalized or transient during a claim month, the facility may report the hemoglobin/hematocrit readings and ESA dosage (if applicable) for the patient for a month if a patient has labs drawn by another provider/facility and those labs are evaluated by an accredited laboratory (a laboratories that is accredited by, for example, the Joint Commission, the College of American Pathologists, the AAB (American Association of Bioanalysts), or State or Federal agency), and the dialysis facility obtains the hemoglobin/hematocrit readings and ESA dosage. Additionally, we propose to only consider a patient qualified for this measure (i) if the patient is alive at the end of the month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a claim is submitted for that patient. We believe that these proposals will provide more flexibility for facilities and will also discourage facilities from drawing blood, even when not necessary, for fear that the patient will fail to come to the facility again during that month. We request comment on this proposal. We also request comment on whether facilities should only have to report data for 98 percent of their patients.

The proposed Anemia Management reporting measure was not included in the list of measures under consideration in accordance with section 1890A(a)(2) of the Act because we had not yet fully assessed the impact of the new FDA-endorsed ESA label on the ESRD population. We have since received and analyzed more, but still incomplete, anemia management data; we believe it is necessary to require facilities to provide complete data so that we may fully understand the effect of the FDA guidance and other factors. The proposed Anemia Management reporting measure will play a critical role in patient safety. As noted above, our monitoring activities indicate that

¹ Hematocrit values are used to calculate hemoglobin levels by taking the hematocrit value and dividing by three.

there has been a slight but noticeable increase in transfusions since the adoption of the ESRD PPS. Additionally, a United States Renal Data System analysis presented in May 2012 found an increase in blood transfusion rates among ESRD patients concurrent with the implementation of the ESRD PPS. Although the association of changes in transfusion rates with the ESRD PPS, FDA label changes, and other factors are not yet known, we believe proactive facility engagement in regular monitoring of patient hemoglobin or hematocrit levels regardless of ESA use is critical to maintaining safe care, protecting the safety of beneficiaries, and monitoring the program effectively. We further believe that the data collected from the proposed measure are necessary for measure development in a clinical area of critical significance to patient safety—*anemia and transfusion*. Delay in proposing to adopt this reporting measure may prevent us from creating clinical measures for use in future years of the program and pose a risk to patients. Finally, we note that section 1881(h) of the Act specifically highlights the importance of anemia management measures, and we do not believe it would be in the best interest of the program to wait an additional year to propose this measure.

For the reasons stated above, we propose to adopt an Anemia Management reporting measure for the PY 2015 ESRD QIP and subsequent payment years. For the technical specifications for this measure, see <http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2015-NPRM.pdf>. We request public comment on this proposal.

4. Measures Under Consideration for Future Payment Years of the ESRD QIP

In addition to the PY 2015 ESRD QIP, we are also considering measures for future payment years of the program. We are specifically considering whether we should propose in future rulemaking to adopt the following two measures,

- NQF #1463: Standardized Hospitalization Ratio for Admissions (SHR) and
- NQF #0369: Dialysis Facility Risk-adjusted Standardized Mortality Ratio (SMR).

We intend to adopt these measures for future payment years of the ESRD QIP, possibly beginning with the PY 2018 program. We are notifying facilities of our intent and soliciting comments on incorporating these measures into future payment years of the ESRD QIP.

a. Standardized Hospitalization Ratio (SHR)

Hospitalizations are an important indicator of patient quality of life and morbidity. The SHR is an NQF-endorsed (#1463), risk-adjusted measure of hospitalization for dialysis patients. The measure is claims-based and describes, as a ratio, the number of ESRD Medicare patient actual admissions versus expected hospitalizations adjusted for the facility's Medicare patient case mix. Please refer to the NQF Measures Web site (www.qualityforum.org) to obtain more detail about this measure.

b. Standardized Mortality Ratio (SMR)

The SMR measure is an NQF-endorsed (#0396) critical patient-centered, outcome measure of overall patient care furnished by facilities. We believe that the SMR measure would encourage appropriate overall patient care by facilities and incentivize facilities to examine the holistic health of the patient rather than treating the patient based on an individual measure-by-measure basis. The SMR measure describes, as a ratio, the number of ESRD Medicare patient actual deaths versus expected deaths adjusted for the facility's Medicare patient case mix. Please refer to the NQF Measures Web site (www.qualityforum.org) to obtain more detail about this measure.

c. Public Reporting of SHR and SMR Measures

Although the SHR and SMR measures may not be adopted for the ESRD QIP until a future payment year, we intend to publicly report these measure rates/ratios to the public via Dialysis Facility Compare (DFC) to encourage facilities to improve their care. Section 4558(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) directs the Secretary to develop, not later than January 1, 1999, and implement, not later than January 1, 2000, a method to measure data reflective of the quality of renal dialysis services provided under the Medicare program. Under this authority, we began reporting the SMR measure on DFC in January, 2001 as a survival measure and used three categories to rate facility performance: “as expected,” “worse than expected,” and “better than expected.” The SMR measure that we are considering adopting for the ESRD QIP was developed in 1999 and facilities are required to submit this data via form 2746. The SHR measure that we are considering adopting for the ESRD QIP was developed in 1995, presented to a Technical Expert Panel after modifications to risk adjustment and statistical modeling in 2007, and

received NQF-endorsement in 2011. The data needed to calculate the SHR measure have been regularly reported to DFC since 1995 and have been used by facilities for quality improvement activities. We plan to add the SHR data to the DFC effective January 2013; additionally we will report the actual SMR rates/ratio on the DFC beginning January 2013.

We originally proposed to adopt the SHR measure for the PY 2014 program, but did not finalize the proposal, in part, because commenters voiced concerns regarding accuracy of the comorbidity data used in the calculation of the measures. Details on public comments and why we did not adopt the SHR measure are articulated in the CY 2012 ESRD PPS final rule (76 FR 70267). Since that time, we have identified that the claim form UB 92 with the type of bill (TOB) field 72X allows a facility to input up to 17 comorbid conditions per claim submission. We acknowledge that patient co-morbidities can change with time and since the capability already exists on the UB 92 TOB, we believe the best means for facilities to update patient co-morbidities is through the ESRD 72x claims form. Details on this form can be found in the Medicare Claims Processing Manual, Chapter 8—Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims (<https://www.cms.gov/manuals/downloads/clm104c08.pdf>).

In addition, because the NQF-endorsed SHR and SMR measures are risk-adjusted for ESRD patients that reside in nursing homes, in order to calculate the measure rates on DFC, we will utilize data from the Minimum Data Set (MDS) to identify those individuals in nursing homes. We would use this data not only for reporting the measure rates on DFC at present, but also for calculating the measures if we adopted them for us in future years of the ESRD QIP. The Omnibus Budget Reconciliation Act (OBRA) of 1987 requires that all Medicare and Medicaid certified nursing homes complete MDS assessments on all of their patients.

We request comment regarding the feasibility of adopting these measures for future payment years of the ESRD QIP.

5. Other Potential Future Measures Under Development

As part of our effort to continuously improve the ESRD QIP, we are working on developing additional, robust measures that provide valid assessments of the quality of care furnished to ESRD beneficiaries by facilities. Some areas of measure development are discussed

below. In addition, we are considering the feasibility of developing quality measures in other areas such as kidney transplantation, quality of life, health information technology for quality improvement at the point of care and the electronic exchange of information for care coordination, and transfusions. We request comment on these potential areas of future measurement and welcome suggestions on other topics for measure development.

a. Thirty-Day Hospital Readmissions

One of the major areas our VBP programs seek to promote is care coordination. Care coordination measures assess caregivers not only on the care directly under their control, but also on their success in coordinating care with other providers and suppliers. Hospital readmission is often the outcome of uncoordinated care. Care coordination measures encourage primary caregivers, ESRD facilities, physicians, and hospitals to work together to improve the quality of care. A 30-day hospital readmissions measure is a primary example of care coordination. This measure is currently under development for ESRD, and we request comment regarding our use of such a measure in future payment years.

b. Efficiency

One of the main goals of our VBP programs is not only to enhance quality of care but also efficiency in providing that care. At present, we are not aware of an efficiency measure that is appropriate for the ESRD population. We are, however, interested in receiving comments regarding this concept.

c. Population/Community Health

We are aware that unintended consequences, specifically those involving access to care, may result from the ESRD QIP. To address these concerns, we are currently monitoring access to care and exploring the development of new measures or adjustments to existing measures that would mitigate the unintended consequences and/or incentivize facilities caring for patients who may, generally, contribute to lower facility measure rates. We request comment on developing such a measure or adjustments to measures, specifically with regard to access to care issues.

6. Proposed Scoring for the PY 2015 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 facility based on the performance standards established

with respect to the measures selected for the performance period. For the PY 2014 ESRD QIP, we adopted a performance scoring methodology that assessed facilities on both their achievement and improvement on clinical measures. We stated that we believe that this scoring methodology will more accurately reflect a facility's performance on the measures because it will enable us to differentiate between 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 stated that we believe that the PY 2014 methodology appropriately incentivizes facilities to both achieve high Total Performance Scores and improve the quality of care they provide (76 FR 70272). We believe that the methodology set forth for PY 2014 continues to incentivize facilities to meet the goals of the ESRD QIP; therefore, with the exception of the proposed changes further discussed in the applicable section below, we propose to adopt a scoring methodology for the PY 2015 ESRD QIP that is nearly identical to the PY 2014 ESRD QIP.

7. Proposed Performance Period for the PY 2015 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a year. For the PY 2014 ESRD QIP, we finalized a performance period of CY 2012. We stated that we believe that, at this point, a 12-month performance period is the most appropriate for the program because this period accounts for any potential seasonal variations that might affect a facility's score on some of the measures, and also provides adequate incentive and feedback for facilities and Medicare beneficiaries (76 FR 70271). We continue to believe that a 12-month performance period will best meet these policy objectives, and we considered what 12-month period would be closest in time to the payment year but would still allow us to time to operationalize the program, calculate scores, and grant facilities a period of time to preview and ask questions regarding these scores before they are published and impact payment. We have determined that CY 2013 is the latest period of time during which we can collect a full 12 months of data and still implement the payment reductions beginning with January 1, 2015 services. Therefore, for the PY 2015 ESRD QIP, we propose to establish CY 2013 as the performance period for all of the measures. We request comments on this proposal.

8. Proposed Performance Standards for the PY 2015 ESRD QIP

Similar to the PY 2014 ESRD QIP, we propose to adopt performance standards for the PY 2015 ESRD QIP measures under section 1881(h)(4)(A) of the Act. This section provides that "the Secretary shall establish performance standards with respect to measures selected * * * for a performance period with respect to a year." Section 1881(h)(4)(B) of the Act further provides that the "performance standards * * * shall include levels of achievement and improvement, as determined appropriate by the Secretary." We use the performance standards to establish the minimum score a facility must achieve to avoid a payment reduction.

a. Proposed Clinical Measure Performance Standards

With respect to the seven proposed clinical measures, we propose to set the PY 2015 improvement performance standard and achievement performance standard (collectively, the "performance standard") for each measure at the national performance rate (which we would define as the 50th percentile) of all facilities' performance on the measure during CY 2011 (the proposed comparison period—discussed in more detail below).

For the PY 2014 ESRD QIP, we set the performance standards at the national performance rate during a baseline period of July 1, 2010–June 30, 2011. This period of time, however, did not allow us to publish the numerical values for the performance standards concurrently with the final rule because of the length of time needed for us to compile claims-based measure data at the individual facility level and calculate the measure rates. Instead, we included an estimate of the numerical values for the performance standards in the final rule, using nine months of data, and posted the numerical values of the performance standards based on the full 12 months of data on <http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014-FR.pdf> by the end of December 2011. In order to ensure that we have enough time to calculate and assign numerical values to the proposed performance standards for the PY 2015 program, we are proposing to set the performance standards based on the national performance rate (that is, the 50th percentile) of facility performance in CY 2011. By choosing this time period for PY 2015, however, the data on which we base the performance standards would only capture 6 months of more recent data when compared to

PY 2014 and would also overlap with 6 months of the data used to calculate the PY 2014 performance standards. We are also concerned that if we finalize this period of time, we would not be adequately addressing stakeholder requests that we take steps to minimize the length of “data lag” between the dates used to calculate the performance standards and the payment year. We recognize that stakeholders might prefer that we base performance standards on data as close in time to PY 2015 as possible.

The period of time closest to the payment year that would allow us to post the numerical values for the performance standards before the end of the first month of the performance period is parallel to that of PY 2014, from July 1, 2011 through June 30, 2012. As with PY 2014, selecting this time period for purposes of calculating numerical values for the performance standards would not allow us to publish these numerical values until late 2012 or early 2013, which is closer in time and may possibly be during the performance period. However, as in PY 2014, we would still be able to provide estimates for the numerical values of the performance standards at the time of final rule publication and post the actual numbers as soon as they are available in December 2012 or January 2013.

Based on these considerations, we are proposing CY 2011 as the basis for the performance standards (that is, the national performance rates). We do, however, request comment concerning whether we should instead use data closer in time to the payment year and set the performance standards using July 1, 2011 through June 30, 2012 data.

For two of the PY 2015 measure topics, Kt/V Dialysis Adequacy and Hypercalcemia, we do not possess data for the entirety of CY 2011, the year on which we propose to base the performance standards. We did not begin collecting uniform data on the Kt/V hemodialysis adequacy measure until January 1, 2012 (see Change Request 7460), and, under the conditions for coverage, facilities were not required to report serum calcium values that will be used to calculate the Hypercalcemia clinical measure until their submission of May 2012 data with the June 2012 national implementation of CROWNWeb. Despite these issues, we do have data on which we can base performance standards. Although facilities are not yet required to report serum calcium levels, approximately 63 percent of facilities, which treat approximately 80 percent of the Medicare ESRD patient population,

have been voluntarily reporting this data via CROWNWeb piloting since July 2008. Additionally, we have compared the serum calcium values reported by facilities in 2010 as part of a clinical data reporting program called ELab,² to values that have been voluntarily reported by facilities in 2010 through CROWNWeb, and the values are significantly similar. We believe that these similarities will also extend to data reported in 2011. Therefore, we propose to calculate performance standards for the Hypercalcemia measure using the data that we collected via CROWNWeb Pilots collected during CY 2011.

Uniform Kt/V reporting for hemodialysis patients did not begin until January 1, 2012 (CR 7640). Before this time, facilities could use a number of different methodologies to calculate Kt/V values, with the result that the values could be different depending on which methodology was used. We have analyzed the data collected during the CROWNWeb pilot and found that 88 percent of facilities that reported to CROWNWeb had reported Kt/V values using a NQF specified calculation method (this method is also specified in Change Request 7640) that yields consistent results and that is part of the specifications for each of the hemodialysis Kt/V measures that we are proposing to adopt for the PY 2015 program. Though we are not able to tell what calculation method a facility used by reviewing a claim, we believe it is reasonable to assume that roughly the same percentage of facilities reported Kt/V on their claims prior to 2012 using the same formula that they used to report it under the CROWNWeb pilot. For this reason, we propose to calculate the performance standards for the three proposed Kt/V measures using CY 2011 claims data. This is the best data we have available at this time to set reliable performance standards for Kt/V. We understand, however, that stakeholders may be concerned about the nuances of the data and we invite public comment on this proposal.

If, after consideration of the comments, we decide to not adopt the adult, hemodialysis Kt/V measure for PY 2015, we propose to continue to use URR as a measure of hemodialysis adequacy for this population. As we have noted, Kt/V is preferred over URR. Because the pediatric hemodialysis measure faces the same methodological issues as the adult hemodialysis measure, we propose that if we do not adopt the Kt/V measure for adult hemodialysis patients, we would also

not adopt the Kt/V measure for pediatric hemodialysis patients. We note that the NQF endorsed measure for Kt/V measure for peritoneal dialysis adequacy does not specify the body surface area formulas or the total body water formulas to utilize; and we would accept the submission of peritoneal adequacy Kt/V values that utilize the methods currently in use as industry standards. We believe it is important to include peritoneal dialysis patients in the ESRD QIP and are soliciting comments on the inclusion of the peritoneal dialysis Kt/V adequacy measure. We propose that, were we to retain the URR measure for adult hemodialysis, we would still adopt the Kt/V peritoneal dialysis measure. We propose that these measures would still comprise a Dialysis Adequacy measure topic and would be scored in the same manner as we propose for the Kt/V measures, below.

Even with the challenges outlined above, we believe that the advantages of adopting the Kt/V hemodialysis measure for PY 2015 outweigh the disadvantages. Therefore, we propose Kt/V as the measure for hemodialysis adequacy for PY 2015, but we specifically solicit comments regarding whether we should continue to use URR for adult hemodialysis patients for PY 2015.³

We also considered calculating performance standards for the Kt/V Dialysis Adequacy measure topic based on data from January 1, 2012–June 30, 2012, to ensure that the data was calculated consistently. We are, however, aware that a shortened data period may affect the measure rates’ reliability. Therefore, we are proposing to calculate performance standards based on the data from CY 2011 discussed above, but we invite comment on an alternative 6 month period beginning on or after the date on which uniform reporting began, January 1, 2012.

b. Estimated Performance Standards

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures because we do not yet have all of the data from CY 2011. However, we are able to estimate these numerical values based on the latest full year of data

³Note that, as further explained below, the issue we have discussed with respect to the reporting of Kt/V values prior to CY 2012 would not be an issue for the calculation of improvement scores because we are proposing CY 2012 as the period used to calculate the improvement threshold; beginning January 1, 2012, all facilities are required to report Kt/V uniformly on their claims.

² <http://www.esrdnet11.org>.

available. In Table 5, we have provided the estimated performance standards for all of the measures, except for the Hypercalcemia measure, based on data from October 1, 2010–September 30, 2011. For the Hypercalcemia measure, we currently have only 6 months of data based on approximately 63 percent of facilities reporting; the estimate, therefore, is based on data from April 2011–October 2011.

TABLE 5—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2015 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Performance standard (%)
Hemoglobin >12 g/dL	2
Vascular Access Type:	
%Fistula	59
%Catheter	13
Kt/V:	
Adult Hemodialysis	93
Adult, Peritoneal Dialysis ..	83
Pediatric Hemodialysis	90
Hypercalcemia	13

¹ As noted above, the performance standard for the Hypercalcemia measure is based on approximately 63 percent of facilities (accounting for approximately 80 percent of the Medicare ESRD population) reporting serum calcium values in CROWNWeb.

In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final numerical values for the PY 2015 performance standards are worse than PY 2014 for a measure, we propose to substitute the PY 2014 performance standard for that measure. We believe that the ESRD QIP should not have lower standards than previous years. We request comments on this proposal.

c. Proposed Performance Standards for PY 2015 Reporting Measures

We established the performance standards for the reporting measures for PY 2014 based upon whether facilities met certain reporting requirements rather than achieved or improved on specific clinical values. We propose to establish the same performance standard for the ICH CAHPS reporting measure for PY 2015 that we established for PY 2014. Under this proposed performance standard, facilities would be required to provide an attestation that they successfully administered the ICH CAHPS survey via a third party in accordance with the measure specifications. We propose that this attestation must be completed in CROWNWeb by January 31, 2014.

For the NHSN Dialysis Event reporting measure we propose to set the

performance standard as successfully reporting 12 months of data from CY 2013. If a facility has not yet enrolled and trained in the NHSN dialysis event system, we are proposing that the performance standard for that facility would also include completion of these requirements.

For the Mineral Metabolism reporting measure we propose to set the performance standard as successfully reporting serum phosphorus and calcium values for all 12 months of the performance period for (i) in-center hemodialysis patients the facility treats at least twice during the applicable month and (ii) all peritoneal and home hemodialysis patients that the facility treats.

For the Anemia Management reporting measure we propose to set the performance standard as successfully reporting hemoglobin or hematocrit and ESA dosage (if applicable) for all 12 months of the performance period for (i) in-center hemodialysis patients the facility treats at least twice during the applicable month and (ii) all peritoneal and home hemodialysis patients that the facility treats.

Further information regarding the reporting requirements is found in sections III.C.2.a, III.C.2.b, III.C.3.c, and III.C.9.c of this proposed rule. We request comment on these proposals.

9. Proposed Scoring for the PY 2015 ESRD QIP Proposed Measures

In order to assess whether a facility has met the performance standards, we finalized a methodology for the PY 2014 program under which we separately score each clinical and reporting measure. We score facilities based on an achievement and improvement scoring methodology for purposes of assessing their performance on the clinical measures. Under the PY 2014 ESRD QIP scoring methodology, a facility's performance on each of the clinical measures is determined based on the higher of (i) an achievement score or (ii) an improvement score (76 FR 70273). We propose to use a similar methodology for purposes of scoring facilities performance on each of the clinical measures for the PY 2015 ESRD QIP.

As in PY 2014, in determining a facility's achievement score for the PY 2015 program, we propose that facilities would, based on their performance in CY 2013 (the proposed performance period), receive points along an achievement range, which we would define as a scale that runs from the achievement threshold to the benchmark. We propose to define the achievement threshold for each of the

proposed clinical measures as the 15th percentile of national facility performance during CY 2011. We believe that this achievement threshold will provide an incentive for facilities to continuously improve their performance while not reducing the incentives to facilities that score at or above the national performance rate for the clinical measures (76 FR 70276). We propose to define the benchmark as the 90th percentile of the national facility performance during CY 2011 because it represents a demonstrably high but achievable standard of excellence that the best performing facilities reached. We further propose that, for the proposed Kt/V Dialysis Adequacy measures and the proposed Hypercalcemia measure, we would use the same data we proposed above to use to calculate the performance standards for purposes of calculating the achievement thresholds and the benchmarks for these measures. We request comment on these proposals.

In determining an improvement score for the clinical measures, we propose that facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We propose to define the improvement threshold as the facility's rate on the measure during CY 2012. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2013 (the proposed performance period) to its performance on the measure during CY 2012. We are proposing to base the improvement threshold on data from CY 2012 rather than CY 2011 (the period of time we have proposed to use to calculate the performance standards, achievement thresholds, and benchmarks) because, as we explain above, we do not have complete facility level CY 2011 data that we can use to calculate an improvement threshold for every facility on the Kt/V Dialysis Adequacy measures and the Hypercalcemia measure. Rather than proposing to adopt a policy under which no facility could receive an improvement score on these measures, we are proposing to use data from CY 2012 to calculate the improvement thresholds. Additionally, we believe by using CY 2012 to calculate the improvement thresholds, we will more closely align timing of the payment reduction with the period of time we use to calculate improvement thresholds. Note that, for the proposed Hypercalcemia measure, we did not require data collection via CROWNWeb until June 2012, and, therefore, the data we are proposing to use to set the

improvement threshold for each facility would only include May 2012–December 2012 data.

Our proposals for the time periods used for the various calculations for clinical measures are depicted below in Table 6. We request comments on our proposal to use data from CY 2012 to calculate improvement thresholds.

When considering the time period we would use to calculate improvement thresholds, we sought to mitigate data lag issues as much as possible by selecting a period in time as close as possible to the performance period.

However, to entirely mitigate this data lag, we also considered a period that would take place during the performance period. Using this approach, to calculate an improvement score, we would derive an improvement threshold from either the first quarter of CY 2013 or the first 6 months of CY 2013 and compare it to the facility's measure rate in the last quarter of CY 2013 or the last 6 months of CY 2013, respectively. We ultimately decided not to propose this approach because, when possible, we prefer to use 12 months of data to calculate measure rates to ensure

more reliable rates, particularly for low-volume facilities. Additionally, using this approach, part of the performance period for purposes of calculating the facility's performance rate and achievement score (all of CY 2013) could overlap with the data we use to calculate the improvement threshold (first quarter or 6 months of CY 2013). Although we are proposing to calculate improvement thresholds based on data from CY 2012, we also request comment regarding use of these alternative periods for purposes of calculating the improvement threshold.

TABLE 6—PROPOSED PERIODS USED FOR PY 2015 CALCULATIONS

Measure	Proposed period of time used in calculating achievement thresholds, benchmarks, and performance standards	Proposed period of time used in calculating improvement thresholds
Hemoglobin >12 g/dL	CY 2011	CY 2012.
Vascular Access Type:		
%Fistula	CY 2011	CY 2012.
%Catheter	CY 2011	CY 2012.
Kt/V:		
Adult Hemodialysis	CY 2011 (data from facilities using all methods to calculate Kt/V).	CY 2012.
Adult, Peritoneal Dialysis	CY 2011 (data from facilities using all methods to calculate Kt/V).	CY 2012.
Pediatric Hemodialysis	CY 2011 (data from facilities using all methods to calculate Kt/V).	CY 2012.
Hypercalcemia	CY 2011 (data from CROWNWeb Pilot reporting).	CROWNWeb—May 1, 2012 to December 31, 2012.

Like the performance standards, at this time, we do not have the necessary data to assign numerical values to the proposed achievement thresholds and benchmarks for the clinical measures. However, we are able to estimate them

based on the latest full year of data available. In Table 7, we have provided the estimated achievement thresholds and benchmarks for all of the measures, except for Hypercalcemia, based on data from October 1, 2010–September 30,

2011. For the Hypercalcemia measure, we currently have only 7 months of data; the estimate, therefore, is based on data from April 2011–October 2011.

TABLE 7—ESTIMATED PROPOSED ACHIEVEMENT THRESHOLDS AND BENCHMARKS FOR THE PROPOSED PY 2015 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold (%)	Benchmark (%)
Hemoglobin >12 g/dL	7	0
Vascular Access Type:		
%Fistula	46	74
%Catheter	23	5
Kt/V:		
Adult Hemodialysis	86	97
Adult, Peritoneal Dialysis	58	94
Pediatric Hemodialysis	78	96
Hypercalcemia	16	10

¹ As noted above, the performance standard for the Hypercalcemia measure is based on approximately 63 percent of facilities (accounting for approximately 80 percent of the Medicare ESRD population) reporting serum calcium values in CROWNWeb.

In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final PY 2015 numerical values for the achievement thresholds and benchmarks are worse than PY 2014 for a measure, we propose to substitute the PY 2014 achievement thresholds

and benchmarks for that measure. We believe that the ESRD QIP should not have lower standards than previous years. We request comments on this proposal.

a. Proposals for Scoring Facility Performance on Clinical Measures Based on Achievement

We propose to award between 0 and 10 points for each of the clinical measures. As noted, we propose that this score be based upon the higher of

an achievement or improvement score on the measure. For purposes of scoring achievement for the measures, we propose to base the score on where a facility's performance falls relative to the achievement threshold and the benchmark for that measure. We propose that, identical to PY 2014, if a facility's measure rate during the performance period is:

- Equal to or greater than the benchmark, the facility would receive 10 points for achievement;
- Less than the achievement threshold, the facility would receive 0 points for achievement; or
- Equal to or greater than the achievement threshold, but below the benchmark, the following formula would be used to derive the achievement score: $[9 * ((\text{Facility's performance period rate} - \text{achievement threshold}) / (\text{benchmark} - \text{achievement threshold})) + .5]$, with all scores rounded to the nearest integer, with half rounded up.

Using this formula, a facility would receive a score of 1 to 9 points based on a linear scale disturbing all points proportionately between the achievement threshold and the benchmark so that the interval in performance between the score needed to receive a given number of achievement points and one additional achievement point is the same throughout the range of performance from the achievement threshold to the benchmark.

b. Proposals for Scoring Facility Performance on Clinical Measures Based on Improvement

We propose that facilities would earn between 0 and 9 points for each of the clinical measures based on how much their performance on the measure during CY 2013 improved from their performance on the measure during CY 2012. A unique improvement range for each measure would be established for each facility. We propose that if a facility's measure rate during the performance period is:

- Less than the improvement threshold, the facility would receive 0 points for improvement; or
- Equal to or greater than the improvement threshold, but below the benchmark, the following formula would be used to derive the improvement score: $[10 * ((\text{Facility performance period rate} - \text{Improvement threshold}) / (\text{Benchmark} - \text{Improvement threshold})) - .5]$, with all scores rounded to the nearest integer, with half rounded up.

Note that if the facility score is equal to or greater than the benchmark, it would

receive 10 points on the measure per the achievement score methodology discussed above.

c. Proposals for Calculating the Reporting Measure Scores

As noted, reporting measures differ from clinical measures in that they are not scored based on clinical values, but rather, are scored based on whether facilities are successful in achieving the reporting requirements associated with each of these proposed measures. The proposed criteria that would apply to each reporting measure is discussed below.

With respect to the proposed Anemia Management, Mineral Metabolism, and NHSN Dialysis Event reporting measures, we propose, for each measure, to award facilities:

- (i) 5 points for meeting the reporting requirements for at least 6-consecutive months during the performance period;
- (ii) 10 points for meeting the reporting requirements for all 12 months of the performance period; and
- (iii) 0 points for meeting the reporting requirements for less than 6-consecutive months during the performance period.

We believe that requiring 6-consecutive months of data rather than 6 non-consecutive months of data for a facility to receive points on these measures will hold facilities to the highest level of quality; facilities will be encouraged to continue to improve their reporting mechanisms throughout the performance period. We are concerned that awarding points for 6 non-consecutive months of reporting may cause facilities to be less diligent in their reporting efforts overall. We specifically request comment regarding whether the proposed 6-consecutive month reporting requirement will improve quality more than a non-consecutive month reporting requirement. We also propose, as discussed in more detail below, that facilities would need to receive a CCN prior to July 1, 2013 in order to receive a score on a reporting measure. Finally, for purposes of the NHSN Dialysis Event reporting measure, we propose that to be awarded 5 or 10 points, any facility that has not yet enrolled and trained in the NHSN dialysis event system must do so and must agree to the required consent (<http://www.cdc.gov/nhsn/PDFs/PurposesEligibilityRequirementsConfidentiality.pdf>).

With respect to the proposed ICH CAHPS reporting measure, we propose to retain the PY 2014 scoring methodology for the PY 2015 ESRD QIP. An in-center hemodialysis facility will receive a score of 10 points if it attests that it successfully administered the

ICH CAHPS survey via a third party during the performance period according to the specification found at <https://www.cahps.ahrq.gov/Surveys-Guidance/ICH.aspx>. Eligible facilities (facilities providing adult, in-center hemodialysis) that do not provide such an attestation would receive 0 points on the measure. We propose that this attestation must be entered via CROWNWeb by January 31, 2014. We note that the ICH CAHPS survey is only available to adult patients who are treated in-center. For purposes of the ICH CAHPS reporting measure, we determine whether a facility treats adult, in-center patients by referencing the facility's information in CMS data sources (that is, SIMS and CROWNWeb). Facilities report the types of patients that they serve in these data sources. If a facility lists adult in-center services, we are proposing that the facility would be required to comply with the ICH CAHPS reporting measure.

We request comment on the proposed methodology for scoring the PY 2015 ESRD QIP reporting measures. We also request comment regarding whether facilities should receive points for partially reporting data and whether such reporting need be for consecutive months.

10. Proposals for Weighting the PY 2015 ESRD QIP Measures and Calculation of the PY 2015 ESRD QIP Total Performance Score

Section 1881(h)(3)(A)(iii) of the Act provides that the methodology for assessing facility total performance shall include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement such as weighting the scores to ensure that 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 2015 ESRD QIP measures for purposes of calculating Total Performance Scores, we considered two criteria. Specifically, we considered the number of measures we have proposed to include in the PY 2015 ESRD QIP as well as the National Quality Strategy priorities.

a. Proposals for Weighting Individual Measures To Compute Measure Topic Scores for the Kt/V Dialysis Adequacy Measure Topic and the Vascular Access Type Measure Topic

Because the Kt/V Dialysis Adequacy measure topic and the Vascular Access Type measure topic are comprised of multiple measures, it is necessary for us

to discuss how we will derive an overall score for each measure topic. For these measure topics, we propose that each measure be scored separately for each facility using the achievement and improvement methodology discussed above. After calculating the individual measure scores within a measure topic, we propose to calculate a measure topic score using the following steps: (1) Dividing the number of patients in the denominator of each measure by the sum of the denominators for all of the applicable measures in the measure topic; (2) multiplying that figure by the facility's score on the measure; (3) summing the results achieved for each measure; and (4) rounding this sum (with half rounded up). We are proposing that, if a facility does not have enough patients to receive a score on one of the measures in the measure topic (this proposal is discussed below), that measure would not be included in the measure topic score for that facility. Only one measure within the measure topic need have enough cases to be scored in order for the measure topic to be scored and included in the calculation of the Total Performance Score. We believe it is important to proportionately weight the measures within a measure topic because we seek to give equal importance to each patient. Finally, we are proposing that the measure topic score would be equal to one clinical measure in the calculation of the Total Performance Score.

For additional explanation of our proposal to calculate measure topic scores, please see the following examples:

Example 1: Facility X serves hemodialysis (HD), peritoneal dialysis (PD), and pediatric patients. For HD patients, Facility X's Kt/V measure rate is 50/60. For PD patients, Facility's X's Kt/V measure rate is 15/20. For pediatric patients, Facility X's Kt/V measure rate is 10/20. There are 100 patients included in the measure topic (60 + 20 + 20). Assume that the facility's measure rates lead to the following measure scores: HD—7; PD—8; pediatric—5. To compute the Kt/V Dialysis Adequacy measure topic score for Facility X, we would calculate the following: $(7 * 60/100) + (8 * 20/100) + (5 * 20/100) = 6.8$, which we would round to 7. The Kt/V Dialysis Adequacy measure topic score would then be treated as one clinical measure when calculating the Total Performance Score.

Example 2: Facility Y serves HD patients and PD patients. For HD patients, Facility Y's Kt/V measure rate is $\frac{5}{60}$; assume that this rate leads to a score of 6. For PD patients, Facility Y's Kt/V measure rate is $\frac{1}{7}$. Facility Y has no Kt/V measure rate for pediatric patients because it does not serve this population. Assume that the minimum case

number for scoring a measure is 11. Because there are only seven cases in Facility Y's denominator, Facility Y would not receive a PD Kt/V measure score. Furthermore, Facility Y did not treat any pediatric patients, so it would not receive a pediatric Kt/V measure score. Therefore, the Kt/V Dialysis Adequacy measure topic score for Facility Y would be 6. The Kt/V Dialysis Adequacy would then be treated as one clinical measure when calculating the Total Performance Score.

We request comment on the proposed method of weighting individual measure scores to derive a measure topic score.

b. Proposals for Weighting the Total Performance Score

We believe that weighting the finalized clinical measures/measure topics equally will incentivize 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. We also believe that, while the reporting measures are valuable, the clinical measures value actual patient outcomes and therefore justify a higher combined weight. We do, however, propose to weight the clinical measures slightly less for the PY 2015 ESRD QIP than we did for the PY 2014 ESRD QIP. For the PY 2015 ESRD QIP, we believe it is important to begin to more rigorously incentivize reporting, specifically since for three of the four reporting measures, we now require actual data submission. We intend to use these data for purposes of developing and creating clinical measures in the future; thus, complete and correct data submission in these areas is essential to the program's overall goal of continued and improved ESRD quality care. For these reasons, we propose to equally weight the clinical measures/measure topics for which a facility receives a score equal to 80 percent of the Total Performance Score; we also propose to equally weight the reporting measures for which a facility receives a score as 20 percent of the Total Performance Score. We request comment on this proposed methodology for weighting the clinical and reporting measures.

We have also considered the issue with awarding a Total Performance Score to facilities that do not report data on the proposed minimum number of cases with respect to one or more of the finalized measures/measure topics. As we stated in the CY 2012 ESRD PPS final rule, we believe it is important to include as many facilities as possible in the ESRD QIP. We have, however, revisited our policy of including any

facility that receives a score on one measure, whether that measure is a clinical or reporting measure, and we have decided to propose a different approach for PY 2015. We believe it is preferable to require a facility to have at least one clinical and one reporting measure to receive a Total Performance Score. By requiring this minimum, we ensure that a facility is not included in the program unless it meets the minimum case requirement for at least one clinical measure/measure topic. In the case of a facility that has sufficient data (11 cases, as proposed below) from the performance period, but lacks sufficient data (11 cases, as proposed below) to calculate the improvement threshold, we propose to only calculate its achievement score, because it would not be possible to calculate its improvement score. We request comment on our proposals to require a facility to qualify for a score on at least one reporting and one clinical measure in order to receive a Total Performance Score.

Finally, we propose that all Total Performance Scores be rounded to the nearest integer, with half being rounded up, and we request comment on this proposal. For further examples regarding measure and Total Performance Score calculations, we refer readers to the figures below.

c. Examples of the Proposed PY 2015 ESRD QIP Scoring Methodology

Below, we provide examples to illustrate the proposed scoring methodology for PY 2015. Figures 1–3 illustrate the scoring for a clinical measure. Figure 1 shows Facility A's performance on an example clinical measure. Note that for this example clinical measure, the facility is attempting to achieve a high rate (that is, the higher the measure rate, the higher the measure score). The example benchmark (which is the 90th percentile of performance nationally in CY 2011) calculated for this measure is 74 percent, and the example achievement threshold (which is the 15th percentile of performance nationally in CY 2011) is 46 percent. Facility A's performance rate of 86 percent during the performance period meets or exceeds the benchmark of 76 percent, 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. Measure Rate at or above the Benchmark.

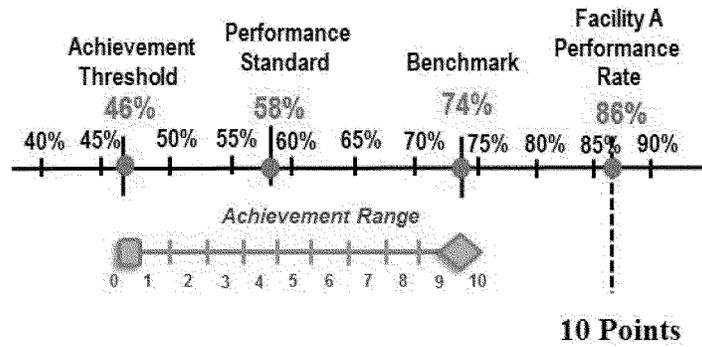
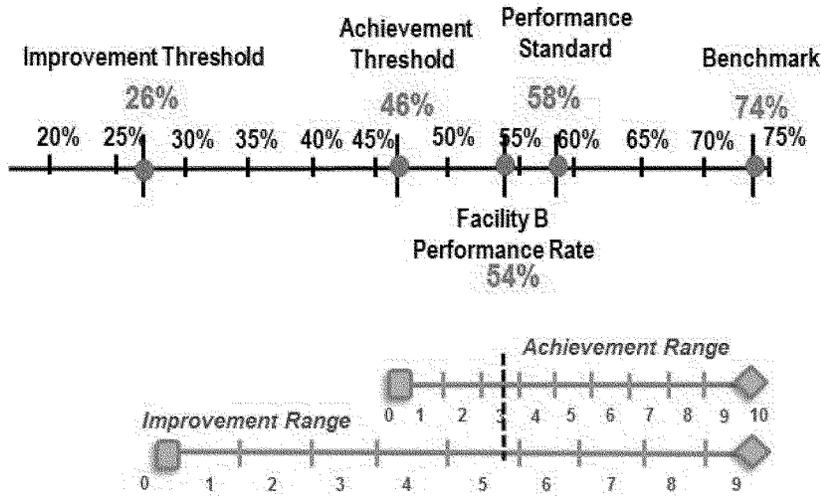


Figure 2 shows the scoring for another facility, Facility B. As illustrated below, the facility's performance on the example clinical measure improved

from 26 percent in CY 2012 to 54 percent during the performance period. The achievement threshold is 46 percent, the performance standard is 58

percent, and the benchmark is 74 percent.

Figure 2. Measure Rate within the Achievement Range and within the Improvement Range.



Because the facility's performance during the performance period is within both the achievement range and the

improvement range, we must calculate both the improvement and achievement score to find the example clinical

measure score. To calculate the achievement score, we would employ the formula discussed above.

$$9 \times \frac{\text{Facility Performance Rate} - \text{Achievement Threshold}}{\text{Benchmark} - \text{Achievement Threshold}} + 0.5$$

The result of this formula for this example is $9 * ((54 - 46)/(74 - 46))$

+ .5, which equals 3.07 and we round to 3.

Likewise, to calculate the improvement score, we employ the improvement formula discussed above.

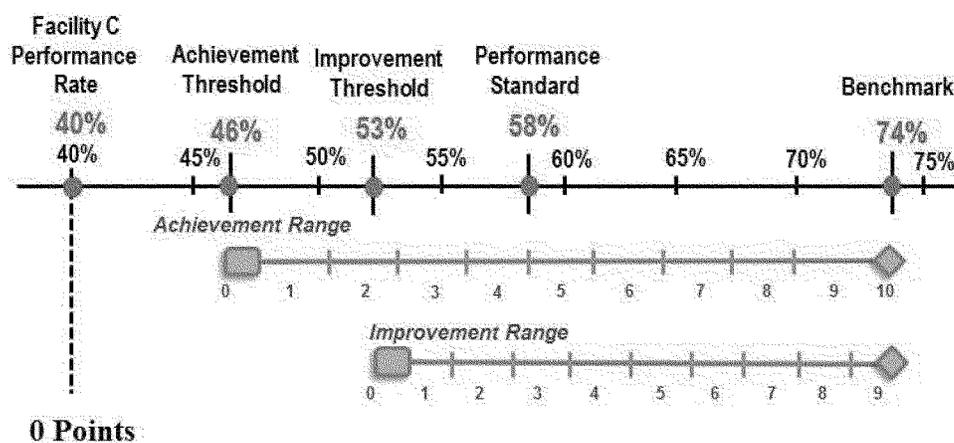
$$10 \times \frac{\text{Facility Performance Rate} - \text{Improvement Threshold}}{\text{Benchmark} - \text{Improvement Threshold}} - 0.5$$

The result of this formula for this example is $[10 * ((54 - 26)/(74 - 26))] - .5$, which equals 5.33 and we round to 5. Therefore, for this example clinical measure, Facility B's achievement score

is 3, and its improvement score is 5. We award Facility B the higher of the two scores. Thus, Facility B's score on this example measure is 5.

In Figure 3 below, Facility C's performance on the example clinical measure drops from 53 percent in CY 2012 to 40 percent in CY 2013, a decline of 13 percent.

Figure 3. Measure Rate below the Achievement Range and the Improvement Range



Because Facility C's performance during the performance period falls below the achievement threshold of 46 percent, it receives 0 points for achievement. Facility C also receives 0 points for improvement because its performance during the performance period was lower than its performance during CY 2012. Therefore, in this example, Facility C would receive 0 points for the example clinical measure.

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

After calculating the scores for each measure, we would calculate the Total Performance Score. As an example, applying the weighting criteria to a facility that receives a score on all finalized measures, we would calculate the facility's Total Performance Score using the following formula:

$$\text{Total Performance Score} = [(.200 * \text{Hemoglobin Greater Than 12g/dL Measure}) + (.200 * \text{Kt/V Dialysis Adequacy Measure Topic}) + (.200 * \text{Vascular Access Type Measure Topic}) + (.200 * \text{Hypercalcemia Measure}) + (.100 * \text{Mineral Metabolism Reporting Measure}) + (.100 * \text{Anemia Management Reporting Measure})] * 10.$$

Measure) + (.05 * NHSN Dialysis Event Reporting Measure) + (.05 * ICH CAHPS Survey Reporting Measure) + (.05 * Mineral Metabolism Reporting Measure) + (.05 * Anemia Management Reporting Measure)] * 10.

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 facility did not receive a score on the proposed Hypercalcemia measure, the facility's Total Performance Score would be calculated as follows:

$$\text{Total Performance Score} = [(.267 * \text{Hemoglobin Greater Than 12g/dL Measure}) + (.267 * \text{Kt/V Dialysis Adequacy Measure Topic}) + (.267 * \text{Vascular Access Type Measure Topic}) + (.05 * \text{NHSN Dialysis Event Reporting Measure}) + (.05 * \text{ICH CAHPS Survey Reporting Measure}) + (.05 * \text{Mineral Metabolism Reporting Measure}) + (.05 * \text{Anemia Management Reporting Measure})] * 10.$$

Again, 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).

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

$$\text{Total Performance Score} = [(.200 * \text{Hemoglobin Greater Than 12g/dL Measure}) + (.200 * \text{Kt/V Dialysis Adequacy Measure Topic}) + (.200 * \text{Vascular Access Type Measure Topic}) + (.200 * \text{Hypercalcemia Measure}) + (.100 * \text{Mineral Metabolism Reporting Measure}) + (.100 * \text{Anemia Management Reporting Measure})] * 10.$$

Again, 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).

11. Proposed Minimum Data for Scoring Measures for the PY 2015 ESRD QIP

We are proposing to only score facilities on clinical measures for which they have a minimum number of cases during the performance period. We have assessed how reliable each proposed clinical measure is using the currently available data. Specifically, we studied the degree the measures assess the actual differences in performance

among facilities as opposed to the variation within a facility. Thus, in order for a facility to be scored on any clinical measure, we are proposing that the facility must report a minimum number of cases qualifying for that measure over the course of the 12-month performance period. This proposed minimum seeks to ensure that facilities are being evaluated based on the care they provide.

a. Proposed Minimum Data for Scoring Measures for the PY 2015 ESRD QIP

Dialysis facilities tend to have a small, relatively stable patient census, with each facility reporting on an average of 50–60 cases per measure. In previous rules, commenters have asked that we consider the effect of case size on measure reliability in the context of the ESRD QIP. We recognize that as a general principle, reliability improves with increasing case size; that is, the reliability of a measure or score describes numerically to what extent that measure or score assesses the actual differences in performance among facilities as opposed to the random variation within facilities. Furthermore, we wish to be responsive to public comment and to ensure that dialysis facilities with extremely small numbers of patients are not penalized by the ESRD QIP due to random variation in their patient samples. Thus, we have developed and propose here a new methodology to make favorable adjustments to the clinical measure rates of facilities with very small numbers of patients. We also propose a case minimum for clinical measures to protect patient privacy, which we believe could be compromised if the publicly reported data for a facility is based on a small patient population.

i. Proposed Case Minimum for Clinical Measures

Given the ESRD QIP's potential to encourage quality improvement, our goal is to ensure the full participation of as many facilities as possible in the program. However, we must ensure that all measure rates capture a large enough number of patients so that the privacy of each patient is protected. A case minimum allows us to achieve these policy objectives of measurement reliability and patient privacy.

For the first 3 payment years of the ESRD QIP, we set the minimum number of cases to be scored on a clinical measure at 11. Eleven cases has historically been the case minimum for displaying measures on DFC. We have determined that in the context of DFC, 11 cases will meet the requirement that individual patients are not identifiable

in the aggregate measure rate. Given that we believe that 11 cases is sufficient to address privacy concerns and that our policy objective is to maximize the number of facilities that participate in the ESRD QIP, we propose to set a proposed case minimum threshold of 11 cases. Under this proposal, facilities must report at least 11 qualifying cases over the course of the 12-month performance period to be scored on a given clinical measure. We seek public comment on this proposal.

ii. Proposed Adjustment Methodology for Clinical Measures

We indicated in the CY 2012 ESRD PPS final rule that we would continue to assess the reliability of our measures in future payment years of the program (76 FR 70259). To further explore this issue in response to comments, we evaluated the reliability of measure rates and the Total Performance Score for facilities of various sizes using the PY 2014 program clinical measures. Specifically, we performed a simulation of the PY 2014 QIP to calculate the Inter-Unit Reliability (IUR) stratified by facility size. The IUR is a statistic commonly adopted for assessing the reliability of measures or scores, and is the ratio of the between-facility variance to the sum of the between-facility variance and the within-facility variance.

We found the reliability of the Total Performance Score to be acceptable for all strata (IUR > 0.6). However, we recognize that facilities with very small numbers of patients are more likely to have a lower IUR. In a facility with a low IUR, the case mix might potentially shift its measure rate higher or lower than the rate the same facility would report if it were treating an "average" ESRD population. In the context of the ESRD QIP, a favorable skew would not have a negative effect on facility payment, but an unfavorable skew potentially could result in the facility receiving a payment reduction. We cannot identify which specific facilities will have a low IUR until after the performance period has concluded. However, in performing the stratification analysis, we found that a favorable adjustment to the two strata with the lowest number of cases would reduce the risk of penalizing facilities in those strata for random within-facility variation. The average number of cases contributing to the Total Performance Score in the second stratum is 25. Accordingly, we have developed and propose below a favorable adjustment to the measure rates for facilities with at least the minimum case threshold of 11 and fewer than the adjustment threshold

of 26 cases. This methodology would give facilities "the benefit of the doubt" and ensure that any error in measure rates due to a small number of cases will not adversely affect payment. Specifically, if a facility reports at least a proposed adjustment threshold of 26 cases during the 12-month performance period on a measure, it would be scored based on its raw performance rate on the measure. If the facility reports between 11 and 25 cases during the 12-month performance period, it would be scored based on its raw performance rate plus a favorable reliability adjustment to account for a possible unfavorable skew in the measure rate due to small sample size.

We propose the following methodology to adjust the measure rate used to score facilities with 11–25 cases for a given measure. The adjustment factors in facility size and the standard error of the measure, which can be estimated using an analysis of variance (ANOVA). This analysis allows us to estimate how much better the measure rate could have been if that facility were treating an "average" population of patients and make a favorable adjustment to the facility's score in that amount. For example, as a facility treats more patients, the reliability of the measure rate improves, and the difference between the facility's measure rate and the measure rate we statistically would expect to see if the facility were treating an "average" panel of patients decreases. Thus, the magnitude of the adjustment factor increases as the number of cases decreases from 25 to 11.

Because the adjustment factor takes into account a facility's performance (standard error of the measure) and the number of cases for the measure, it is computed separately for each measure. The specific methodology we propose follows:

- ANOVA provides an estimate sw of the square root of within facility variance, given by the within subject mean square.
- Then for the i th facility, the standard error of the average measure (denoted by x_i) is given by

$$SE(x_i) = sw / \sqrt{n_i}$$

where n_i is the number of patients in the i th facility. Now denote C as the minimum case number. We propose the following adjustment for the original score by introducing a weight depending on facility size.

- Let

$$w_i = 1 - \frac{n_i}{c} \text{ if } n_i < C,$$

and $w_i = 0$ if $n_i \geq C$, where C is the lower bound of cases for facilities that will not receive any adjustment.

- For measures where large values of x_i are good (i.e., for the PY 2015 ESRD QIP, the fistula measure and the Kt/V Dialysis Adequacy measure topic):
 - The new score is: $t_i = x_i + w_i * SE(x_i)$. (If $t_i > 100\%$, we set $t_i = 100\%$).
- In cases where lower values of x_i are better (i.e., for the PY 2015 ESRD QIP, the Hemoglobin Greater Than 12g/dL, catheter, and Hypercalcemia measures):
 - The new score is: $t_i = x_i - w_i * SE(x_i)$. (If $t_i < 0\%$, we set $t_i = 0\%$).

This approach gives facilities an allowance to account for the uncertainty in the estimate x_i by accounting for the size of the patient population in both weights and standard errors. As explained above, this allowance decreases when the case size increases (from 11 to 26 or more)—the larger the case size, the smaller the allowance. For example, when $C=26$, this implies that for measures with 26 cases and above, no allowance is made. We seek public comment on this methodology and the proposed adjustment threshold.

In summary, based on these analyses, we propose for PY 2015 a new approach to account for facilities with low case numbers. A facility would fall into one of three categories with respect to each clinical measure.

- If the facility reported at least the adjustment threshold for a clinical measure (that is, at least 26 cases meeting the measure specifications), we would calculate the measure score with no adjustment.
- If the facility reported fewer cases than the case minimum for a clinical measure (that is, fewer than 11 cases meeting the measure specifications), we would not calculate a score for the measure.
- If the facility reported at least the case minimum, but fewer than the adjustment threshold for a measure (that is, at least 11 but fewer than 26 cases meeting the measure specifications), we would use an adjustment to calculate a score for the measure.

We believe that this proposal balances the competing interests of privacy, measure and Total Performance Score reliability, and allows for the inclusion of as many facilities in the ESRD QIP as possible. We request public comment on the case minimum proposals.

While one model is presented above, we invite comment on alternative approaches that are consistent with our intent to include as many facilities as

possible in the ESRD QIP and at the same time address concerns from stakeholders regarding the reliability of measures where there are small numbers of cases. We believe that this adjustment is appropriate for the ESRD QIP considering the particular measure set and scoring methodology for PY 2015. As the program grows and evolves, we will continue to assess reliability based on the measures and scoring methodology for that payment year.

b. Proposed Minimum Data Requirements for Reporting Measures by New Facilities

For purposes of the PY 2014 ESRD QIP, we stated that a facility that receives a CCN on or after July 1, 2012 has the option to choose whether or not it is scored on each reporting measure (76 FR 70275). We considered using the same approach for PY 2015 as we did in PY 2014 (that is, allowing new facilities to choose whether or not they will be scored on each reporting measure). Under that approach, if a new facility reports enough information to receive 10 points on a reporting measure, the facility is scored on that measure. If a new facility scores zero or 5 points on a reporting measure, it is not scored on that measure. As the program evolves, we believe it is important to continuously push improvement in all facilities—both old and new. Additionally, we wish to incentivize new facilities to put reporting mechanisms in place as soon as possible. For these reasons, we propose to modify the reporting measure minimum data requirement from that of PY 2014.

For PY 2015, we propose that any facility receiving a CCN before July 1, 2013 be scored on the reporting measures. However, since a facility receiving a CCN after January 1, 2013 would not be able to report a full 12 months of data, we do not believe it is appropriate to require it to do so in order to receive a full 10 points on the reporting measures. Instead, we propose to score these facilities proportionately for the time for which they have a CCN during the performance period. To earn 10 points on the ICH CAHPS reporting measure, we propose to require that a facility receiving a CCN between January 1, 2013 and June 30, 2013 attest that it successfully administered the survey during the time for which it had a CCN during the performance period. For purposes of the Anemia Management, NHSN Dialysis Event, and Mineral Metabolism reporting measures, we propose that if a facility receives a CCN on or after January 1, 2013, but

before July 1, 2013, it would receive 10 points for reporting for all months for which it has a CCN and 5 points for consecutively reporting half of the months for which it has a CCN during the performance period. If a facility has a CCN for an odd number of months, we would round down to calculate the number of months for which it must report to receive 5 points. Finally, we propose to begin counting the number of months for which a facility is open on the first day of the month after the facility receives a CCN. For example, assume a facility receives a CCN on March 15, 2013. In order for this facility to receive 10 points on the applicable reporting measure, it must report data from April 1, 2013—December 31, 2013 (or 9 months of data). In order for it to receive 5 points, it must report half of the months for which it is open, consecutively. For this facility to receive 5 points, it would need to report 4.5 months of data. Since we have proposed to round down, this facility would be required to report 4 months of data to receive 5 points.

We realize that facilities receiving a CCN on or after July 1, 2013, may have difficulty meeting the requirements of the reporting measures, such as enrolling and training for the NHSN Dialysis Event reporting measure or hiring a third-party to administer the ICH CAHPS survey, because of the short period of time left in the performance period. We also do not believe it is appropriate to reduce payment for a one year period based on less than 6 months of performance. Therefore, we propose to exclude facilities receiving a CCN on or after July 1, 2013 from the requirements of the reporting measures. Because we have proposed, as discussed above, that a facility will not receive a Total Performance Score unless it receives a score on at least one clinical and one reporting measure, finalizing this proposal would result in facilities not being eligible for a payment reduction if they receive a CCN on or after July 1, 2013. We request comment regarding these proposals. We also elicit comments regarding whether there would be a more appropriate way to score these new facilities on reporting measures so that they may be eligible for inclusion in the ESRD QIP.

12. Proposed Payment Reductions for the PY 2015 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 facilities such that facilities achieving the lowest Total Performance Scores receive the

largest payment reductions. For PY 2014, we adopted an approach under which a facility did not have to meet or exceed the performance standards with respect to each of the finalized clinical measures to avoid receiving a payment reduction under the ESRD QIP. Rather, even if a facility failed to meet or exceed the performance standards with respect to one or more of these measures, the facility could avoid a payment reduction if it achieved a minimum Total Performance Score that is equal to or greater than the minimum Total Performance Score it would receive if it had met the performance standards for each of the clinical measures or, in the case of the Vascular Access Type Measure, for the two subcomponent measures.

For PY 2014, in calculating this minimum Total Performance Score, we excluded the reporting measures because we believed this approach best underscored the importance of the clinical measures. For PY 2015, we propose to retain the same approach as in PY 2014. We discuss the methodology for deriving the performance standards for the measure topics, above. We request comments on these proposals.

Alternately, in order to better incentivize compliance with reporting measures, we also considered raising the minimum Total Performance Score to include 50 percent of the total points a facility could have received had it met all of the reporting requirements for each measure. In other words, because a facility could receive up to 40 points in PY 2015 for meeting all of the reporting measure requirements, we considered raising the minimum Total Performance Score by 20 points (one-half of 40). This approach would ensure that facilities receiving a CCN before August 1, 2013 could still achieve the minimum Total Performance Score by meeting, on average, the performance standards for the clinical measures and achieving as many points on the reporting measures as is possible. We request comment regarding whether the reporting measures should be scored at greater than 0 when calculating the minimum Total Performance Score.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest Total Performance Scores receive the largest payment reductions. For PY 2014, we adopted an approach we intend to continue for PY 2015. We believe that this consistency will allow the program to be more understandable to both facilities and the general public. Therefore, we propose that the payment reduction scale be the same as the PY 2014 program. Therefore, for each 10

points a facility falls below the minimum Total Performance Score, it would receive an additional 0.5 percent payment reduction on its ESRD payments for PY 2015, with a maximum reduction of 2.0 percent. As we stated in the CY 2012 ESRD PPS final rule, we believe that such a sliding scale will incentivize facilities to meet the performance standards and continue to improve their performance because even if a facility fails to achieve the minimum Total Performance Score, such facility will still be incentivized to strive for, and attain, better performance rates in order to reduce the amount of its payment reduction (76 FR 70281). We request comments on the proposed payment reduction scale.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate the minimum Total Performance Score. Based on the estimated performance standards listed above, we estimate that a facility must meet or exceed a minimum Total Performance Score of 52 to avoid a payment reduction. Facilities failing to meet this minimum will receive payment reductions in the estimated amounts indicated in the Table 8 below.

TABLE 8—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2015 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction %
100–52*	0
51–42	0.5
41–32	1.0
31–22	1.5
21–0	2.0

13. Proposed Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and Total Performance Scores is accurate. To that end, we have procured the services of a data validation contractor who will be tasked with validating a national sample of facilities' records as they report data under the ESRD QIP. Beginning in CY 2013, we propose to begin a pilot data validation program for the ESRD QIP. Because data validation for the ESRD QIP is new to both facilities as well as CMS, we believe that the first year of validation should result in no payment reductions to facilities. Accordingly, we propose that, beginning in CY 2013, we would randomly sample the records of approximately 750 facilities. We

anticipate that a CMS-designated contractor would request approximately 10 records from each of these facilities. We propose that the facility must comply with this request for records within 60-days of receiving notice. The contractor would review these records to ensure accuracy and reliability of the data reported by the facility for purposes of the ESRD QIP.

As noted above, we propose that, in the first year of this program, no facility will receive a payment reduction resulting from the data validation process. In future years of the program, we intend to evolve our pilot program into a full, data validation effort. We are also discussing a data validation measure whereby facilities would be scored based on the accuracy of their records. Finally, we are contemplating increasing a facility's payment reduction by one tier (for example, from 0.5 percent to 1.0 percent) if its data is incorrect beyond a certain threshold. In future years, we intend to propose more detailed procedures regarding data validation process that may result in penalties. We request comment on our data validation proposals for PY 2015 and the methods we are considering for PY 2016.

14. Proposals for Scoring Facilities Whose Ownership Has Changed

During our first year of implementation of the ESRD QIP, PY 2012, facilities requested guidance regarding how a change in ownership affects any applicable ESRD QIP payment reduction. We propose that, for all future years of the ESRD QIP, the application of an ESRD QIP payment reduction would depend on whether the facility retains its CCN after the ownership transfer. If the facility's CCN remains the same after the facility is transferred, for purposes of the ESRD QIP, we would consider the facility to be the same facility (despite the change in ownership) and we would apply any ESRD QIP payment reduction for the transferor to the transferee. Likewise, as long as the facility retains the same CCN, we would calculate the measure scores using the data submitted during the applicable period regardless of whether the ownership changed during one of these periods. If, however, a facility receives a new CCN as a result of a change in ownership, we would treat the facility as a new facility for purposes of the ESRD QIP as of the date it received the new CCN. We believe that these proposals are the most operationally efficient and will allow facilities the most certainty when they change ownership. We propose to apply these rules beginning with the PY 2014

ESRD QIP, and we request public comment on these proposals.

15. Proposals for Public Reporting Requirements

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

In the PY 2012 ESRD QIP final rule, we adopted uniform requirements based on sections 1881(h)(6)(A) through 1881(h)(6)(D) of the Act, establishing procedures for facilities to review the information to be made public and the procedures for informing the public through facility-posted certificates for the first 3 payment years of the ESRD QIP (76 FR 636 through 639). We propose that these requirements generally apply to PY 2015 and subsequent payment years. However, we are proposing to make some modifications, as outlined below, to these requirements and that these modifications, if finalized, become effective upon the effective date of this final rule; thus, these requirements, if finalized, would apply in PY 2014 and for subsequent payment years. All other previously finalized requirements would remain the same. First, for the first year of the program, PY 2012, we did not explicitly state that we would be publishing a list of facility performance on or after December 1 of the year before the payment consequence year. We did, however, make this list available for the public via the CMS Web site. For the PY 2013 ESRD QIP and subsequent payment years, and in accordance with section 1881(h)(6)(D) of the Act, we propose to publish such aggregate list on the CMS Web site at www.cms.gov and any other Web site controlled by CMS. This list will include information on the facility, specifically:

- (i) Name and address;
- (ii) Measure rates (which may include numerators and denominators) and scores;
- (iii) And Total Performance Scores.

This list will also indicate those facilities which do not have enough data to calculate one or more measure rates and/or a Total Performance Score. We believe it is important to publish such a list because it allows beneficiaries, the public, and facilities access to this information without having to individually download a certificate for each facility, and, because of such access, we believe it will ultimately improve quality. The data will be more accessible, Medicare beneficiaries and their families will have the information more easily to make choices about their care, and facilities can more readily compare their performance to other facilities or across facilities. Therefore, beginning in January 2013, we propose to publish a list of facility information described above for each payment year after facilities have the ability to review their scores.

Second, for PY 2012, we required facilities to prominently post certificates within five days of us making these certificates available for download from Dialysis Facility Reports (DFR) in accordance with section 1881(h)(6)(C) of the Act (76 FR 637). We are proposing to modify the previously finalized requirements for posting certificates in two ways. We no longer believe it is necessary for facilities to post these certificates within five days of their availability. The certificates are provided in late December, and it was our experience in the PY 2012 program that many individuals responsible for the certificates were away on holiday during this period of time. Therefore, we are proposing to change this requirement so that, beginning with the PY 2014 program, facilities will be required to post their certificates on or before the first business day after January 1 of each payment year. Certificates are typically available for download on or around December 15, and we believe that this two week amount of time is long enough to allow facilities to post them. Therefore, beginning PY 2014, we propose that facilities be required to post their Performance Score Certificates on or before the first business day after January 1 of each payment year in a prominent place for the duration of that payment year and otherwise comply with the requirements listed in the PY 2012 final rule (76 FR 637).

Third, for the PY 2012 ESRD QIP, we required facilities to post one copy of the certificate in their facility (76 FR

637). Beginning PY 2014, we propose to require facilities to post two copies of this certificate, one copy in English and one copy in Spanish. Both of these certificates (which are posted as a single file) will be provided by CMS, both must be posted by the first business day after January 1 of the payment year, and both must be posted for the entirety of such year in a prominent location. We are proposing to require the certificate to be posted in both English and Spanish to make the certificate more understandable to native Spanish speakers. Thus, to best serve a greater number of ESRD patients, we propose to finalize the requirement that facilities must post both an English and a Spanish certificate prominently in their facility. The only additional burden for facilities in adding this Spanish certificate is its printing and posting.

IV. Limitation on Payments to All Providers, Suppliers and Other Entities Entitled to Bad Debt

A. Background

Under section 1861(v)(1) of the Act and current regulations at 42 CFR 413.89 and 413.178, Medicare pays some or all of the uncollectible deductible and coinsurance amounts to those entities eligible to receive reimbursement for bad debt. To determine if bad debt amounts are allowable, the requirements at § 413.89 must be met. Chapter 3 of the Provider Reimbursement Manual (PRM) (CMS Pub. 15, Part I) provides guidance on the standards governing bad debt reimbursement.

Under section 1861(v)(1)(T) of the Act and § 413.89(h)(1) of the regulations, Medicare payments for allowable bad debt amounts for hospitals are reduced by 30 percent for cost reporting periods beginning on or after October 1, 2001. Also, under section 1861(v)(1)(V) of the Act and § 413.89(h)(2) of the regulations, Medicare payments for allowable bad debt amounts for patients that are not dual eligible individuals in skilled nursing facilities (SNFs) with cost reporting periods beginning on or after October 1, 2005, are currently reduced by 30 percent. Section 413.89(h)(2) also defines a dual eligible individual for bad debt purposes as an individual that is entitled to benefits under Part A of Medicare and is determined eligible by the State for Medical Assistance under Title XIX of the Act as described in 42 CFR 423.772 paragraph (2) under the definition of a "full-benefit dual eligible individual."

For all other providers, suppliers, and entities eligible to receive bad debt payment, including critical access

hospitals (CAHs), rural health clinics (RHCs), Federally qualified health centers (FQHCs), community mental health centers (CMHCs), swing bed hospitals, as defined at 42 CFR 413.114(b), and patients that are dual eligible individuals in SNFs, Medicare pays 100 percent of allowable bad debt amounts. Although Medicare pays end-stage renal disease (ESRD) facilities 100 percent of allowable bad debt amounts, these payments are currently capped at the facility’s reasonable cost in accordance with § 413.178(a). In addition, for health maintenance organizations (HMOs) reimbursed on a cost basis and competitive medical plans (CMPs) defined under section 1876 of the Act, and for health care prepayment plans (HCPPs) defined under section 1833(a)(1)(A) of the Act, Medicare pays a portion of bad debt amounts under 42 CFR 417.536(f) of our regulations.

B. Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 Public Law 112–96

Sections 3201(a) and (b) of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96) amended section 1861(v)(1)(T) and section 1861(v)(1)(V) of the Act, respectively, by further reducing the percentage of allowable bad debt attributable to the deductibles and coinsurance amounts payable to hospitals and SNFs. Section 3201(b) of The Middle Class Tax Extension and Job Creation Act of 2012 revised the SNF bad debt reductions to include both dual eligible beneficiaries and non-dual eligible beneficiaries under section 1861(v)(1)(V) of the Act and to apply such reductions to swing

bed hospitals for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years.

Finally, section 3201(c) of The Middle Class Tax Extension and Job Creation Act of 2012 added a new subparagraph 1861(v)(1)(W) to the Act, which applied a reduction in bad debt payments to “providers” not addressed under subparagraphs 1861(v)(1)(T) or 1861(v)(1)(V) of the Act. For the purpose of subparagraph 1861(v)(1)(W) of the Act, section 3201(c) of The Middle Class Tax Extension and Job Creation Act of 2012 defined “providers” as a supplier or any other type of entity that receives payment for bad debts under the authority of section 1861(v)(1)(A) of the Act. These providers include, but are not limited to, CAHs, RHCs, FQHCs, CMHCs, HMOs reimbursed on a cost basis, CMPs, HCPPs and ESRD facilities.

C. Summary of Provisions of This Proposed Rule

1. Self-Implementing Provisions of Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96)

The provisions of subsections 3201(a), (b), and (c) of The Middle Class Tax Extension and Job Creation Act of 2012 permit no discretion on the part of the Secretary and thus, are self implementing, with the exception of ESRD facilities as discussed below. We are proposing to codify these provisions, as summarized below, in our regulations.

- Payment of allowable bad debt to hospitals for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years would be reduced by 35 percent.

- Payment of allowable bad debt to SNFs and swing bed hospitals for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year would be reduced by 35 percent for coinsurance amounts for services furnished to a beneficiary who is not a dual eligible individual.

- Payment of allowable bad debt to SNFs and swing bed hospitals for coinsurance for services furnished to a beneficiary who is a dual eligible individual would be:
 - For cost reporting periods beginning during fiscal year 2013, reduced by 12 percent;
 - For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent and;
 - For cost reporting periods beginning during fiscal year 2015, reduced by 35 percent.
- Payment of allowable bad debt to all other providers, suppliers and any other entity that receives payment for bad debts under the authority of section 1861(v)(1)(A) of the Act would be:
 - For cost reporting periods beginning during fiscal year 2013, reduced by 12 percent;
 - For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent;
 - And for cost reporting periods beginning during fiscal year 2015 and subsequent fiscal years, by 35 percent.

A summary of the changes in Medicare bad debt payment percentages required by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 is reflected in Table 9 below:

TABLE 9—SUMMARY OF MEDICARE BAD DEBT REIMBURSEMENT BY PROVIDER TYPES FOR COST REPORTING PERIODS THAT BEGIN DURING FY 2013, 2014, 2015 AND SUBSEQUENT YEARS ⁴

<i>Provider type</i>	<i>Allowable bad debt amount during FY 2012 (percent)</i>	<i>Allowable bad debt amount during FY 2013 (percent)</i>	<i>Allowable bad debt amount during FY 2014 (percent)</i>	<i>Allowable bad debt amount during FY 2015 & subsequent FYs (percent)</i>
Hospitals	70	65	65	65
SNFs: Non-Full Dual Eligibles	70	65	65	65
Swing Bed Hospitals: Non-Full Dual Eligibles	100	65	65	65
SNFs: Full Dual Eligibles	100	88	76	65
Hospital Swing Beds: Full Dual Eligibles	100	88	76	65
CAHs	100	88	76	65
ESRD Facilities	100	88	76	65
CMHCs	100	88	76	65
FQHCs	100	88	76	65
RHCs	100	88	76	65
Cost Based HMOs	100	88	76	65
Health Care Pre-Payment Plans	100	88	76	65
Competitive Medical Health Plans	100	88	76	65

⁴ ESRD facility bad debt payments will continue to be subject to the cap up to the facility’s reasonable costs.

2. Remove and Reserve § 413.178

We are proposing to move specific requirements to reimburse ESRD bad debt amounts from § 413.178 to § 413.89 and remove and reserve § 413.178.

3. Technical Corrections

We are also proposing a technical correction to 42 CFR 417.536(f)(1) to refer to 42 CFR 413.89 as the appropriate cross reference to Medicare bad debt reimbursement policy, to revise the existing language describing bad debt to conform to § 413.89(a), and to remove requirements that already are set out at § 413.89.

D. Proposed Changes to Medicare Bad Debt Policy

In this rule, we are proposing to conform existing regulations text found at § 413.89(h) to the self-implementing provisions of section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012. We currently cap bad debt reimbursement to an ESRD facility's reasonable costs under § 413.178(a). In this rule, we are proposing to move the current provision at § 413.178(a) to proposed § 413.89(h)(3), and to add ESRD facilities to the list of facilities to which § 413.89 "Bad debts, charity, and courtesy allowances," applies. We also propose to remove duplicate provisions and reserve § 413.178 for further use. In addition, we are making a technical correction to § 417.536(f)(1) to clarify Medicare bad debt reimbursement policy.

1. Proposed Changes to 42 CFR 413.89(h)

Under each paragraph of our existing regulations at § 413.89(h), we describe the limits on bad debt payment to be reductions to the amount of bad debt otherwise treated as allowable costs. Under § 413.89(a), bad debts are deductions from revenue and are not to be included in allowable cost. Therefore, we are proposing to clarify that the limits on bad debt payments are reductions to amount of allowable bad debt.

We propose to revise § 413.89(h)(1)(iv) to set forth the percentage reduction in reimbursable bad debt payments to hospitals for cost reporting periods beginning during fiscal years 2001 through 2012.

We propose to add a new § 413.89(h)(1)(v), which would set forth the percentage reduction in reimbursable bad debt payments required by section 1861(v)(1)(T)(v) of the Act to hospitals for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years.

We propose to revise § 413.89(h)(2) to add paragraphs (h)(2)(i) and (h)(2)(ii). Paragraph (h)(2)(i) would set forth the percentage reduction in reimbursable bad debt payments required by section 1861(v)(1)(V)(ii) of the Act for SNFs and swing bed hospitals for cost reporting periods beginning during fiscal year 2006 and subsequent fiscal years for a patient that was not a dual eligible individual. Paragraph (h)(2)(ii) would set forth the reduction in reimbursable bad debt payments for SNFs and swing bed hospitals, for cost reporting periods beginning during fiscal year 2013, fiscal year 2014, fiscal year 2015, and subsequent fiscal years, for a patient that was a dual eligible individual.

We propose to revise § 413.89(h)(3) to set forth the percentage reduction in allowable bad debt payments required by section 1861(v)(1)(W) of the Act for ESRD facilities for cost reporting periods beginning during fiscal year 2013, fiscal year 2014, fiscal year 2015 and subsequent fiscal years and to reimburse the reduced amount of bad debt up to the facility's costs as discussed below.

We propose to add a new § 413.89(h)(4) to set forth the percentage reduction in reimbursable bad debt payments for all other entities required by section 1861(v)(1)(W) of the Act not described in § 413.89(h)(1), (h)(2), or (h)(3) that would be eligible to receive reimbursement of bad debt for cost reporting periods beginning during fiscal year 2013, fiscal year 2014, fiscal year 2015 and subsequent fiscal years.

2. Rationale for Removing 42 CFR 413.178

For ESRD facilities, § 413.178(a) states that CMS will reimburse each facility its allowable Medicare bad debts, as defined in § 413.89(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period. This cap on bad debt payments will remain in place along with applying the reductions in bad debt payments discussed above.

Currently, we reimburse an ESRD facility 100 percent of its allowable bad debt up to the facility's reasonable cost. We considered applying the FY reduction percentage after the cap is applied, however, we are proposing to apply the FY reduction percentage to allowable bad debt prior to applying the cap. We believe that our proposed application of the reduction percentage is more appropriate and consistent with how we currently determine the amount of allowable bad debt that is capped at the facility's cost.

We are proposing to make the following revisions to § 413.89(h)(3) to implement the ESRD facilities' bad debt reduction effective October 1, 2012 in accordance with section 1861(v)(1)(W) of the Act and to apply the cap on ESRD facilities' bad debt payments as required under § 413.178(a). For illustrative purposes only, we have included examples of the computation of bad debt payments for each proposed revision to § 413.89(h)(3).

We are proposing to add § 413.89(h)(3)(i) for cost reporting periods that begin before October 1, 2012, where the cap on bad debt payments would be applied as follows:

1. Unrecovered costs = \$90.00
2. Allowable bad debt = \$110.00
3. Allowable bad debt of \$110.00 is capped at the unrecovered costs of \$90.00, therefore, the facility would receive \$90.00.

We are proposing to add § 413.89(h)(3)(ii) for cost reporting periods that begin during FY 2013, where the amount of allowable bad debt is reduced by 12 percent and the cap would be applied as follows:

1. Unrecovered costs = \$90.00
2. Allowable bad debt = \$110.00
3. Allowable bad debt of \$110.00 would be reduced by 12 percent to \$96.80 which is capped at the unrecovered costs, therefore, the facility would receive \$90.00.

We are proposing to add § 413.89(h)(3)(iii) for cost reporting periods that begin during FY 2014, where the amount of allowable bad debt is reduced by 24 percent and the cap would be applied as follows:

1. Unrecovered costs = \$90.00
2. Allowable bad debt = \$110.00
3. Allowable bad debt of \$110.00 would be reduced by 24 percent to \$83.60 which does not exceed the unrecovered costs, therefore, the facility would receive \$83.60.

We are proposing to add § 413.89(h)(3)(iv) for cost reporting periods that begin during a subsequent FY, where the amount of allowable bad debt is reduced by 35 percent and the cap would be applied as follows:

1. Unrecovered costs = \$50.00
2. Allowable bad debt = \$110.00
3. In this example, allowable bad debt of \$110.00 would be reduced by 35 percent to \$71.50 which is capped at the unrecovered costs. Because, under this example, unrecovered costs are set at \$50.00, the facility would receive \$50.00.

We propose to remove current regulations text at § 413.178(a) since the requirement to apply the cap on bad debt payments will be at proposed § 413.89(h)(3). We also propose to remove current regulations text at § 413.178(b), (c), and (d)(1) since these provisions already exist in the discussions of our bad debt requirements § 413.89, Chapter 3 of the PRM Part I, and in the Medicare cost report instructions in the PRM Part II. In addition, we are proposing to move the current general bad debt exception at § 413.89(i) to new paragraph

§ 413.89(i)(1) in order to propose moving the ESRD facilities' bad debt exception provision currently discussed at § 413.178(d)(2) to proposed new paragraph § 413.89(i)(2). Since we are proposing to remove all existing regulations under § 413.178 we are proposing to reserve this section for future use.

3. Technical Corrections to 42 CFR 417.536(f)(1)

In this rule, we are proposing to revise the regulations text at 417.536(f)(1) to correct the cross-reference to the Medicare bad debt reimbursement regulation, so that § 417.536(f)(1) would reference 42 CFR 413.89 instead of the current outdated reference to § 413.80. In addition, we are revising the existing language at 42 CFR 417.536(f)(1) to conform to the description of bad debt in § 413.89(a) and we are removing §§ 417.536(f)(1)(i) and (ii) since these provisions already exist in the discussions of our bad debt requirements § 413.89, Chapter 3 of the PRM Part I, and in the Medicare cost report instructions in the PRM Part II.

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

In this proposed rule, we are not proposing any changes to regulatory text for the ESRD PPS in CY 2013.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as

specified above. However, this proposed rule does make 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.

1. ESRD QIP

a. Display of Certificates for the PY 2015 ESRD QIP

Section III.C.15 of this proposed rule discusses a disclosure requirement for the PY 2014 and PY 2015 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 with their Total Performance Scores under the ESRD QIP. This section also requires each facility that receives an ESRD QIP certificate to display it prominently at the facility.

To comply with this requirement, we proposed to issue one English and one Spanish ESRD QIP certificate beginning in PY 2014 to facilities via a generally accessible electronic file format. We have previously finalized other display requirements for the program, including that each facility prominently display the applicable ESRD QIP certificate in the patient area, take the necessary measures to ensure the security of the certificate in the patient areas, and have staff available to answer questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency.

The burden associated with the aforementioned requirements is the time and effort necessary for facilities to print the applicable ESRD QIP certificates, display the certificates prominently in patient areas, ensure the safety of the certificates, and respond to patient inquiries in reference to the certificates. We do not anticipate that posting the Spanish certificate will add more time or burden to the Collection of Information requirements outlined in the CY 2011 ESRD PPS final rule (76 FR 70298 through 70299) for the PY 2014 ESRD QIP. Therefore, this analysis only applies to the burden associated with the PY 2015 and beyond requirements.

We estimate that approximately 5,633 facilities will receive ESRD QIP certificates in PY 2015 and will be required to display them. We also estimate that it will take each facility 10 minutes per year to print, prominently display, and secure the ESRD QIP certificates, for a total estimated annual burden of 939 hours (10/60 hours * 5,633 facilities). According to the Bureau of Labor Statistics, the mean

hourly wage of a registered nurse is \$33.23. Since we anticipate nurses (or administrative staff) will post these certificates, we estimate that the aggregate cost of this requirement will be \$31,203 (\$33.23/hour × 939 hours). We estimate that approximately one-third of ESRD patients, or 100,000 patients, will ask a question about the ESRD QIP certificate. We further estimate that it will take each facility approximately five minutes to answer each patient question about the applicable ESRD QIP certificate, or 1.52 hours per facility each year. The total estimated annual burden associated with this requirement is 8,563 hours (1.52 hours/facility × 5,633 facilities). The total estimated annual burden for both displaying the ESRD QIP certificates and answering patient questions about the certificates is 9,502 hours (8,563 hours + 939 hours). While the total estimated annual burden associated with both of these requirements as discussed is 9,502 hours, we do not believe that there will be a significant cost associated with these requirements because we are not proposing to require facilities to complete new forms. We estimate that the total cost for all ESRD facilities to comply with the collection of information requirements associated with the certificates each year would be less than \$315,752 (\$33.23/hour × 9,502 hours).

b. Proposed NHSN Dialysis Event Reporting Requirement for the PY 2015 ESRD QIP

As stated above in section III.C.2 of this proposed rule, we propose to include reporting dialysis events to the NHSN as a reporting measure for the PY 2015 ESRD QIP. Specifically, we would require facilities to submit 12 months of dialysis event data to the NHSN. The burden associated with this requirement for existing facilities is the time and effort necessary for facilities to submit 12 months of data. According to our most recent data, 5,490 facilities treat in-center hemodialysis and/or pediatric hemodialysis patients and are, then, eligible to receive a score on this measure; therefore, we estimate that approximately 5,490 facilities will submit the required data. Based on data previously collected, we further estimate that the average number of dialysis events is 0.08 per patient per month and that each facility has approximately 75 patients. Accordingly, we estimate the number of dialysis events in a 12-month period for all facilities to be 395,230 (0.08 events/patient/month × 75 patients/facility × 5,490 facilities × 12 months) for the PY

2015 ESRD performance period. We estimate it will require 10 minutes to collect and submit data on these events and the estimated burden for submitting 12 months of data will be 65,880 hours (395,230 dialysis events \times 10/60 minutes). If the dialysis events were distributed evenly across all 5,490 facilities that would result in an additional 12 hour (67,596 hours/5,490 facilities) burden for each facility at a cost of \$399 (\$33.23/hour \times 12 hours) per facility. In total, we believe that the cost for all ESRD facilities to comply with the reporting requirements associated with NHSN Dialysis Event measure would be approximately \$2.2 million (\$399 \times 5,490 facilities = \$2,190,510) per year.

In addition, we recognize that some facilities are new and would not have completed the required training and enrollment required by the NHSN. We estimate that the number of ESRD facilities increases by 3 percent per year. Accordingly, we believe that 169 facilities (.03 \times 5,633 facilities) will be new in PY 2015. As noted in the CY 2011 ESRD QIP final rule (76 FR 70299), we estimate that it will take each new provider 8 hours to enroll and complete the required training. The total estimated burden for these facilities to enroll and train is 1,352 hours (169 \times 8 hours) or \$44,927 (\$33.23/hour \times 1,352 hours). In sum, we estimate the total cost for all facilities to comply with the NHSN Dialysis Events reporting requirement to be less than \$2.2 million (\$2,190,510 + \$44,927).

c. ICH CAHPS Survey Attestation Requirement for the PY 2015 ESRD QIP

As stated above in section III.C.1 of this proposed rule, we proposed to include a measure that assesses facility usage of the ICH CAHPS survey as a reporting measure for the PY 2015 ESRD QIP. The burden associated with this requirement is the time and effort necessary for facilities to administer the ICH CAHPS survey through a third party and submit an attestation to CMS that they successfully administered the survey.

We estimate that approximately 5,489 facilities treat adult, in-center hemodialysis patients and are, therefore, eligible to receive a score on this measure. We estimate that all 5,489 facilities will administer the ICH CAHPS survey through a third-party and submit an attestation to that effect. We estimate that it will take each facility's third-party administrator 16 hours per year to be trained on the survey features. We further estimate that it will take each facility approximately five minutes to submit the attestation

each year. The estimated total annual burden on facilities is 88,281 hours ((16 hours \times 5,489 facilities) + ((5/60 minutes) \times 5,489 facilities) which is valued at approximately \$3 million (88,281 hours \times \$33.23), or \$547 per facility (\$3,000,000/5,489). We estimate that it would take each patient 30 minutes to complete the survey (to account for variability in education levels) and that approximately 75 surveys per year would be taken per facility.⁵ Interviewers from each facility would spend a total of approximately 37.5 hours per year with patients completing these surveys (30/60 minutes \times 75 minutes) or \$1,247 (37.5 hours \times \$33.23) for an estimated annual burden of 205,838 hours (37.5 hours \times 5,489 facilities) which is valued at approximately \$6.9 million (205,838 hours \times \$33.23/hour). We estimate that time burden for ESRD facilities to comply with the collection of information requirements associated with administering the ICH CAHPS survey each year would be approximately \$1,794 (\$547 + \$1,247) or \$9.9 million (\$1,794 \times 5,489 facilities = \$9,847,266) across all ESRD facilities.

d. Data Validation Requirements

Section III.C.13 of the proposed rule outlines our data validation proposals. We proposed to randomly sample records from 750 facilities; each sampled facility would be required to produce approximately 10 records. The burden associated with this validation requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with these requirements. If 750 facilities are tasked with providing the required documentation, the estimated annual burden across all facilities would be 1,875 hours (750 facilities \times 2.5 hours) at a total of \$62,307 (1,875 hours \times \$33.23/hour) or \$83.08 (\$62,307/750) per facility in the sample. We also anticipate that the sampled facilities will be reimbursed by our validation contractor for the costs associated with

⁵ Last year, we stated that we believed that 200 surveys would be administered per facility per year (76 FR 70299). Upon further review, however, we note that the ICH CAHPS specifications require a sample of 200 surveys only for those facilities with a large patient population. Facilities with fewer than 200 patients are required to survey a sample of patients, aiming for a 40 percent response rate. (http://www.cahps.ahrq.gov/~media/Files/SurveyDocuments/ICH/Admin_Survey/53_fielding_the_ich_survey.pdf). Since we estimate that each facility serves approximately 75 patients, we believe that the average facility, at most, would survey 75 patients per year.

copying and mailing the requested records.

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-1352-P], Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

2. Reductions to Bad Debt Payments for All Medicare Providers

The statutorily mandated reductions of bad debt payments to providers, suppliers, and other entities that are currently receiving bad debt payments will not result in any changes to or any additional collection of information requirements.

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 examined the impacts of this proposed rule as required by Executive Order 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 economically significant 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 comments on the regulatory impact analysis provided.

2. Statement of Need

This rule proposes a number of routine updates for renal dialysis services in CY 2013, proposes to implement the third year of the ESRD PPS transition, and proposes to make several policy changes and clarifications to the ESRD PPS. These include proposed updates and changes to the ESRD PPS and composite rate base rates, wage index values, wage index budget-neutrality adjustment factors, outlier payment policy, and transition budget-neutrality adjustment. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2013.

This rule proposes to implement the QIP for PY 2015 and beyond by establishing measures, scoring, and payment reductions to incentivize improvements in dialysis care as directed by section 1881(h) of the Act. Failure to establish QIP program parameters in this rule would prevent continuation of the QIP beyond PY 2014.

This proposed rule implements the reduction percentages of bad debt reimbursement required by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012. Section 3201(c) of The Middle Class Tax Extension and Job Creation Act of 2012 added a new subparagraph-1861(v)(1)(W) to the Act, which applied a reduction in bad debt payments to "providers" not addressed under subparagraphs 1861(v)(1)(T) or 1861(v)(1)(V) of the Act. For the purpose of subparagraph 1861(v)(1)(W) of the Act, section 3201(c) of The Middle Class Tax Extension and Job Creation Act of 2012 defined "providers" as a supplier or any other type of entity that receives payment for bad debts under the authority of section 1861(v)(1)(A) of the Act. These providers include, but are not limited to, CAHs, RHCs, FQHCs, CMHCs, HMOs reimbursed on a cost basis, CMPs, HCPPs and ESRD facilities.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in

an increase of approximately \$320 million in payments to ESRD facilities in CY 2013, which includes the amount associated with the increase in the ESRDB market basket reduced by the productivity adjustment, updates to outlier amounts, and the effect of changing the blended payments from 50 percent under the composite rate payment and 50 percent under the ESRD PPS to 25 percent under the composite rate payment and 75 percent under the ESRD PPS.

We estimate that the proposed requirements related to the ESRD QIP for PY 2015 will cost approximately \$12.4 million and the predicted payment reductions will equal about \$8.5 million to result in a total impact from the proposed ESRD QIP requirements of \$20.9 million.

In section IV of this proposed rule, we discuss the provisions required by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012, which apply percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement; these provisions are specifically prescribed by statute and thus, are self-implementing. Table 9 in section IV.C.1 of this proposed rule depicts a comparison of the bad debt payment percentages prior to and after FY 2013. We estimate these self implementing provisions of section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 will result in savings to the Medicare program of \$10.92 billion over the period from 2012 through 2022.

B. Detailed Economic Analysis

1. CY 2013 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 in CY 2013. To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of payments in CY 2012 and CY 2013 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used the December 2011 update of CY 2011 National Claims History file as a basis

for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2011 claims to 2012 and 2013 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 II.B. of this proposed rule. In addition, in order to prepare an impact analysis, since some ESRD facilities 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 2011 amounts for the CYs 2012 and 2013 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 continues to be an appropriate amount. Because some ESRD facilities will receive blended payments during the transition and receive payment for ESRD drugs and biologicals based on their average sales price plus 6 percent (ASP+6), we estimated price growth for these drugs and biologicals based on ASP+6 percent. We updated the last available quarter of actual ASP data for the top twelve drugs (the second quarter of 2012) thru 2013 by using the quarterly growth in the Producer Price Index (PPI) for Drugs, consistent with the method for addressing price growth in the ESRDB market basket. This resulted in increases of 1.5 percent, 0.6 percent, 2.8 percent, 0.3 percent, 0.9 percent and 1.4 percent, respectively, for the third quarter of 2012 thru the fourth quarter of 2013. 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 10 below shows the updates used for the drugs.

We updated payments for laboratory tests paid under the laboratory fee schedule to 2012 and 2013 using the statutorily required update of the CPI-U increase with any legislative adjustments. For this proposed rule, the growth from 2011 to 2012 is 0.7 percent and the growth from 2011 to 2013 is 0.3 percent.

TABLE 10—PRICE INCREASES FROM 2011 TO 2012 AND 2011 TO 2013 OF FORMER SEPARATELY BILLABLE PART B DRUGS

	Price update 2011 to 2012 (%)	Price update 2011 to 2013 (%)
EPO	0.3	5.8
Paricalcitol	-27.4	-25.5
Sodium ferric glut	-20.3	-20.7
Iron sucrose	-13.1	-11.0
Levocarnitine	22.7	29.3
Doxercalciferol	-72.2	-77.1
Calcitriol	90.7	65.7
Vancomycin	-8.2	-1.9
Alteplase	13.2	19.4
Aranesp	6.4	12.3
Daptomycin	9.5	15.0
Ferumoxytol	-7.0	-2.9
Other Injectibles	-7.4	-3.1

Table 11 shows the impact of the estimated CY 2013 ESRD payments compared to estimated payments to ESRD facilities in CY 2012.

TABLE 11—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2013 ESRD PROPOSED RULE
[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2013 changes in outlier policy (%)	Effect of 2013 changes in wage indexes (%)	Effect of total 2013 changes ³ (%)
	A	B	C	D	E
All Facilities	5,633	37.0	0.4	0.0	3.1
Type:					
Freestanding	5,089	34.0	0.4	0.0	3.0
Hospital based	544	2.9	0.2	0.2	3.7
Ownership Type:					
Large dialysis organization	3,663	24.5	0.5	0.0	3.0
Regional chain	915	6.3	0.3	0.1	3.1
Independent	617	3.9	0.2	0.0	3.2
Hospital based ¹	429	2.2	0.2	0.3	3.7
Unknown	9	0.0	0.3	1.3	4.2
Geographic Location:					
Rural	1,249	6.1	0.5	-0.2	3.0
Urban	4,384	30.9	0.4	0.0	3.1
Census Region:					
East North Central	916	5.5	0.5	0.1	3.2
East South Central	464	2.8	0.6	-0.4	2.7
Middle Atlantic	623	4.5	0.4	0.1	3.2
Mountain	332	1.7	0.3	-0.2	2.8
New England	167	1.2	0.5	0.6	3.6
Pacific	662	5.0	0.2	0.5	3.3
Puerto Rico and Virgin Islands	41	0.3	-0.2	-2.4	0.4
South Atlantic	1,244	8.5	0.5	-0.3	2.9
West North Central	411	2.0	0.3	0.2	3.4
West South Central	773	5.4	0.4	-0.1	3.0
Facility Size:					
Less than 4,000 treatments ²	1,043	2.8	0.3	0.2	3.4
4,000 to 9,999 treatments	2,163	10.4	0.5	0.0	3.1
10,000 or more treatments	2,270	23.4	0.4	0.0	3.1
Unknown	157	0.3	0.3	0.0	2.9
Percentage of Pediatric Patients:					
Less than 2%	5,524	36.6	0.4	0.0	3.1
Between 2% and 19%	45	0.3	0.3	0.0	3.1
Between 20% and 49%	9	0.0	-1.9	-0.1	2.0
More than 50%	55	0.0	-0.3	0.1	2.2

¹ Includes hospital based facilities not reported to have large dialysis organization or regional chain ownership.

² Of the 1,043 Facilities with less than 4,000 treatments, only 322 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these Low volume Facilities is a 3.5% increase in payments.

³Includes the effect of ESRDB Market Basket minus productivity increase of 2.5% to the ESRD PPS base and the Composite Rate. Includes the effect of the change in the drug add-on percentage from 14.3% to 14.0% for those facilities that opted to be paid under the transition. Includes the effect of the blend changing from 50/50 to 25/75 for CY 2012 to CY 2013 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 the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.7 of this proposed rule, is shown in column C. For CY 2013, the impact on all facilities as a result of the changes to the outlier payment policy would be a 0.4 percent increase in estimated payments. The estimated impact of the changes to outlier payment policy ranges from a 1.9 percent decrease to a 0.6 percent increase. Most ESRD facilities are anticipated to experience a positive effect in their estimated CY 2013 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the wage index on ESRD facilities and reflects the CY 2013 wage index values for the composite rate portion of the blended payment during the transition and the ESRD PPS payments. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 2.4 percent decrease in estimated payments in CY 2013. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the reduction in the wage index floor, (which only affects facilities in Puerto Rico in CY 2013). The other categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.4 percent decrease to a 1.3 percent increase due to the update of the wage index.

Column E reflects the overall impact (that is, the effects of the proposed outlier policy 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 50 percent of payments based on the composite rate system and 50 percent based on the ESRD PPS in 2012, to 25/75, respectively, for 2013, for those facilities that opted to be paid under the transition). We expect that overall, ESRD facilities will experience a 3.1 percent increase in estimated payments in 2013. ESRD facilities in

Puerto Rico and the Virgin Islands are expected to receive a 0.4 percent increase in their estimated payments in CY 2013. This small increase is primarily due to the negative impact of the wage index. The other categories of types of facilities in the impact table show positive impacts ranging from an increase of 2.0 percent to 4.2 percent in their 2013 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, ESRD facilities are paid directly for the renal dialysis bundle and other provider types such as laboratories, DME suppliers, and pharmacies, may no longer bill Medicare directly for renal dialysis services. Rather, effective January 1, 2011, such other providers can only furnish renal dialysis services under arrangements with ESRD facilities and must seek payment from ESRD facilities rather than Medicare. Under the ESRD PPS, Medicare pays ESRD facilities one payment for renal dialysis services, which may have been separately paid to suppliers by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2013, the third 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 2013 will be approximately \$8.7 billion. This estimate is based on various price update factors discussed in section VII.B.1.a in this proposed rule and takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 4.6 percent in CY 2013.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount or blended payment amount for patients treated in facilities going through the ESRD PPS transition. As a result of the projected 3.1 percent overall increase in the proposed ESRD PPS payment amounts in CY 2013, we estimate that there will be an increase in beneficiary co-insurance payments of 3.1 percent in CY

2013, which translates to approximately \$70 million.

e. Alternatives Considered

We considered eliminating the AY modifier use by ESRD facilities in CY 2013, which could address program integrity concerns but could also require Medicare beneficiaries to incur additional injections, medical visits and co-insurance liabilities and accordingly, we did not pursue this alternative. Rather, we decided to monitor the use of the AY modifier and consider the elimination of the AY modifier in future rulemaking if we determine that it is being used inappropriately.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2015 ESRD QIP

The ESRD QIP provisions are intended to prevent 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 ESRD QIP that reduces ESRD payments by up to 2 percent for dialysis 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 facility's Total Performance Score is described in section III.C.10 of this proposed rule. Any reductions in ESRD payments would begin on January 1, 2015 for services furnished on or after January 1, 2015.

As a result, based on the ESRD QIP outlined in this proposed rule, we estimate that, of the total amount of dialysis facilities (including those not receiving an ESRD QIP Total Performance Score), approximately 14 percent or 801 of the facilities would likely receive a payment reduction for PY 2015. Facilities that do not receive a TPS are not eligible for a payment reduction.

The ESRD QIP impact assessment assumes an initial count of 5,633 dialysis facilities paid through the PPS. Table 12 shows the overall estimated distribution of payment reductions resulting from the PY 2015 ESRD QIP.

TABLE 12—ESTIMATED DISTRIBUTION OF PY 2015 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (%)	Number of facilities	Percent of facilities
0.0	4563	85.1
0.5	470	8.8
1.0	190	3.5
1.5	77	1.4
2.0	64	1.2

* **Note:** This table excludes 268 facilities that did not receive a score because they did not have enough data to receive a Total Performance Score.

To estimate whether or not a facility would receive a payment reduction under the proposed approach, we scored each facility on achievement and improvement for each of the proposed clinical measures using the most recent data available for each measure shown in Table 13.

TABLE 13—DATA USED TO ESTIMATE PY 2015 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
Hemoglobin Greater Than 12 g/dL	Jan 2010–Dec 2010	Jan 2011–Sep 2011
Vascular Access Type:		
% Fistula	Oct 2010–Mar 2011	Apr 2011–Sep 2011.
% Catheter	Oct 2010–Mar 2011	Apr 2011–Sep 2011.
Kt/V:		
Adult HD	Jul 2010–Dec 2010	Jan 2011–Sep 2011.
Adult PD	Jul 2010–Dec 2010	Jan 2011–Sep 2011.
Pediatric HD	Jul 2010–Dec 2010	Jan 2011–Sep 2011.
Hypercalcemia	Mar 2010–Dec 2010	Apr 2011–Oct 2011.

For the all of the measures except Hypercalcemia, we used claims data for these calculations. For the Hypercalcemia measure, we used CROWNWeb data. Clinical measures with less than 11 cases for a facility were not included in that facility’s Total Performance Score. Clinical measures with 11–25 cases for a facility received an adjustment as outlined in section III.C.1 of this proposed rule. Each facility’s Total Performance Score was compared to the estimated minimum Total Performance Score and the payment reduction table found in section III.C.12 of this proposed rule. Facilities were required to have a score on at least one clinical measure to receive a Total Performance Score. For these simulations, reporting measures were not included due to lack of data availability. Therefore, the simulated facility Total Performance Scores were

calculated using only the clinical measure scores. To estimate the total payment reductions in PY 2015 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the one year period between October 2010 and September 2011 by the facility’s estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in October 2010 through September 2011 times the estimated payment reduction percentage). For PY 2015 the total payment reduction for all of the 801 facilities expected to receive a reduction is approximately \$8.5 million (\$8,523,594). Further, we estimate that the total costs associated with the collection of information requirements for PY 2015 described in section V.C.2 of this proposed rule would be

approximately \$12.4 million for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of \$20.9 million (\$12,398,455 + 8,523,594 = \$20,922,049) as a result of the PY 2015 ESRD QIP. Table 14 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2015. The table details the distribution of ESRD 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). Given that the time periods used for these calculations will differ from those we propose to use for the PY 2015 ESRD QIP, the actual impact of the PY 2015 ESRD QIP may vary significantly from the values provided here.

TABLE 14—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2015

	Number of facilities	Number of Medicare treatments 2011 (in millions) ³	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	5,633	37.0	5,364	801	–0.12
Facility Type:					
Freestanding	5,089	34.0	4,956	679	–0.10

TABLE 14—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2015—Continued

	Number of facilities	Number of Medicare treatments 2011 (in millions) ³	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payments reduction (percent change in total ESRD payments)
<i>Hospital-based</i>	544	2.9	408	122	-0.31
<i>Ownership Type:</i>					
<i>Large Dialysis</i>	3,663	24.5	3,586	459	-0.09
<i>Regional Chain</i>	915	6.3	876	119	-0.12
<i>Independent</i>	617	3.9	583	125	-0.20
<i>Hospital-based (non-chain)</i>	429	2.2	314	96	-0.33
<i>Unknown</i>	9	0.0	5	2	-0.20
<i>Facility Size:</i>					
<i>Large Entities</i>	4,578	30.8	4,462	578	-0.09
<i>Small Entities¹</i>	1,046	6.1	897	221	-0.24
<i>Unknown</i>	9	0.0	5	2	-0.20
<i>Urban/Rural Status:</i>					
<i>Rural</i>	1,249	6.1	1,186	173	-0.11
<i>Urban</i>	4,384	30.9	4,178	628	-0.12
<i>Census Region:</i>					
<i>Northeast</i>	784	5.7	741	117	-0.13
<i>Midwest</i>	1,320	7.5	1,223	229	-0.16
<i>South</i>	2,476	16.7	2,407	346	-0.11
<i>West</i>	991	6.7	954	96	-0.08
<i>US Territories²</i>	62	0.3	39	13	-0.24
<i>Census Division:</i>					
<i>East North Central</i>	916	5.5	847	175	-0.18
<i>East South Central</i>	464	2.8	451	65	-0.12
<i>Middle Atlantic</i>	623	4.5	582	100	-0.14
<i>Mountain</i>	332	1.7	318	37	-0.08
<i>New England</i>	167	1.2	159	17	-0.10
<i>Pacific</i>	662	5.0	636	59	-0.08
<i>South Atlantic</i>	1,244	8.5	1,209	188	-0.12
<i>West North Central</i>	411	2.0	376	54	-0.11
<i>West South Central</i>	773	5.4	747	93	-0.10
<i>US Territories²</i>	41	0.3	39	13	-0.24
<i>Facility Size (# of total treatments):</i>					
<i>Less than 4,000 treatments</i>	1,043	2.8	899	143	-0.17
<i>4,000–9,999 treatments</i>	2,163	10.4	2,121	299	-0.10
<i>Over 10,000 treatments</i>	2,270	23.4	2,249	324	-0.10
<i>Unknown</i>	157	0.3	95	35	-0.47

¹ Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.

² Includes Puerto Rico and Virgin Islands.

³ Based on claims data through September 2011.

b. Alternatives Considered for the PY 2015 ESRD QIP

In developing the proposed PY 2015 ESRD QIP, we selected measures that we believe are important indicators of patient outcomes and quality of care as discussed in sections III.C.1, III.C.2, and III.C.3 of this proposed rule. 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. We also considered proposing to adopt the Standardized Hospitalization Ratio Admissions (SHR) measure and the Standardized Mortality Ratio (SMR) measures as part of the PY 2015 ESRD QIP. While we decided not

to propose to adopt the SHR and SMR measures for the PY 2015 ESRD QIP, we will publicly report these measure rates/ratios to the public via DFC to encourage facilities to improve their care. We believe the measures selected will allow us to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis facilities.

In developing the proposed scoring methodology for the PY 2015 ESRD QIP, we considered a number of alternatives including various improvement ranges, achievement thresholds, and benchmarks. We also considered whether some of the new measures should be scored based on only achievement. We also discussed scoring some of the clinical measures using a binary methodology (that is, facilities receive either zero or 10 points for missing or achieving a standard, respectively). We ultimately decided to

propose to mirror the PY 2014 ESRD QIP scoring methodology as closely as possible. We aim to design a scoring methodology that is straightforward and transparent to facilities, patients, and other stakeholders, and we believe one of the ways to obtain this transparency is to be as consistent as possible from year-to-year of the program. We believe that this consistency will allow us to better assess the impacts of the ESRD QIP upon facilities and beneficiaries. Finally, we believe that all scoring methodologies for Medicare VBP programs should be aligned as appropriate given their specific statutory requirements, and the scoring methodology proposed for the ESRD QIP is similar to the Hospital Inpatient VBP Program.

When deciding upon how to best score the Vascular Access Type and Kt/V Dialysis Adequacy measure topics, we considered combining all of the

measures within the measure topic into one composite measure (that is, having one, combined numerator and one, combined denominator for all of the measures within the topic) rather than individually scoring each measure and weighting it appropriately in the measure topic. We believe that it is important to mirror the NQF specifications for each measure as much as possible; we also heeded the suggestion of the Measures Application Partnership to further test composite measures before implementing them. Therefore, we decided to propose measure topics where each measure within the measure topic is scored individually and then weighted appropriately.

In order to receive credit for a month of reporting, we considered proposing to require facilities to report the required information for less than 100 percent of their patients for the Mineral Metabolism and Anemia Management reporting measures. Specifically, we considered lowering the threshold to reporting 98 percent of patients for a month in order to receive credit for that month. We ultimately decided that, in order to encourage the best care for patients, it is appropriate to hold facilities to the higher standard. Because the measures allow facilities to report values taken by other providers/facilities and because we require reporting only for those hemodialysis patients that a facility sees at least twice in a claim month or for those peritoneal dialysis patients for which a facility submits a claim, we believe that the measures afford facilities enough flexibility while also requiring the best quality care.

We also considered multiple baseline periods for purposes of scoring facilities on achievement and improvement. We considered periods of the same time and duration, periods occurring at different times, and periods with various durations. We ultimately decided that a baseline period of 12 months for both the achievement and improvement scores is best because it is consistent with the PY 2014 program. Additionally, a 12-month baseline period prevents issues related to seasonality. We decided to propose achievement and improvement baseline periods occurring over different periods of time because we believe that this approach mitigates data lag as much as possible and also allows us to score all of the measures on both achievement and improvement. Finally, we decided to propose an achievement baseline period spanning a calendar year (CY 2011) because this approach allows us to publish the numerical values for the performance standards before the beginning of the performance period.

In deciding upon the minimum number of cases required for a facility to be scored on a measure, we reviewed and discussed many options. We considered keeping the program the same as PY 2014 by excluding measures with less than 11 cases and applying no adjustment. We also discussed excluding measures with less than 26 and less than 51 cases. Finally, we discussed an adjustment applicable to measures with 26–50 cases. We believe that, given the alternatives, the proposed methodology strikes an appropriate balance between maximizing facility inclusion in the program and preventing results for very

small facilities from limiting the reliability of total performance scores.

Finally, in deciding upon the calculation of the minimum Total Performance Score, we considered a score that includes a value for each of the reporting measures. We decided, however, to propose to adhere to the PY 2014 methodology—calculating the minimum Total Performance Score as if the reporting measures were excluded from the calculation. Again, we believe that consistently scoring the ESRD QIP will allow us to better assess its impacts and allow facilities to plan for future years of the program.

3. Reductions to Bad Debt Payments for All Medicare Providers

Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 that requires reductions in bad debt reimbursement to all providers, supplies and other entities eligible to receive bad debt reimbursement will have a significant impact on the operations of all affected entities. However, these provisions are specifically prescribed by statute and thus, are self-implementing. It is estimated that the savings in the CY 2013 would be \$330 million.

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/SAVINGS ESRD PPS FOR CY 2013

Category	Transfers
Annualized Monetized Transfers	\$250 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$70 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2015	
Category	Transfers
Annualized Monetized Transfers	–\$8.5 million.*
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	12.4 million.**

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS ESRD PPS FOR CY 2013—Continued

Category	Transfers
Savings from Congressionally Mandated Reductions of Bad Debt Payments in CY 2013	
Category	Transfers
Annualized Monetized Bad Debt Payments	\$ - 330 million.
From Whom to Whom	Federal government to Medicare providers.

* It is the reduced payment to the ESRD facilities, which fall below the quality standards as stated in section III.C.12 of this proposed rule.

** It is the cost associated with the collection of information requirements for all ESRD facilities.

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 19 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration’s (SBA) 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. For more information on SBA’s size standards, see the Small Business Administration’s Web site at http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf (Kidney Dialysis Centers are listed as 621492 with a size standard of \$34.5 million).

The claims data used to estimate payments to ESRD facilities in this RFA analysis and RIA do not identify which dialysis facilities are part of a large dialysis organization (LDO), regional chain, or other type of ownership because each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFA analyses and RIAs presented in proposed and final rules that updated the basic case-mix adjusted composite payment system, we considered each ESRD facility to be a small entity for purposes of the RFA analysis. 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 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 of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 19 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 Table 11. Using the definitions in this ownership category, we consider the 617 facilities that are independent and the 429 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 of 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), and are not, therefore, 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 3.7 percent increase in payments for CY 2013. An independent facility (as defined by ownership type) is estimated to receive a 3.2 percent increase in payments for 2013.

Based on the proposed QIP payment reduction impacts to ESRD facilities for PY 2015, we estimate that of the 801 ESRD facilities expected to receive a payment reduction, 221 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 14 above. We anticipate the payment reductions to average approximately \$10,462 per facility among the 801 facilities receiving a payment reduction, with an average of \$12,509 per small entity facilities receiving a payment reduction. Using our projections of facility performance, we then estimated the impact of anticipated payment

reductions on ESRD small entities, by comparing the total payment reductions for the 221 small entities expected to receive a payment reduction, with the aggregate ESRD payments to all small entities. We estimate that there are a total of 897 small entity facilities. For this entire group of 897 ESRD small entity facilities, a decrease of 0.24 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 will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 178 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 178 rural hospital-based dialysis facilities will experience an estimated 3.4 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.

In addition, section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 that requires reductions in bad debt reimbursement to all providers, supplies and other

entities eligible to receive bad debt reimbursement will have a significant impact on the operations of a substantial number of small entities and small rural hospitals. However, these provisions are specifically prescribed by the Congress and thus, are self-implementing. Thus, we are not providing a Regulatory Flexibility Act Analysis to codify these mandated reductions in bad debt payments.

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 2012, that threshold is approximately \$139 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 \$139 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 will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XI. Files Available to the Public Via the Internet

This section lists the Addenda referred to in the preamble of this 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 Web site at <http://www.cms.gov/ESRDPayment/PAY/List.asp>, should contact Michelle Cruse at (410) 786-7540.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMOs), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332) and sec. 3201 of Pub. L. 112-96 (126 Stat. 156).

Subpart F—Specific Categories of Costs

2. Section 413.89 is amended by revising paragraphs (h)(1) introductory text, (h)(1)(iv), (h)(2), (h)(3), and (i), and by adding paragraphs (h)(1)(v) and (h)(4) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(h) * * *

(1) *Hospitals.* In determining reasonable costs for hospitals, the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

* * * * *

(iv) For cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent.

(v) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(2) *Skilled nursing facilities and swing bed hospitals.* For the purposes of this paragraph (h)(2), a dual eligible individual is defined as an individual

that is entitled to benefits under Part A of Medicare and is determined eligible by the State for medical assistance under Title XIX of the Act as described under paragraph (2) of the definition of a “full-benefit dual eligible individual” at § 423.772 of this chapter. In determining reasonable costs for a skilled nursing facility and for post-hospital SNF care furnished in a swing bed hospital, as defined in 42 CFR 413.114(b) of this part, the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

(i) *For non-dual eligible individuals—*(A) For cost reporting periods beginning during fiscal years 2006 through 2012, by 30 percent, for a patient in a skilled nursing facility.

(B) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(ii) *For dual eligible individuals—*(A) For cost reporting periods beginning during fiscal year 2013, by 12 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(B) For cost reporting periods beginning during fiscal year 2014, by 24 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(C) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(3) *End-stage renal dialysis facilities.* In determining reasonable costs for an end-stage renal dialysis facility, the amount of allowable bad debt (as defined in paragraph (e) of this section) is:

(i) For cost reporting periods beginning before October 1, 2012, reimbursed up to the facility’s costs.

(ii) For cost reporting periods beginning during fiscal year 2013, reduced by 12 percent and reimbursed up to the facility’s costs.

(iii) For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent and reimbursed up to the facility’s costs.

(iv) For cost reporting periods beginning during a subsequent fiscal year, reduced by 35 percent and reimbursed up to the facility’s costs.

(4) *All other providers.* In determining reasonable costs for all other providers, suppliers and other entities not described elsewhere in paragraph (h) of this section that are eligible to receive

reimbursement for bad debts under this section, the amount of allowable bad debts (as defined in paragraph (e) of this section) is reduced:

(i) For cost reporting periods beginning during fiscal year 2013, by 12 percent.

(ii) For cost reporting periods beginning during fiscal year 2014, by 24 percent.

(iii) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(i) *Exceptions applicable to Bad Debt Reimbursement.* (1) Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For end-stage renal dialysis services furnished on or after January 1, 2011 and paid for under the end-stage renal dialysis prospective payment system described in § 413.215, bad debts arising from covered items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule,

including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

§ 413.178 [Removed and Reserved]

3. Section 413.178 is removed and reserved.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

4. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart O—Medicare Payment: Cost Basis

5. Section 417.536 is amended by revising paragraph (f)(1) to read as follows:

§ 417.536 Cost payment principles.

* * * * *
(f) * * *

(1) Bad debts attributable to Medicare deductible and coinsurance amounts are allowable only if the requirements of § 413.89 of this chapter are met, subject to the limitations described under § 413.89(h) and the exceptions for services described under § 413.89(i).

* * * * *

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

Dated: June 22, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 27, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–16566 Filed 7–2–12; 4:15 pm]

BILLING CODE 4120–01–P