DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 417

[CMS–1352–F]

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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: Final rule.

SUMMARY: This final rule updates and makes revisions to the end-stage renal disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013. This rule also sets forth requirements for the ESRD quality incentive program (QIP), including for payment year (PY) 2015 and beyond. In addition, this rule implements changes to bad debt reimbursement for all Medicare providers, suppliers, and other entities eligible to receive Medicare payment for bad debt and removes the cap on bad debt reimbursement to ESRD facilities. (See the Table of Contents for a listing of the specific issues addressed in this final rule.)

DATES: *Effective Date:* These regulations are effective on January 1, 2013.

Applicability Date: The regulations setting forth the reductions in Medicare bad debt pursuant to section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96) are applicable for cost reporting periods beginning October 1, 2012.

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SUPPLEMENTARY INFORMATION:

Table of Contents

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

Acronyms

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

AMCC Automated Multi-Channel Chemistry
ASP Average Sales Price
AV Arteriovenous
BLS Bureau of Labor Statistics
BMI Body Mass Index
BSA Body Surface Area
CAH Critical Access Hospital
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
CMHC Community Mental Health Center
CMP Competitive Medical Plans
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
FQHC Federally Qualified Health Center
FY Fiscal Year
GDP Gross Domestic Product
HAI Healthcare-associated Infections
HCPCS Healthcare Common Procedure Coding System
HCPP Health Care Prepayment Plan
HD Hemodialysis
HHD Home Hemodialysis
HMO Health Maintenance Organization
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
RHC Rural Health Clinic
RRF Residual Renal Function
RUL Reasonable Useful Lifetime
SBA Small Business Administration
SHR Standardized Hospitalization Ratio
SIMS Standard Information Management System
SMR Standardized Mortality Ratio
SNF Skilled Nursing Facility
SSA Social Security Administration
TEP Technical Expert Panel
The Act Social Security Act
The Affordable Care Act The Patient Protection and Affordable Care Act
URR Urea Reduction Ratio
VAT Vascular Access Type
VBP Value Based Purchasing

I. Executive Summary

A. Purpose

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

This final rule updates and makes 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), the 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 final rule also sets forth requirements for the ESRD quality incentive program (QIP), including for 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 and Elimination of the Cap on Bad Debt Reimbursement to ESRD Facilities

This final rule also implements 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. Additionally, this rule will remove the cap on bad debt reimbursement to ESRD facilities.

B. Summary of the Major Provisions

1. ESRD PPS

• *Update to the composite and ESRD PPS base rate for CY 2013:* For CY 2013, the ESRD PPS base rate is $240.36. This amount reflects the application of the ESRD bundled (ESRDB) market basket reduced by the productivity adjustment, or 2.3 percent, and the wage index budget-neutrality adjustment factor of 1.000613 to the CY 2012 ESRD PPS base rate of $234.81. The base rate is applicable to both the ESRD PPS portion of the blended payment under the transition and payments under the full PPS. During the transition, we are required to update the composite rate for ESRD facilities receiving a blended payment. For CY 2013, the composite base rate is $145.20. 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:* There are no 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 average sales price (ASP) drug expenditure data and other data, we estimate a 2.9 percent decrease in aggregate drug expenditures and a 4.0 percent increase in enrollment. Using these estimates, we project a 6.6 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 will result in a decrease to the drug add-on equal to 0.9 percentage points. We will 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 CY 2013 ESRDB market basket increase factor is 2.9 percent. The current forecast of the CY 2013 MFP adjustment is 0.6 percent. The resulting final CY 2013 MFP-adjusted ESRDB market basket update is equal to 2.3 percent.

• *The transition budget-neutrality adjustment factor:* For CY 2013, we are applying the transition budget-neutrality adjustment methodology established in CY 2011. This results in a 0.1 percent adjustment. Therefore, for CY 2013, a 0.1 percent increase will be applied to both the blended payments made under the transition and payments made under the full 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 making 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 we will continue to do so. Therefore, in CY 2013, we are reducing the wage index floor from 0.550 to 0.500. 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 (0.500×1.001141) 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 will decrease from $71.64 to $47.32 and the MAP amount will decrease from $45.44 to $41.39 as compared to CY 2012 values. For adult patients, the fixed-dollar loss amount drops from $141.21 to $110.22 and the MAP amount drops from $78.00 to $59.42. 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 epoetin 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 MAPs 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 on ESRD claims. In this 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 rule, we reiterate the purpose of the AY modifier and emphasize that we are continuing our monitoring efforts. We also indicate that we may consider eliminating the AY modifier in future rulemaking if we believe that the AY modifier is not being used for the purpose intended.

2. ESRD QIP

This final rule also implements new requirements for the ESRD QIP. It will 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 in-center 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 a catheter measure.
- To address effective bone mineral metabolism management:
  - Mineral Metabolism, a reporting measure.
- To address safety:
  - National Healthcare Safety Network (NHSN) Dialysis Event reporting measure.
- To assess patient and caregiver experience:
  - In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting measure.

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

This final rule also establishes CY 2013 as the performance period for the PY 2015 ESRD QIP. It also establishes performance standards for each measure and adopts 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 and Elimination of the Cap on Bad Debt Reimbursement to ESRD Facilities

This rule also implements 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 moving 42 CFR 413.178(a) to 42 CFR 413.89(h)(3), and moving 42 CFR 413.178(d)(2) to 42 CFR 413.89(i)(2) and removing and reserving the remainder of 42 CFR 413.178. Additionally, we are making a technical correction to the cross reference in 42 CFR 417.536(f)(1) to Medicare bad debt reimbursement policy. Finally, this final rule will eliminate the cap on bad debt reimbursement to an ESRD facility at its unrecovered costs.

C. Summary of Costs and Benefits

In section VI.B of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section VI.B of this final 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 3.0 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.6 percent increase in payments compared with freestanding facilities with an estimated 2.9 percent increase. Urban facilities are expected to receive an estimated payment increase of 3.0 percent compared to an estimated 2.9 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 decrease is offset primarily by the impact of the market basket increase, resulting in an estimated 0.6 percent increase in payment. The estimated 3.0 percent overall payment increase will result in a $250 million cost to Medicare and a $60 million cost to beneficiaries. In 2013, a 2.3 percent market basket increase will result in a $190 million cost to Medicare and a $50 million cost to beneficiaries. The outlier fixed dollar loss and MAP adjustments in CY 2013 will result in a $30 million cost to Medicare and a $10 million cost to beneficiaries. The difference in cost to Medicare is due to the effects of changing the blend of payments from 50/50 to 25/75 and the 0.1 percent transition budget-neutrality adjustment.

2. Impacts for ESRD QIP

The overall economic impact of the ESRD QIP is an estimated $24.6 million for PY 2015. We expect the total payment reductions to be approximately $12.1 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 generally self-implementing. There will be a $10.92 billion savings to the program over 10 years resulting from these self-implementing reductions in bad debt reimbursement. We are also removing the cap on reimbursement for bad debt to ESRD facilities for cost reporting periods beginning on or after January 1, 2013, which will result in a cost to the Medicare program of $170 million over 10 years.

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 (75 FR 49030) 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 April 6, 2011, we published in the **Federal Register** an interim final rule with comment period (76 FR 18930) titled, ''Changes in the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment'', which revised the ESRD transition budget-neutrality adjustment for CY 2011. In the interim final rule, we revised the 3.1 percent transition budget-neutrality adjustment reduction to a zero percent transition budget-neutrality adjustment for renal dialysis services furnished on April 1, 2011 through December 31, 2011 (76 FR 18933). 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, clarifications, and technical changes. In the CY 2013 ESRD PPS proposed rule (77 FR 40956), we summarize the updates, changes, and clarifications that were finalized in the CY 2012 ESRD PPS final rule (76 FR 70228).

B. Summary of the Proposed Provisions and Responses to Comments on the CY 2013 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers'' (77 FR 40952), hereinafter referred to as the CY 2013 ESRD PPS proposed rule appeared in the **Federal Register** on July 11, 2012, with a comment period that ended on August 31, 2012. In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of routine updates for CY 2013, (2) implement the third year of the transition, and (3) make several policy changes and clarifications. We received approximately 40 public comments on the ESRD PPS proposals, including comments from ESRD facilities; national renal, nephrologist and patient organizations; patients; manufacturers; health care systems; and nurses. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2013 ESRD PPS.

C. 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 final rule implements the third year of the transition for those ESRD facilities that did not elect to receive 100 percent of the payment amount under the ESRD PPS. For CY 2013, under 42 CFR 413.239(a)(3), facilities that are transitioning 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, we continue to update the composite rate portion of the blended payment during the transition, (that is, CY 2011 through 2013), which includes updates to the drug add-on adjustment required by section 1881(b)(12)(F) of the Act, discussed in section II.C.1.a of this final rule, as well as the wage index values (which includes a budget-neutrality factor) used to adjust the labor component of the composite rate discussed in section II.C.5 of this final rule. For CY 2013, we proposed 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 transition budget-neutrality adjustment can be found in section II.C.4 of this final rule.

As discussed in the CY 2013 ESRD PPS proposed rule (76 FR 40957), section II.C.3 of this final rule, and in 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, for the years in which the transition applies, the composite base rate 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 the CY 2013 ESRD PPS proposed rule (77 FR 40957), we proposed for CY 2013 a composite rate of $145.49, which reflected the CY 2012 composite rate of $141.94 increased by an ESRDB market basket of 3.2 reduced by the productivity adjustment of 0.7 percent, resulting in an update of 2.5 percent, based on the first quarter 2012 IGI forecast of the ESRDB market basket.

We received four public comments supporting our proposal to increase the composite base rate by 2.5 percent for ESRD services furnished in CY 2013 and paid under the blended payment methodology during the transition period.

In section II.C.3.b of this final rule, we finalize the CY 2013 ESRDB market basket update of 2.9 percent, and the MFP adjustment of 0.6 percent, which results in a forecasted rate of increase to the base rate of 2.3 percent. This final update is based on the third quarter 2012 IGI forecast of the ESRDB market basket. Consequently for CY 2013, we are finalizing the composite base rate under the ESRD PPS payment of $145.20 for ESRD services furnished during CY 2013 and paid under the blended payment methodology. This amount reflects the CY 2012 composite rate of $141.94 increased by the CY 2013 ESRD market basket increase factor of 2.9 percent reduced by the productivity adjustment of 0.6 percent. The resulting CY 2013 MFP-adjusted ESRD market basket update is 2.3 percent ($141.94 × 1.023 = $ 145.20).

a. 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 42 CFR 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. Under § 413.239(a)(3), in CY 2013, ESRD facilities that elected to receive payment under the transition will be paid a blended amount consisting of 25 percent of the basic case-mix adjusted composite payment system payment and 75 percent of the ESRD PPS payment. Thus, we must continue to update the composite rate portion of the blended payment amount during the ESRD PPS transition (CY 2011 through 2013), 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 the services in the composite rate and an add-on to the composite rate portion of the blended payment to account for the difference between pre-Medicare Modernization Act payments for separately billed drugs and the revised drug pricing specified in the statute. For the drug add-on for CY 2013 (77 FR 40957 through 40959), we did not propose any changes to the drug add-on methodology, but merely updated 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.

As we indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40957), we continue to estimate growth in drug expenditures based on the trends in available data. To account for increases in drug prices and utilization for CY 2013 we used the 6 years of available drug expenditure data based on ASP pricing. 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). We indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40958) that for the CY 2013 PPS final rule, we would use additional updated CY 2011 claims with dates of service for the same timeframe. This updated CY 2011 data file would include claims received, processed, paid, and passed to the National Claims History File as of June 30, 2012. We further stated that while the CY 2011 claims file used in the proposed rule was 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.

In the CY 2013 ESRD PPS proposed rule (77 FR 40958), 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 were 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 was 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.

We further stated in the CY 2013 ESRD PPS proposed rule (77 FR 40958), that 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.

For this CY 2013 final rule, using the full year 2011 drug expenditure figure based on the June 2012 update of the CY 2011 National Claims History File, we calculated the average annual change in drug expenditure from 2006 through 2011. This average annual change showed a decrease of 2.9 percent in drug expenditures from 2006 through 2011. We used this 2.9 decrease to project drug expenditures for both 2012 and 2013. We note that the decrease in the drug expenditures percentage is a result of our use of updated data.

ii. Estimating Per Patient Growth

In the CY 2013 ESRD PPS proposed rule (77 FR 40958), we explained that 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 had estimated 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 was 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 CYs 2012 and 2013.

For this final rule, we estimate a 4.0 percent estimated growth in enrollment between CYs 2012 and 2013. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change of a 2.9 percent decrease between CYs 2012 and 2013 (0.971) by enrollment growth of 4.0 percent (1.04) for the same timeframe. The result is a per-patient growth factor equal to 0.934 (.971/1.04=.934). Thus, in this final rule, for CY 2013 we are projecting a 6.6 percent decrease (-6.6% percent $= -.063 = .934 - 1$) in per patient growth in drug expenditures between CYs 2012 and 2013.

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

We explained in the CY 2013 ESRD PPS proposed rule (77 FR 40958), that 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 the CY 2006 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.

We further explained in the CY 2013 ESRD PPS proposed rule (77 FR 40958), that 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 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 Change Request 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.

Finally, we explained in the CY 2013 ESRD PPS proposed rule (77 FR 40958) that 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, and 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. For CY 2013, we did not make any update to the per treatment drug add-on amount of $20.33 established in CY 2008.

As discussed in detail below, in this final rule, for CY 2013, we are finalizing a zero update to the per treatment drug add-on amount of $20.33 established in CY 2008.

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

As discussed above, in the CY 2013 ESRD PPS proposed rule (77 FR 40958), we estimated a 3.0 percent decrease in drug expenditures between CYs 2012 and 2013. Combining this decrease with a 4.6 percent increase in enrollment, as described above, we projected a 7.3 percent decrease in per patient growth of drug expenditures between CYs 2012 and CY 2013. Therefore, in the CY 2013 ESRD PPS proposed rule, we projected 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 revised 14.0 percent add-on for 2013). This figure was derived by applying the 7.3 percent decrease to the CY 2012 drug add-on of $20.33. This resulted 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. We indicated that 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 proposed 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 proposed to apply a zero update and maintain the $20.33 per treatment drug add-on amount for CY 2013. We sought comment on our proposed zero update to the drug add-on.

We further stated in the CY 2013 ESRD PPS proposed rule (77 FR 40959), that 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.3.a of the CY 2013 ESRD PPS 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 resulting in a 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 proposed a drug add-on adjustment to the composite rate for CY 2013 of 14.0 percent.

We did not receive any comments on our proposals to use a zero update to the drug add-on or on the proposed drug-add on adjustment to the composite rate for CY 2013 of 14.0 percent.

In this final rule, for CY 2013, we estimate a 2.9 percent decrease in drug expenditures between CYs 2012 and 2013. Combining this increase with a 4.0 percent increase in enrollment, we project a 6.6 percent decrease in per patient growth of drug expenditures between CYs 2012 and 2013. Therefore, we project that the combined growth in per patient utilization and pricing for CY 2013 results in a decrease to the drug add-on equal to 0.9 percentage points. This figure is derived by applying the 6.6 percent decrease to the CY 2012 drug add-on of $20.33. This results in a revised drug add-on of $18.98, which is 13.1 percent of the final CY 2013 base composite rate of $145.20. Applying no decrease to the drug add-on of $20.33 results in a 14.0 percent drug add-on. Similar to last year and as discussed above, for CY 2013, we are finalizing a zero update to the drug add-on and maintaining the $20.33 per treatment drug add-on amount.

The current $20.33 per treatment drug add-on reflected a 14.3 percent drug add-on adjustment to the composite rate in effect for CY 2012. Using the latest ESRDB market basket minus productivity adjustments to update the composite rate portion of the ESRD PPS payment (forecast of 2.3 percent in CY 2013 effective January 1, 2013, as discussed in section II.C.3 of this final rule), results in a decrease to the CY 2013 drug add-on adjustment from 14.3 to 14.0 percent in order to maintain the drug add-on amount of $20.33. This decrease occurs because the drug add-on adjustment is a percentage of the composite rate. Because the final CY 2013 composite rate is higher than CY 2012 composite rate, and since the drug add-on remains at $20.33, the percentage decreases. Therefore, we are finalizing for CY 2013 the drug add-on adjustment of 14.0 to the composite rate.

2. ESRD PPS Base Rate

In the CY 2013 ESRD PPS proposed rule (77 FR 40959) and 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 42 CFR 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 42 CFR 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).

We also indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40959) that 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 adjusted by the rate of increase in the ESRD market basket, reduced by the productivity adjustment. Accordingly, in the CY 2013 ESRD PPS proposed rule, we applied the 2.5 percent increase to the CY 2012 ESRD PPS base rate of $234.81, which resulted in a proposed CY 2013 ESRD PPS base rate of $240.68 ($234.81 × 1.025 = $240.68). The 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, for CY 2013, we proposed a wage index budget-neutrality adjustment factor of 1.000826 to be applied to the CY 2013 ESRD PPS base rate (that is, $240.68), which yielded a proposed CY 2013 ESRD PPS wage index budget-neutrality adjusted base rate of $240.88 ($240.68 × 1.000826 = $240.88).

Comment: All commenters supported our CY 2013 ESRD PPS wage index budget-neutrality adjusted base rate. Two commenters thanked CMS for providing an update to the base rate, and one commenter specifically appreciated the base rate increase at a time when the Medicare ESRD program is undergoing significant changes and noted that it is important to retain savings where applicable.

Response: We thank the commenters for their support. In this final rule, using updated data for CY 2013, we applied the 2.3 percent increase (ESRDB market basket update less productivity) to the CY 2012 ESRD PPS base rate of $234.81, which results in an ESRD PPS base rate for CY 2013 of $240.21 ($234.81 × 1.023 = $240.21). In addition, we applied the wage index budget-neutrality adjustment factor of 1.000613 to the updated base rate of $240.21, yielding an ESRD PPS wage index budget-neutrality adjusted base rate for CY 2013 of $240.36 ($240.21 × 1.000613 = $240.36).

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 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. 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.

We proposed to use the same methodology described in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162) to compute the CY 2013 ESRDB market basket increase factor and labor-related share based on the best available data (76 FR 40503). Consistent with historical practice, we estimated 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 third quarter of 2012 of the CY 2008-based ESRDB market basket (with historical data through the second quarter of 2012), and consistent with our historical practice of estimating market basket increases based on the best available data, the CY 2013 ESRDB market basket increase factor is 2.9 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. 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 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 third quarter of 2012 of the 10-year moving average of MFP, the CY 2013 MFP factor is 0.6 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 proposed 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 market basket increase factor for CY 2013 for the ESRDB market basket is based on the 3rd quarter 2012 forecast of the CY 2008-based ESRDB market basket

update, which is estimated to be 2.9 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 0.6 percent, which is based on IGI's 3rd quarter 2012 forecast. The resulting MFP-adjusted ESRDB market basket update for CY 2013 is equal to 2.3 percent, or 2.9 percent less 0.6 percentage point.

We received two comments in support of the market basket update. We are finalizing the update to the ESRDB market basket of 2.3 percent for CY 2013.

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. Although the statute uses the term ''phase-in,'' we use the term ''transition'' in our discussions in order 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 two parts that comprise the transition budget-neutrality adjustment factor. 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 explained that 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.

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 the CY 2013 ESRD PPS proposed rule, we did not propose to change the methodology used to calculate either part of the transition budget-neutrality adjustment factor. We did, however, propose to use updated data to calculate the second part of the transition budget-neutrality adjustment factor. The first part, which is the Part D payment amount added to the composite rate, 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. In the CY 2013 ESRD PPS proposed rule, we used the December 2011 claims file. In this final rule, we used the June 2012 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 VI.C of this final 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 as if there were no transition to the total estimated payments under the transition, which results in a zero percent reduction factor for CY 2013. In the CY 2013 ESRD PPS proposed rule, we proposed a zero percent reduction to all payments made to ESRD facilities (that is, the zero 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 (77 FR 40957). We solicited comments on the proposed second part of the CY 2013 transition budget-neutrality adjustment.

We received three comments as set forth below.

Comment: All of the commenters supported using updated data and maintaining a zero percent budget-neutrality transition adjustment for CY 2013.

Response: We thank the commenters for their support of our proposed use of updated data and a transition budget-neutrality factor of zero percent for renal dialysis services furnished during January 1, 2013 through December 31, 2013. As we indicated above, for the proposed rule, we used the December 2011 claims file to compute the transition budget-neutrality adjustment factor. For this final rule, we used the June 2012 claims file. As a result of using the June 2012 claims file, we calculated the transition budget-neutrality factor to be a reduction of 1 minus the ratio of estimated payments under the ESRD PPS as if there were no transition to the total estimated payments under the transition, which results in a 0.1 percent increase factor for CY 2013. We believe the claims data we used to perform our analysis resulted in the change in the transition budget-neutrality adjustment factor from the zero factor used in previous years to the 0.1 percent increase factor for CY 2013. We note that in past years, the transition budget-neutrality factor has not always been an absolute zero, but was rounded to zero percent. The June 2012 claims file represents 2011 data, the first year of the PPS. In 2011, the utilization for separately billable drugs, laboratory tests and other items dropped significantly. For ESRD facilities that are paid under the transition, the decrease in utilization contributed to the payment for the composite rate portion of the blended payment being lower than the payment for the ESRD PPS portion of the blended payment. Therefore, total payments for all facilities under the transition were lower than what payments would have been under the ESRD PPS, if there were no transition. This widening difference resulted in the transition budget-neutrality adjustment rounding to 0.1 for CY 2013. We are finalizing for CY 2013 a transition budget-neutrality adjustment of 0.1 percent.

5. 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 core-based statistical area (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 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 did not propose any changes to the methodology finalized in the CY 2012 final rule and will update the wage index values using the FY 2013 Inpatient Prospective Payment System (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 the Office of Management and Budget's (OMB's) urban and rural definitions and corresponding wage index values. Additional discussion on the labor-related share can be found in section II.c.3 of this final rule. For CY 2013, we did not propose to change the labor-related shares, as finalized in the CY 2012 rule, as discussed in section II.C.3 of this final 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 the proposed rule, for CY 2013 we did not propose any changes to the methodology for the wage index used to adjust the composite rate portion of the ESRD PPS blended payment.

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. The wage index floor is applied to both the composite rate portion of the blend and to the ESRD PPS. In the CY 2013 ESRD PPS proposed rule, we did not propose any changes to the wage index floor methodology or reduction. Consequently, for CY 2013 we indicated in the proposed rule that we would continue to reduce the wage index floor by 0.05, which will reduce the wage index value for the wage index floor from 0.550 to 0.500. For CY 2013, the wage index floor of 0.500 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 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.

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 below 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.

After the CY 2012 ESRD PPS final rule was published, we determined that for CY 2012 there was a rural hospital with wage data on which to base an area wage index 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 the CY 2013 ESRD PPS proposed rule we corrected 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 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 Hinesville-Fort Stewart, GA.

c. 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 CYs 2012 and 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 did not propose 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 did not propose any changes to the methodology. Consequently, for the 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 can be found through Dialysis Facility Compare (DFC). The DFC can be found at the Dialysis Facility Compare Web page on the Medicare.gov Web site at *www.Medicare.gov/Dialysis.* 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 final rule, we used 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 was applied to the wage index values for the composite rate portion of the blended payment. Therefore, in this final rule, we are finalizing for CY 2013, the wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment of 1.001141, which is applied directly to the ESRD wage index values. For the ESRD PPS (that is, for the full ESRD PPS payments and the ESRD PPS portion of the blended payments during the transition), we are finalizing the wage index budget-neutrality adjustment factor of 1.000613 that will 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. We note that this would apply to areas in Puerto Rico, subject to the floor. Therefore, for the composite rate portion of the blended payment, we are finalizing for CY 2013, to 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 (1.001141×0.500) because under the composite rate, the wage index budget-neutrality adjustment is applied to the wage index value. Under the ESRD PPS, the wage index budget-neutrality adjustment factor is applied to the base rate.

d. ESRD PPS Wage Index Tables

The CY 2013 ESRD PPS 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/vESRDPayment/PAY/list.asp.* The wage index tables list two separate columns of wage index values. One column represents the wage index values for the composite rate portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied. The other column lists the wage index values for the ESRD PPS, which does not reflect the application of the wage index budget-neutrality adjustment factor, because we finalized for CY 2012 and subsequent years that we will apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

We received one comment. The comment and our response are set forth below.

Comment: We received a comment from an LDO that expressed concern about the negative impact of the wage index floor on dialysis providers in Puerto Rico. The commenter expressed concern that wages for dialysis facilities in Puerto Rico are not accurately captured by the current hospital wage index methodology. The commenter urged CMS to determine an alternate basis for calculating the wage index floor in Puerto Rico, stating that it does not believe that the wage index as reported for Puerto Rico is representative of the wage levels of dialysis providers in Puerto Rico relative to a sample of other states. Specifically, the commenter provided its own analysis of its random sampling of cost report salaries comparing ESRD facilities in Puerto Rico with ESRD facilities in Florida, Georgia, Ohio, South Carolina and Virginia. The commenter recommended that reimbursement for Puerto Rico be based on ''some measure other than the hospital wage index, such as basing the wage index on cost report salaries relative to other state salaries.'' The commenter further explained that Puerto Rico requires that only registered nurses (RN) provide dialysis therapy, and therefore, in the dialysis setting, the occupational mix would be weighted more toward RNs than the mix for hospital.

Response: We understand that the commenter is concerned about wage

index values in Puerto Rico, however, it is our policy to use wage indices for all ESRD facilities that are based on the IPPS pre-floor, pre-reclassified hospital wage data. We discuss this in detail above. We believe that this is an appropriate mechanism for obtaining wage index values to be used to geographically adjust the ESRD PPS base rate for all ESRD facilities. It has been the same method that we have used previously for the basic case-mix adjusted composite rate payment system. We refer the commenter to the discussion on the methodology used to determine wage index values in the CY 2013 IPPS final rule (77 FR 53365 through 55367). We will, however, consider the commenter's recommended approach if we determine in the future that a change to the methodology for determining geographic wage index values is warranted.

In the CY 2012 ESRD PPS proposed rule (76 FR 40509 and 40510), we proposed to continue to reduce the wage index floor by 0.50 for each of the remaining years of the transition (that is, CYs 2012 and 2013). We also stated that ''we continue to believe that artificially adjusting wage index values by substituting a wage index floor is not an appropriate method to address low wages in certain geographic locations'' and that, accordingly, we will no longer apply a wage index floor beginning January 1, 2014 (76 FR 70241). We will include in the CY 2014 ESRD PPS proposed rule, the methodology we propose to use to address wages in rural Puerto Rico when we no longer apply the wage index floor.

Therefore, we are finalizing the wage index floor value of 0.500 for CY 2013.

6. 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 vascular 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 for the treatment of ESRD, were included in computing the final ESRD PPS base rate and, therefore, would not be separately paid under the ESRD PPS. We further stated that any anti-infective drug or biological used for the treatment of ESRD-related conditions would be considered a renal dialysis service and not eligible for separate payment. We noted that this policy also applies to any drug or biological that may be developed in the future.

In the CY 2012 ESRD PPS final rule (76 FR 70243), we explained that 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 (76 FR 70243), we allowed ESRD facilities to receive separate payment for vancomycin when furnished to treat non-ESRD related conditions. When ESRD facilities furnish vancomycin to treat non-ESRD related conditions, they place the AY modifier on the claim. We stipulated that in accordance with ICD–9–CM guidelines as described in the CY 2011 ESRD PPS final rule (75 FR 49107), an ESRD facility must report on the claim 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 (76 FR 70243). Finally, in response to comments, we stated that we would consider allowing separate payment for daptomycin (76 FR 70243).

In the CY 2013 ESRD PPS proposed rule (77 FR 40963), we explained that after consultation with our medical experts, we proposed to allow ESRD facilities to receive separate payment for daptomycin when furnished to treat non-ESRD related conditions for CY 2013 and subsequent years. When ESRD facilities furnish daptomycin to treat non-ESRD-related conditions, they would place the AY modifier on the claim. We also explained that if ESRD facilities submitted claims for daptomycin with the AY modifier, then the ESRD facility would also be required to report the diagnosis code for which the daptomycin is indicated in accordance with ICD–9–CM diagnostic coding guidelines. We sought public comments on our proposal to permit separate payment for daptomycin when furnished to treat non-ESRD-related conditions. As we discussed in the proposed rule, we will continue to monitor the use of anti-infectives furnished by ESRD facilities including those that are identified as non-ESRD related (77 FR 40963). The comments we received and our responses are set forth below.

Comment: We received eight comments in support of our proposal to allow for separate payment for daptomycin when furnished for non-ESRD related conditions. One commenter encouraged CMS to consider the appropriateness of other anti-infective drugs and biologicals which could be used in the future for both ESRD and non-ESRD conditions, with the primary goal to help reduce drug resistance in this compromised and susceptible patient population.

Response: We thank the commenters for their support. We believe that the commenter is suggesting that CMS should frequently consider whether other drugs should be included in the ESRD PPS. We will consider allowing separate payment for other anti-infective drugs and biologicals as we may determine appropriate.

We are finalizing the proposal 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. In accordance with ICD–9–CM diagnostic coding guidelines as described in the CY 2011 ESRD PPS final rule (75 FR 49107), the ESRD facility must indicate on the claim the diagnosis code for which the daptomycin is indicated.

During our monitoring of claims we have noted that there are ESRD facilities that are indicating a type of organism rather than a diagnosis that would indicate that the anti-infective was furnished for non-ESRD-related conditions. We reiterate that the diagnosis code for which vancomycin or daptomycin is used must be indicated on the claim. We also reiterate that treatment of any skin infection that is related to renal dialysis access management will be considered a renal dialysis service and will continue to be paid under the ESRD PPS, and no separate payment will be made. We will continue to monitor the use of anti-infectives furnished by ESRD facilities including those that are identified as non-ESRD related to ensure proper billing of these drugs.

b. Alteplase and Other Thrombolytics

In the CY 2012 ESRD PPS final rule (76 FR 70246 through 70247), we explained that after the CY 2011 ESRD PPS final rule was published, 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. Medicare 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 discussion on the outlier policy is in section II.C.7 of this final rule. 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 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, we noted in the CY 2012 ESRD PPS final rule (76 FR 70249), that for CY 2012 we had not proposed to exclude separate payment of thrombolytic drugs under the composite rate portion of the blended payment and therefore, separate payment would be made for thrombolytics for the composite rate portion of the blended payment in CY 2012.

For CY 2013, we proposed 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 (77 FR 40963). We believe that this is consistent with the changes we made to our outlier policy regarding excluding thrombolytic drugs from outlier eligibility as discussed above. We note that these conclusions are specific to ESRD. We solicited comments on our proposal to exclude thrombolytic drugs from separate payment under the composite rate portion of the blended payment during the transition.

The comments and our responses are set forth below.

Comment: We received five comments pertaining to our proposal to no longer provide separate payment for thrombolytic drugs under the composite rate portion of the blended payment in CY 2013. In general, commenters agreed with CMS that both heparin and alteplase or other thrombolytic drugs are used for access management, but a few commenters disagreed with our assertion that heparin and alteplase are used for the same purpose. Some commenters specifically noted that CMS's proposal not to allow separate payment for alteplase and thrombolytic drugs under the composite rate portion of the blended payment during the transition period for CY 2013 is flawed because the drugs are used to achieve different clinical results and utilize different mechanisms of action. In particular, the commenters noted that heparin is used to prevent clotting whereas alteplase is used to avoid a poorly functioning catheter. Some commenters provided examples of the efficacy of alteplase and thrombolytics, as compared to heparin. Some commenters, including a renal organization and a pharmaceutical manufacturer, disagreed that heparin can be used as a substitute for alteplase, citing the different mechanisms of action for the two drugs. One commented that because heparin and thrombolytics achieve different clinical results, they should not be treated as substitutes for payment purposes.

Response: We believe alteplase and heparin are used for the same renal dialysis-related purpose, namely, vascular access management. In the CY 2012 ESRD PPS final rule (76 FR 70246 through 70249), we addressed similar comments regarding the use of alteplase and heparin in the context of our proposal to eliminate thrombolytics from the outlier policy. We noted that in the development of the ESRD PPS, we recognized that alteplase and heparin were pharmacologically different (that one is a thrombolytic that lyses clots and the other is an anticoagulant that prevents clots, respectively) (76 FR 70248). We further stated, however, that we believed that both drugs enable the catheter or graft to function either through clot prevention or clot degradation, thereby providing effective dialysis vascular access. We further believe that, for purposes of payment for renal dialysis services, it is sufficient that these products can be used for the purpose of providing dialysis vascular access. Consistent with the ESRD Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, drugs used as substitutes for any of the listed items, or used to accomplish the same effect, are covered under the composite rate and are not separately payable. Because heparin is a composite rate drug and thrombolytics are used to achieve the same renal dialysis-related clinical outcome, we believe it is appropriate to exclude thrombolytic drugs from separate payment under the composite rate portion of the blended payment during the transition.

Comment: One ESRD facility commented that the high cost of alteplase compared to heparin would prevent substitution of alteplase for heparin. The commenter argued that CMS's policy in the ESRD Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 of covering under the composite rate drugs used as substitutes for composite rate drugs, or used to accomplish the same effect, is without regard to innovation, cost, effectiveness, and efficiencies, and may result in increased cost to the Medicare program. The commenter also noted that the cost of thrombolytics is included in the ESRD PPS for those not in the transition and that elimination of separate payment for those in the transition would negatively impact reimbursement. A pharmaceutical company stated that the proposed changes may negatively affect catheter care because disallowing outlier payments and separate payment for thrombolytics creates a financial incentive for facilities to avoid restoring patency with alteplase.

Response: In the CY 2012 ESRD PPS final rule (76 FR 70247), we explained that the ESRD PPS provides an opportunity for ESRD facilities to make decisions based on the medical needs of patients and not on the basis of financial gain. We further explained that we are not implying that thrombolytics or any access management drug should not be used when clinically indicated. We noted that Medicare payment policy is not intended to dictate, determine, or influence clinical practice or favor one course of treatment over another. Rather, by accounting in the ESRD PPS base rate for the cost of drugs and biologicals that had been separately payable under the composite rate system, we believe that we provide adequate payment to maintain patency of the access site regardless of whether patency is maintained using heparin or a thrombolytic. For additional information regarding this issue, we refer the commenters to the comment responses in the CY 2012 ESRD PPS final rule (76 FR 70247 through 70249).

We disagree with the commenter that ESRD facilities receiving blended payments during the transition are unfairly disadvantaged because they will not receive separate payment for thrombolytics for the portion of the

blended payment based on the composite rate. Even when the composite rate system was in place before the ESRD PPS was implemented, it was our policy not to pay separately for drugs that could be used to accomplish the same effect as composite rate drugs. Accordingly, it is consistent with that policy not to provide separate payment for thrombolytics for the composite rate portion of blended payments during the remainder of the transition.

For all of the reasons stated above, we continue to believe that alteplase and other thrombolytics should not be eligible for separate payment under the composite rate portion of the blended payment. After consideration of public comments, we are finalizing our CY 2013 proposal to exclude alteplase and other thrombolytics from separate payment, which we believe is consistent with the CY 2012 ESRD PPS changes made to the outlier policy to exclude thrombolytic drugs from outlier payments.

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 will use the ASP methodology.

In the CY 2013 ESRD PPS proposed rule (77 FR 40963), we proposed for CY 2013 and subsequent years to continue to use the ASP methodology, including any modifications finalized in the 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 explained that we would use this methodology for payment analyses that CMS may perform. We did not receive public comments on our proposal to apply the ASP methodology or any modifications to the ASP for these purposes, as updated in the PFS rule or in updating the ASP pricing. Therefore, we are finalizing that for CY 2013 and subsequent years we will continue to use the ASP methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute 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.

7. 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) provide 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).

In the CY 2013 ESRD PPS proposed rule (77 FR 40964), we explained that drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services are specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010 and rescinded and replaced by Transmittal 2094, dated November 17, 2010. We also explained that 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 stop issuing 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 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. In the CY 2013 ESRD PPS proposed rule (77 FR 40964), we explained that we planned to identify, through our monitoring efforts, those 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.

We indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40964), that Medicare regulations at 42 CFR 413.237(a)(2) through (a)(6), and (b) specify the methodology used to calculate outlier payments. We explained that 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. We further explained that 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. We also stated that 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. Finally, we explained that in accordance with 42 CFR 413.237(c), 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 and that 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.

Comment: Several commenters agreed that no changes need to be made to the methodology and commended CMS for its transparency regarding the data and methodology used to update the MAP and fixed dollar loss thresholds. Some commenters expressed appreciation of CMS's clear explanation of eligible outlier services.

Response: We thank the commenters for their support. We will continue to issue guidance regarding the renal dialysis items and services that could qualify for outlier payment.

a. Impact of Changes to the Outlier Policy

In the CY 2013 ESRD PPS proposed rule (77 FR 40964), we explained that we did not propose any changes to the methodology used to compute the MAP or fixed dollar loss amounts. Rather, we explained that we were 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. In this final rule, for CY 2013, we used the June 2012 update of the CY 2011 National Claims History File to update the outlier services MAP amounts and fixed dollar loss amounts. That is, for CY 2013, the MAP and fixed dollar loss amounts are based on utilization data from the 2011 ESRD PPS claims. For this final rule, 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. The estimates for the 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 CY2012 (based on 2010 data price inflated to 2012) *		*Column II* Updated outlier estimates based on 2011 data price inflated to 2012 *		*Column III* Final outlier policy for CY2013 (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	$37.84	$59.49	$38.65	$61.38
Adjustments						
Standardization for outlier services [2]	1.0024	0.9738	1.0927	0.9878	1.0927	0.9878
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	$40.52	$57.59	$41.39	$59.42
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$71.64	$141.21	$44.16	$103.47	$47.32	$110.22
Patient months qualifying for outlier payment	5.7%	5.4%	7.8%	5.2%	7.6%	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 epoetin 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 CY 2011, 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) with the outlier service MAP amounts in Column II (which are 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 the CY 2012 amount. Based on the use of the most recently available data, the fixed-dollar loss amount for pediatric patients will decrease from $71.64 to $47.32 and the MAP amount will decrease from $45.44 to $41.39 as compared to CY 2012 values. For adult patients, the fixed-dollar loss amount drops from $141.21 to $110.22 and the MAP amount drops from $78.00 to $59.42.

We estimate that the percentage of patient months qualifying for outlier payments under the current policy will be 5.1 percent and 7.6 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).

Comment: All of the commenters supported CMS's decision to lower the threshold for both the fixed dollar loss

and MAP amounts for pediatric and adult patients. The commenters stated that they believed that outlier payment mechanisms are fundamental to the long-term success of prospective payment systems to ensure patients get the care they need, even when there are financial disincentives. The commenters further expressed that it is important for CMS to ensure that the information it uses to determine the outlier thresholds each year is as current as possible and agreed with CMS in using the 2011 ESRD claims and utilization for CY 2013.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that some ESRD facilities may not have the necessary resources available to identify outlier services on the claim, and therefore are not receiving the outlier payments to which they are entitled. One commenter suggested that CMS make available data indicating that the outlier policy is beneficial to small ESRD facilities. The commenter further explained that this policy could be detrimental to small facilities because, although the facilities' base rate is reduced by 1 percent to account for outlier services, the facilities may be unable recoup this amount because of resource limitations.

Response: Outlier services are the items and services that were separately paid prior to the implementation of the ESRD PPS and are also separately paid under the composite rate portion of the blended payment for those ESRD facilities under the transition. We do not believe that it should be difficult for small facilities to identify outlier services on claims because these facilities should have had experience identifying these items on claims before the PPS was implemented. Specifically, the items eligible for outlier payments under the ESRD PPS are the same items that had been separately paid under the basic case-mix adjusted composite rate system and are separately paid under the composite rate portion of the blended payment for ESRD facilities receiving payment under the transition. Consequently, we believe that identifying items eligible for outlier payment is not an additional burden nor do we believe that it is difficult for small ESRD facilities.

In terms of demonstrating that the outlier policy is beneficial to small ESRD facilities, we note that the outlier policy is intended to account for the cost of beneficiaries with high resource utilization; it is not intended to account for facility size. Instead, our low-volume adjustment accounts for facility size by adjusting for the cost of treating a low volume of ESRD patients. Although we will continue to monitor the impact of our outlier policy, as noted above, we believe that all facilities, regardless of size, should be able to identify outlier services on claims and be compensated for the cost of treating beneficiaries with high resource utilization.

b. Outlier Policy Percentage

In the CY 2013 ESRD PPS proposed rule (77 FR 40965), we explained that 42 CFR 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. We further explained that because of the decrease in utilization associated with the implementation of the ESRD PPS, the 1 percent target for outlier payments was not achieved in CY 2011. For this final rule, using the June 2012 update of the CY 2011 National Claims History File, we found that outlier payments represented approximately 0.3 percent of total payments. That is, the historical data previously used to set the outlier thresholds for CY 2011 projected greater use of outlier services than was observed under the expanded ESRD PPS, leading to lower outlier payments than expected. Use of 2011 data to recalibrate the thresholds, reflecting lower utilization of epoetin and other outlier services, will 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 final 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.

Comment: One commenter recommended that CMS estimate and publish the amount of the shortfall in outlier payments paid during CY 2011. The commenters recommended that CMS develop a mechanism to return these funds to the ESRD facilities so that these funds may be used to offset the costs associated with numerous ''unfunded mandates'' imposed on these facilities. One commenter suggested that CMS set less than 1 percent aside for outliers and allocate the leftover funds to the ESRD PPS base rate.

Response: We disagree that the shortfall in outlier payments should be used to make additional payments to ESRD facilities to account for not achieving the 1 percent threshold. The 1 percent outlier policy is a prospective payment mechanism in which thresholds are established and adjusted on a yearly basis based on historical data. In the FY 1997 Inpatient Prospective Payment System (IPPS) final rule (61 FR 46229 and 46230), we explained that we believe our outlier policies are consistent with the statute and the goals of the prospective payment system. Many of the factors used to set prospective payment amounts for a given year are based on estimates. These factors include not only the outlier thresholds, but also the market basket rate of increase, the update factors and the required budget-neutrality provisions. We do not believe that Congress intended that the standardized amounts should be adjusted (upward or downward) to reflect differences between projected and actual outlier payments for a given year. Moreover, retroactive adjustments would be extremely difficult or impracticable (if not impossible) to administer. We further explained that the thresholds for a given year reflect certain levels of costs, so that if costs are held down, fewer cases qualify for outlier payments and outlier payments are lower than expected. We believe that the same explanation applies to the ESRD PPS.

D. 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 items and 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 42 CFR 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.'' We further 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. We indicated that, 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 (75 FR 49173). We stated in the CY 2013 ESRD PPS proposed rule that the composite rate represented the routine items and services provided to Medicare beneficiaries for outpatient maintenance dialysis and therefore was full payment for those items and services. Therefore, 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 by Medicare (77 FR 40965).

We also explained in the CY 2011 ESRD PPS final rule (75 FR 49048), 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 inadvertent 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 and 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 ESRD PPS final rule (76 FR 70243), with regard to antibiotics, we provided for separate payment for vancomycin when furnished to treat 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). In the CY 2013 ESRD PPS proposed rule (77 FR 40963), we proposed to allow for separate payment for daptomycin if furnished for non-ESRD-related conditions and finalized in section II.C.6.2 of this final rule.

As described at 42 CFR 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 inadvertently 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 42 CFR 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 that as of CY 2012, we would no longer issue 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. 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 because all drugs and biologicals with a rate available on the ASP pricing file when the modifier AY is not present may be eligible for outlier consideration.

We explained in the CY 2013 ESRD PPS proposed rule, that as a result of our monitoring efforts, we continue to find composite rate drugs reported on ESRD claims and reiterated that composite rate items and services are not to be reported on the ESRD facility claims. We noted that we are instituting measures to ensure that composite rate drugs are prevented from being applied to the outlier payment. These measures will be discussed through administrative issuances, as appropriate. We also noted that we would continue to monitor the reporting of composite rate items and services on ESRD claims and plan to take actions to recoup inappropriate and duplicative payments. Finally, we noted that if the inclusion of composite rate items and services such as laboratory tests, drugs and supplies on claims will be required to be reported, we will discuss this requirement in future rulemaking (77 FR 40966).

We received one comment on this issue. The comment and our response are set forth below.

Comment: One commenter concluded that any action to recoup inappropriate and duplicative payments for reporting composite rate items and services should be pursued on a going forward basis rather than retrospectively.

Response: CMS has a fiduciary responsibility to ensure that accurate payments are made. If we were to identify inappropriate payments that had been made because composite rate items and services were reported on claims for the purpose of receiving separate payment we would pursue recoupment of those payments in accordance with applicable laws and regulations.

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

In the CY 2013 ESRD PPS proposed rule (77 FR 40966), we indicated that we had become aware that some ESRD facilities are requiring ESRD beneficiaries to purchase renal dialysis drugs from the ESRD facility and are instructing beneficiaries not to use their Part D plan for their purchases. We explained that 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 for those services. Furthermore, section 1881(b)(2)(A) of the Act states that payments shall be made to an ESRD 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.

Furthermore, 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 or 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 drugs and biologicals could be used for dialysis purposes and therefore, are considered ESRD-related when used for those purposes. We indicated that we presumed these drugs and biologicals to be renal dialysis services in whatever form they are furnished, unless indicated on the claim 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 are considered renal dialysis services (75 FR 49050 and 49051).

In the CY 2013 ESRD PPS proposed rule, we reiterated 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 also expect that ESRD facilities will not restrict access to necessary drugs for financial purposes by requiring patients to purchase medically necessary drugs and biologicals. We expect that ESRD facilities will 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.

We received no comments on the clarification of our policy regarding ESRD facility responsibilities for ESRD-related drugs and biologicals.

3. Use of AY Modifier

As we indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40967), in the CY 2011 ESRD PPS final rule, we developed a mechanism to be used by ESRD facilities to identify and be paid separately for non-ESRD-related items and services, such as drugs, biologicals, and equipment and supplies (75 FR 49052 and 75 FR 49168). We provided this mechanism in order to support a Medicare beneficiary's need for non-ESRD-related items and services (that is, predominantly drugs and laboratory tests) during a dialysis treatment and 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 on the claim for those supplies and equipment, signifying that they were used for services that were not ESRD-related and eligible for separate payment outside of the ESRD PPS (75 FR 49168). Change Request 7064, Transmittal 2033, titled ''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 on 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 signal separate payment outside of the ESRD PPS. In the CY 2012 ESRD PPS final rule, we provided for the use of the AY modifier with vancomycin if used for non-ESRD-related conditions and with the requirement that the ESRD facilities include the diagnosis code of the condition on the claim (76 FR 70243). In the CY 2013 ESRD PPS proposed rule (77 FR 40967), we proposed to allow the use of the AY modifier for separate payment when daptomycin is furnished by an ESRD facility to an ESRD Medicare beneficiary for non-ESRD related conditions. We are finalizing this policy above. ESRD facilities are required to indicate an appropriate diagnosis code on the claim that reflects the condition requiring the use of daptomycin.

We explained in the CY 2013 ESRD PPS proposed rule (77 FR 40967) that our monitoring activities have identified that ESRD facilities and clinical laboratories are appending the AY modifier for items that we believe are ESRD-related. We noted in the proposed rule (77 FR 40967) that some ESRD facilities and clinical laboratories appear to be appending the AY modifier on many items and services reported on claims. We reiterated in the proposed rule that the purpose of the AY modifier is to allow beneficiaries the convenience to receive non-ESRD-related items (for example, drugs and laboratory tests) during their dialysis treatment and to allow the ESRD facility to receive a separate 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 is required for non-ESRD-related conditions. The AY modifier is not intended to be used to receive a separate payment for items that are ESRD-related and therefore included in the ESRD PPS base rate. We further stated that we would continue to monitor the use of the AY modifier and intend to take steps to recoup inappropriate payments. In the event that we believe 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.

We received several comments on our clarification of this policy and our responses are set forth below.

Comment: We received six comments regarding the AY modifier. Commenters supported maintaining the AY modifier for non-ESRD conditions. Several commenters provided reasons for supporting the AY modifier. For example, some commenters concurred that the AY modifier is intended to allow Medicare beneficiaries the convenience of receiving non-ESRD related items and services during the course of dialysis treatment; and to allow the ESRD facility or laboratory to receive a separate payment when furnishing non-ESRD items or services. It also enables optimal coordinated care to Medicare beneficiaries by minimizing their need for additional doctor visits and duplicative or unnecessary lab tests. Five commenters largely encouraged CMS to continue the use of the modifier for reporting non-ESRD related items or services for payment and to furnish supporting data on AY modifier misuse. A few commenters suggested that CMS should consider drafting guidance on the appropriate use of the AY modifier.

A few commenters expressed concern over the possible elimination of the AY modifier and identified possible resulting hardships for Medicare ESRD

beneficiaries. One commenter noted that the elimination of the AY modifier would force facilities to send dialysis patients to labs or infusion centers to receive IV medications that would risk the vascular access and add transportation and time burdens for the beneficiary.

Response: We thank commenters for their support of the use of the AY modifier. We agree that the elimination of the AY modifier could result in additional hardships for ESRD beneficiaries.

Comment: One commenter suggested that, rather than eliminating the AY modifier, CMS should rely upon the contractors to educate providers, audit payments for AY items, and request documentation when appropriate. Another commenter encouraged CMS to provide data on the exact abuses or the scope of modifier misuse noting that patients should not suffer because of modifier abuse, but rather CMS should work with facilities and providers to ensure policy compliance.

Response: With regard to the suggestion that the responsibility for AY modifier monitoring education should rest on the CMS contractors (that is, the Medicare Administrative Contractors (MACs)), we note that we do provide education and instructions to the A/B MACs through administrative issuances and MedLearn articles that they can then use to educate providers. For example, CMS Change Request #7064 and subsequent Medicare Learning Network Matters (MLN) article # MM7064, published on January 14, 2011, notifies contractors that ESRD-related laboratory services, drugs and supplies will be subject to Part B consolidated billing edits and no longer separately payable when furnished to ESRD beneficiaries. However, these consolidated billing edits do not apply when the items and services are not ESRD-related. When items and services are furnished to an ESRD beneficiary for conditions other than ESRD, the AY modifier must be present on the claim to bypass billing edits and allow for a separate payment outside of the ESRD PPS. CMS MLN #MM7064 may be viewed at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7064.pdf*. Finally, we are in the process of updating the ESRD Benefit Policy Manual, Pub 100–02, chapter 11, to reflect the policy requirements under the ESRD PPS, including the use of the AY modifier.

With regard to the comment concerning monitoring the use of the AY modifier and the suggested functions to be performed by the MACs, as we discussed in the CY 2013 ESRD PPS proposed rule (77 FR 40967), we are continuing to monitor the use of the AY modifier and intend to take steps to recoup inappropriate payments. Although we are updating our manual, we believe that we have provided adequate instructions as to the appropriate use of the AY modifier. We expect that the contractors will convey information regarding the proper use of the AY modifier to the ESRD facilities, and will also audit payments and request documentation as necessary. However, CMS has the responsibility to ensure that payments are made appropriately. Therefore, we will continue to monitor the use of the AY modifier. If we believe that the AY modifier is not being used as intended, or it is being used in order to receive separate payment for renal dialysis items and services that are in the bundled payment, we will be forced to reconsider its use.

E. Miscellaneous Comments

We received thirty-five comments from Medicare beneficiaries, family members, ESRD facilities, nurses, physicians, professional organizations, renal organizations, and manufacturers related to issues that were not specifically addressed in the CY 2013 ESRD PPS proposed rule.

Comment: We received comments from patients, their families, renal associations and manufacturers requesting changes in how CMS pays for home dialysis and home dialysis training. Many of these commenters described the benefits of home dialysis. Most commenters asked CMS to increase the number of weekly allowable dialysis sessions and eliminate the medical justification requirement for additional sessions. One commenter questioned why payment for in-facility dialysis was the same as for home dialysis, noting the differences between staff and supply use between in-facility and home dialysis. Some commenters contended that patient requests for home dialysis are being denied. Commenters also stated that beneficiaries with ESRD are not provided with the same home training opportunities as beneficiaries whose care is covered by other payment sources. Many of the commenters stated that payment for home dialysis training is insufficient and does not reflect the true cost of training. Some commenters indicated various ranges of time required for home training in terms of time per day and number of training sessions. One home dialysis organization stated that ESRD facilities only receive payment for 18, rather than 25, training sessions for new patients.

Response: CMS developed a reimbursement mechanism with the 2011 implementation of the ESRD PPS that we believe supports home-based dialysis. That is, the ESRD PPS payment, which includes drugs, laboratory tests, staff time, supplies, patient-level adjustments, facility-level adjustments and outlier payments, is the same regardless of the location where the dialysis services are furnished or the dialysis modality, which we believe supports beneficiaries' ability to elect to receive dialysis at home, where appropriate. It is not, however, CMS's intent to encourage, discourage or require any particular dialysis modality. Rather, we believe that decisions regarding whether to receive dialysis and which dialysis modality to use should be made by beneficiaries in consultation with their physicians. This includes the decision whether to receive home hemodialysis or home peritoneal dialysis, rather than in-facility dialysis. We believe that the decision to perform home dialysis includes determining the beneficiary's abilities, the beneficiary's desire to perform home dialysis and the beneficiary's physical and emotional status.

With regard to the comment asking why the payment is the same for in-facility as home dialysis, we believe that our policy to pay the same amount, including the patient-level and facility-level adjustments, as well as the outlier policy for home and in-facility dialysis, provides adequate payment to account for the short-term increase in staff time necessary to train beneficiaries for home dialysis. Training costs are included in the ESRD PPS base rate, however, we also provide an add-on adjustment for each training session that represents one hour of nursing time to conduct one-on-one training treatments for each training treatment furnished by a Medicare certified home dialysis training facility. The add-on payment for one hour of training per training session does not imply that it takes only one hour per training session to properly educate a beneficiary to perform home dialysis. We believe that our payment is adequate for training and home dialysis.

We have been and will continue to monitor and analyze trends in home dialysis and home dialysis training. We have seen a continuing increase in overall home dialysis since mid-2009, including in 2011. In particular, we have observed an increase in home hemodialysis and a decline in home peritoneal dialysis with an overall higher rate of home peritoneal dialysis. In addition, our monitoring shows that

ESRD facilities receive payments for more treatments for home hemodialysis than for in-facility hemodialysis. We also have seen an increase in home training in 2011, particularly in retraining. Consequently, we do not believe that the ESRD PPS and our training adjustment discourage beneficiaries from receiving home dialysis.

Commenters also requested that we increase the maximum number of dialysis sessions and eliminate the medical justification requirement for dialysis treatments after a beneficiary has received three sessions in one week. We note that, although three is the maximum number of sessions that we will cover without a showing of medical necessity, we will cover additional sessions where those sessions are medically necessary. We are aware that there are observational studies that support additional weekly dialysis treatments and that there is some industry support for additional treatments. We have and will continue to monitor and analyze the number of dialysis treatments that Medicare beneficiaries receive to determine whether a change in this longstanding policy is warranted.

In addition, in the CY 2011 ESRD PPS final rule (75 FR 49064) we stated in response to a MedPAC comment that we would consider whether it would be appropriate to utilize a larger unit of payment, rather than a per treatment payment, after the transition period. We further stated that ''we may evaluate whether the ERSD PPS has resulted in improved outcomes, the degree to which home dialysis has increased, and whether interested stakeholders would favor an alternative to the per treatment approach.'' We will continue to monitor the impact of the ESRD PPS and will take these comments into consideration if we determine that any changes to the per treatment payment approach are warranted.

With regard to the comment that ESRD facilities receive payment for 18 rather than 25 training treatments for new patients, we believe that the commenter is confusing the adjustment for beneficiaries who are receiving home dialysis training but are not in their first four months of dialysis, with beneficiaries who have been newly diagnosed with ESRD and are receiving their first four months of dialysis. The home dialysis training adjustment applies to those beneficiaries who are not in their first four months of dialysis treatments. This adjustment does not apply for those beneficiaries newly diagnosed with ESRD. Instead, facilities receive the onset of dialysis adjustment for these beneficiaries. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49094), we believe that the costs associated with the onset of dialysis adjustment and the training add-on adjustment overlap (that is, costs for services could be accounted for in both adjustments). Accordingly, we finalized a policy that ESRD facilities will not receive the home dialysis training adjustment when they are receiving the onset of dialysis adjustment. This does not mean that an ESRD facility may not furnish home training services during the onset period. Rather, the onset of dialysis payment adjustment of 51 percent per treatment accounts for the administrative and labor costs associated with new patients, including the costs to train patients.

We are unable to address the comment contending that ESRD beneficiaries are not offered the same home dialysis training opportunities as those offered to ESRD beneficiaries covered by private payers because we are not familiar with these payment sources.

Comment: One patient support group recommended that CMS use revenue code 0820 when reporting home dialysis instead of revenue code 0821, which is currently used to describe both in-facility and home dialysis services. The commenter contends that this will correctly identify patients on home dialysis in Medicare claims data.

Response: Our current Medicare policy for reporting home dialysis services with revenue code 0821 appended with ESRD condition code 74 (Dialysis in the Home) allows us to distinguish beneficiaries receiving dialysis at home from those receiving treatment in an ESRD facility.

Comment: We received twelve comments regarding the Agency's plan to include oral-only drugs in the ESRD PPS bundled payment for CY 2014. Commenters expressed concern about the administrative burden, compliance with state laws, and associated costs in furnishing oral-only drugs within the scope of the ESRD service. A few commenters requested that CMS ask for community input so that the inclusion of the oral-only drugs will be an uneventful transition for patients. ESRD industry associations cautioned that the inclusion of oral-only drugs into the ESRD PPS CY 2014 bundled payment may limit patient access to the most clinically appropriate drugs and threaten optimal health outcomes for ESRD Medicare beneficiaries. Some commenters recommended that CMS include patient protections to ensure patient care is not compromised and that oral-only drugs continue to be furnished at the recommended doses. Many commenters requested that the Agency share advance information about the methodology and data sources that the Agency will use to calculate the reimbursement rates for drugs and therapies and encouraged CMS to use the most recent year of available data to establish a payment rate for oral-only drugs. Other commenters requested that CMS adopt a methodology that measures the actual utilization on a per treatment basis and includes costs associated with drug administration when reimbursing oral-only drugs as part of the ESRD PPS.

Response: We thank the commenters for their comments. In the CY 2011 ESRD PPS final rule (75 FR 49038 through 49044), we responded to comparable comments regarding the inclusion of oral-only drugs in CY 2014. We received many suggestions from stakeholders on how oral-only drugs should be included in the ESRD PPS bundled payment. We have reviewed and will continue to review all of the comments, which we will consider as we formulate our proposals on this issue. We intend to address the inclusion of oral-only drugs in the ESRD PPS in the CY 2014 ESRD PPS proposed rule.

Comment: We received three comments from industry associations requesting that CMS release the rate-setting file to allow the industry to test the Agency's assumptions and complete its own analysis of the payment policies set forth in the CY 2013 ESRD PPS proposed rule. One commenter encouraged CMS to make data available to the public generally, not just dialysis facilities in particular, to allow for a more complete assessment of the ESRD PPS program.

Response: We received comparable requests and comments in response to the CY 2012 ESRD PPS proposed rule and responded to those comments in the CY 2012 ESRD PPS final rule (76 FR 70254 to 70255). We believe that we have provided and will provide data sufficient to analyze the payment policies included in the proposed rule, by posting the impact file for CY 2012 on the ESRD PPS Payment Web site. We will also post a provider-level impact file and the wage index file for CY 2013 shortly after publication of this final rule. We also explained that we have not made the rate setting file available ''because the release of patient identifiable data is not necessary to accomplish the purpose of analyzing our proposals. Applicable Federal privacy laws and regulations, including the Privacy Act and HIPPA Privacy Rule only permit us to disclose personal

identifiable information when it is necessary to administer the program, or for health care operations and payment.''

Comment: We received 8 comments requesting modification to the standardization factor methodology and calculation for CY 2013. Many of these commenters encouraged CMS to use the most current data available in order to establish the standardization factor, rather than historical estimates. Some commenters indicated that because we had adjusted the outlier fixed dollar loss and MAP amounts to account for outlier payments below the 1 percent threshold in CY 2011, we should provide a comparable adjustment to the standardization factor and the ESRD PPS base rate to account for payments for patient- and facility-level adjusters that were not utilized. Some commenters continue to contend that the ESRD PPS base rate established in CY 2011 is incorrect and that CMS should return the payment amounts removed from the base rate to account for the adjusters, thereby increasing the base rate. Other commenters stated that the ESRD PPS base rate should be adjusted to account for payments allocated for the patient- and facility-level adjusters that had not ultimately been paid to the ESRD facilities. A few commenters requested that CMS modify the payment for case-mix and co-morbidity adjustments.

Response: In the CY 2011 ESRD PPS final rule, we described the data sources that were used in constructing the ESRD PPS payment bundle, the development of the ESRD PPS base rate, and the payment adjusters (75 FR 49064 through 49127). In the CY 2013 ESRD PPS proposed rule, we proposed to update the base rate by the rate of increase in the ESRD market basket, reduced by the productivity adjustment (77 FR 40959). The base rate was developed using 2007 claims, in accordance with section 1881(b)(14)(A)(ii) of the Act, which requires CMS to use the lowest per patient utilization year. We also explained the methodology used to determine the case-mix adjustment amount, including co-morbidities (75 FR 49087 through 49116). In the CY 2013 ESRD PPS proposed rule, we stated that we were not proposing any changes to the methodology used to compute the MAP or fixed dollar loss amounts, but were 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 (77 FR 40964). The methodology for calculating and updating the base rate was finalized last year through notice and comment rulemaking, as were the methodologies for updating the outlier threshold. In the CY 2013 ESRD PPS proposed rule, we did not propose to change how the base rate is calculated or updated. We also did not propose in the CY 2013 ESRD PPS proposed rule to modify the payment adjusters. We do not believe that because we lowered the MAP and fixed dollar loss amounts to adjust for outlier payment expenditures that were below the 1 percent target, we must adjust the standardization factor for the ESRD PPS base rate. We will, however, continue to monitor our payments and consider if any changes need to be made in the future.

Comment: One commenter requested clarification when billing Medicare for Lipid Profile laboratory services furnished to ESRD beneficiaries. Another commenter encouraged CMS to furnish guidance for blood draws and laboratory collections under the ESRD PPS.

Response: ESRD-related laboratory tests may not be billed with the AY modifier and no separate payment shall be made when an ESRD facility or laboratory furnishes ESRD-related laboratory tests to an ESRD beneficiary. We discuss laboratory tests furnished under the PPS in our CY 2011 and CY 2012 ESRD PPS final rules (75 FR 49053 through 49056 and 76 FR 70249 through 70250, respectively). Furthermore, the Lipid Profile laboratory test is appropriately included in the ESRD PPS payment bundle when Lipid abnormalities result from, or are related to the beneficiary's ESRD. For example, some forms of dialysis, particularly peritoneal dialysis, are associated with increased cholesterol and triglyceride levels, and a Lipid Profile laboratory test to assess these levels would be included in the bundled payment. If, however, the Lipid Profile laboratory test is furnished for reasons other than for the treatment of ESRD, the laboratory services may be billed with the AY modifier and are eligible for separate payment. With regard to the comment requesting guidance for blood draws and laboratory collections, we refer the commenter to Change Request 7617, Transmittal 150, entitled, ''Implementation of Changes in End Stage Renal Disease Payment for Calendar Year 2012'' issued on November 16, 2011.

Comment: One commenter requested that CMS consider the implementation of pediatric co-morbidities to the pediatric case mix adjustments, while another commenter requested consideration of a case-mix adjustment for race. One association called for CMS to establish a new technology adjuster in a non-budget-neutral manner, stating that new technologies have the potential to lead to better diagnosis, treatment, and patient outcomes.

Response: We thank the commenters for their suggestions, but note that we did not propose to implement these adjusters in the CY 2013 ESRD PPS proposed rule. We refer the commenters to the CY 2011 ESRD PPS final rule (75 FR 49128 through 49134; 75 FR 49108 and 49115; 75 FR 49174), in which we explained the methodology used to develop the ESRD PPS for the pediatric population, discussed the reasons for not including a patient-level case mix adjuster for race, and responded to comments suggesting that we provide separate payment for new and innovative drugs and technologies.

Comment: Some commenters requested that the cost reports be amended to reflect the actual cost of care. Some of the recommendations included that the cost report should provide flexibility to allow for innovation, eliminate the limitation on medical director fees, recognize the cost of supporting the ESRD networks, and allow immediate recognition on cost reports of ''new or innovative items/services,''

Response: We thank the commenters for their suggestions. We plan to analyze the cost reports to determine if there are any changes required and will consider the suggestions provided.

We received a number of other comments on a variety of topics that we believe are outside the scope of the proposed rule. The commenters requested that ESRD beneficiaries be able to maintain disability benefits while employed; expressed concern about the ''corporate practice of medicine'' by dialysis facilities; noted that securing the necessary documentation for acute co-morbidities is problematic and urged CMS to furnish co-morbidity claims data from the CMS database; advocated for inclusion of their product in the ESRD PPS payment; and disputed over payment changes to its product under Part D. We appreciate the comments; however, because these comments were not in response to any proposals or discussions in the proposed rule, they are beyond the scope of this final rule. We refer the commenters to the CY 2011 ESRD PPS final rule, where we believe that we addressed many of these issues (75 FR 49030).

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 ESRD payment reductions based on quality performance are being made to dialysis facilities, 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 final 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, which we have implemented 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. In this final rule, we describe each of these elements, as applicable, and our final policies for their application to PY 2015 and future payment years of the ESRD QIP.

B. Summary of the Proposed Provisions and Responses to Comments on the ESRD QIP for PY 2015

A proposed rule, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers'' (77 FR 40952), hereinafter referred to as the CY 2013 ESRD PPS proposed rule, appeared in the **Federal Register** on July 11, 2012, with a comment period that ended on August 31, 2012. In that proposed rule, we made proposals for the ESRD QIP, including introducing and expanding measures, refining the scoring methodology, modifying the program's public reporting requirements, establishing how the ESRD QIP payment reduction applies to facilities whose ownership has changed, and initiating a data validation pilot program. We received approximately 55 public comments on these proposals from many interested parties including dialysis facilities, organizations representing dialysis facilities, nephrologists, nurses, dietitians, home health advocacy groups, pharmaceutical manufacturers, patients, advocacy groups, and the Medicare Payment Advisory Commission (MedPAC). In this section of the final rule, we provide a summary of each proposed requirement, a summary of the public comments received on these requirements, our responses to these comments, and the final policies that we will adopt for the program.

C. 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 payments to providers and suppliers to the quality of care of the 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 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 overall. 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 high-quality, safer, and more efficient care. In addition to the priorities of the National Quality Strategy, our measure development and selection activities for the ESRD QIP take into account other national priorities, such as those established by the National Priorities Partnership (*http://www.qualityforum.org/npp/*), 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 Proposals

For PY 2014, we adopted measures for the ESRD QIP that fall under three of the six VBP measure priority domains based on the National Quality Strategy:

- 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 2014, we also proposed to change the requirements for the Mineral Metabolism reporting measure.

For PY 2015, we proposed 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 should not only promote the health of ESRD patients, but also uphold the goals of the National Quality Strategy (NQS). To that end, we proposed to include 11 measures in the PY 2015 ESRD QIP. We also proposed to include these measures and measure topics in subsequent payment years. The proposed measures would evaluate facilities on the following topics that fall under the NQS clinical quality of care measure domain:

- 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 proposed to expand a previously adopted reporting measure addressing safety:

- NHSN Dialysis Event reporting measure.

We also proposed 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 we did not propose to adopt measures that address care coordination, population/community health, or efficiency and cost of care, we solicited comments in the proposed rule on potential measures that would fall into each of these areas. We discussed the following measures that are under consideration for possible adoption in subsequent payment years: 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 discussed 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 welcomed, and continue to welcome, further comments on these and other potential measures for future payment years.

3. 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?LinkIdentifier=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 took these comments into consideration when we proposed measures for the PY 2015 ESRD QIP.

4. PY 2014 Mineral Metabolism Measure

In the CY 2012 ESRD PPS final rule, we adopted the Mineral Metabolism reporting measure for the PY 2014 ESRD QIP 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 proposed 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. There are circumstances, however, that are 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 proposed to modify the PY 2014 measure to 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. We also proposed that if a patient is hospitalized or transient during a claim month, the facility could 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 stated our belief 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 requested comment on this proposal.

We also requested 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 noted that the PY 2014 attestations for both the Mineral Metabolism and ICH CAHPS measures will become available in CROWNWeb in December 2012. As noted in the CY 2012 ESRD PPS final rule, these attestations must be made before January 31, 2013 (76 FR 70269, 70271).

We received the following comments on these proposals:

Comment: Many commenters were appreciative of our willingness to revisit our requirements for the PY 2014 Mineral Metabolism attestation. Some commenters suggested that we modify the exclusion to include the following patients: (i) Beneficiaries who are regularly treated at the facility and who fit into one of these categories: (a) Beneficiaries who die within the applicable month; (b) beneficiaries that receive fewer than 7 treatments in a month; and (c) beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. Commenters stated that these exclusions are consistent with our own measures, CROWNWeb, and the URR reporting specifications; additionally, these exclusions seek to hold facilities accountable only for those beneficiaries to whom they regularly give care and for whose care they can affect. One commenter believed that home dialysis patients should only be included if they attend their monthly visit. One commenter requested that we use NQF inclusion criteria for purposes of defining the exclusions of the Mineral Metabolism reporting measure.

Response: Upon further review, we agree with commenters who believe that the exclusions should be modified. We recognize that treating a patient twice may not provide enough time to effectuate quality patient care. We agree with the commenters who suggested that an in-center hemodialysis patient should be excluded if treated by a facility fewer than seven times during the month, regardless of whether the patient is officially admitted to that facility. With seven treatments, we believe that a facility should have had adequate opportunities to draw blood necessary to measure serum calcium and phosphorus levels. We also believe that the threshold of seven will discourage unnecessary testing of in-center hemodialysis patients by facilities because they will know that, since in-center patients are typically treated three times per week, a patient must have been treated by the facility for at least two weeks to be included; thus, the facility need not feel pressure to draw blood for every in-center patient during the first few visits of the month. Based on these considerations, we will not finalize our proposal to exclude only in-center patients who have been treated fewer than two times by the facility during the claim month. Instead, we will exclude any patient who is treated by the facility fewer than seven times during the reporting month.

We do not believe that it is necessary to specifically exclude transient patients from this measure because, as noted, any patient that is treated by the facility at least seven times during the applicable reporting month is present at the facility for enough time that the facility should be held accountable for that patient. Likewise, for the same reasons mentioned above, we do not believe we need to separately exclude patients who are deceased at the end of the reporting month. Provided that the patient is treated by the facility at least seven times during that month, the facility should be able to draw blood necessary to monitor serum calcium and serum phosphorus levels even if the patient is deceased at the end of the month.

We continue to believe that facilities should be required to attest that they monitored the serum calcium and phosphorus levels of home dialysis patients irrespective of whether those patients attend a monthly appointment. We believe that it is incumbent upon a facility to make home dialysis patients aware that they must attend monthly appointments to be properly treated. In addition, since the mechanisms that cause cardiovascular and bone disease do not differ between home and in-center hemodialysis patients, we believe that the inclusion of home dialysis patients in the Mineral Metabolism reporting measure is appropriate. Therefore we will finalize our proposal that we will include any home hemodialysis patient for which a facility submits a claim with respect to the reporting month in this measure.

We also believe it is important to include transplant patients until they are officially discharged from a facility; regular monitoring can help ensure that a transplant remains effective and that the facility is continuing to provide the best care possible.

We believe it is important to monitor serum calcium and serum phosphorus levels in adult and pediatric patients alike because improper bone mineral metabolism management can lead to serious, negative outcomes, including death, in both populations. Although we are aware that specific target values for calcium and phosphorus have not been set for the pediatric population, we still believe that this measure will lead to better observation of mineral metabolism in these patients if one or both of these values are unusually high or low. Additionally, we believe that the inclusion of pediatric patients in this measure is consistent with current guidelines on the frequency of mineral

metabolism testing as reported in KDIGO guidelines chapter 3 ''Diagnosis of CKD–MBD: biochemical abnormalities.'' Thus, we believe that this measure is appropriate for both adult and pediatric patients.

Finally, we do not believe that we must use NQF inclusion criteria for this measure. Although we seek to align our measures and our selection criteria with NQF as much as possible, as we stated in the CY 2011 ESRD PPS Final Rule, we believe it is appropriate, at this time to employ a measure that has not been NQF-endorsed (76 FR 70271 through 72).

For the reasons stated above, we are finalizing that to earn 10 points on the Mineral Metabolism reporting measure, facilities must attest in CROWNWeb that they have monitored the serum calcium and serum phosphorus levels on a monthly basis for (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

Comment: Several commenters encouraged us to not adopt a percentage reporting threshold because it does not distinguish between beneficiaries legitimately excluded and those that were merely missed. Other commenters requested that we use both exclusions and a threshold, recognizing that there are some circumstances preventing blood draws that facilities cannot control; one commenter suggested a threshold of 90 percent or an allowance of two patients to ensure that small facilities are not disproportionally affected. Another commenter recommended that we use a threshold of 95 percent. Another commenter stated that requiring 98 percent reporting may make it difficult for patients to travel because dialysis facilities may encourage them otherwise to ensure compliance with the measure.

Response: We agree with the commenters who argued that, even with exclusions, there are circumstances in which facilities cannot attest to monitoring the serum calcium and serum phosphorus levels for every patient at least once per month. For example, a facility may wait until later to draw blood from a patient because it believes that patient will be treated by the facility for the entirety of the month, but learns that the patient has been hospitalized unexpectedly for all or part of the applicable month. Therefore, we believe that we should not require an attestation of 100 percent monitoring. Based on data from the CROWNWeb pilot, we believe that facilities report serum calcium and serum phosphorus levels for approximately 96 percent of their patients. Therefore, we will finalize that facilities must attest to monitoring calcium and phosphorus on a monthly basis for at least 96 percent, in total, of (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.[1]

We are concerned that small facilities may be disproportionately impacted by this 96 percent reporting threshold because, for example, a facility with 10 patients could miss monitoring for only one patient and fail to meet the threshold. We have previously stated that, to disincentivize cherry picking, we seek to ensure that one patient does not skew a facility's score. We do, however, seek to ensure the highest quality of care regardless of the facility size. Taking these two competing interests into consideration, we believe that it is appropriate to allow facilities that treat less than 11 Medicare patients during the performance period to attest that they have met the requirements for this measure if they monitored the serum calcium and serum phosphorus levels on a monthly basis for at least all but one of its (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. We believe 11 is the appropriate cut-off because, as we explain below, a case minimum of 11 allows us to include as many facilities as possible while also taking into account privacy and reliability. We believe that one is the appropriate number because, as noted above, although we seek to ensure the highest quality of care regardless of facility size, we also seek to mitigate cherry-picking by ensuring that one patient does not skew a facility's score.

Comment: Many commenters noted that it is impractical for facilities to obtain labs from other providers because other providers are not required to measure these data, do not share data with dialysis facilities, and, even if facilities could obtain these data, they could not be sure that the labs were consistent or reported under the same standards.

Response: We recognize that it may be difficult for facilities to coordinate with hospitals and other care providers in order to obtain lab values. Accordingly, we are not mandating facilities to do so. In the proposed rule (77 FR 40969), we stated that facilities may obtain lab values from other providers. This proposal was specifically designed to afford facilities more flexibility in acquiring serum calcium and phosphorus values. Facilities are highly encouraged to coordinate with other providers, but this measure does not mandate them to do so. We believe that the commenters' concerns about inconsistent lab data are mitigated by the requirement that the lab must be accredited. Facilities can use these values for the purpose of monitoring the serum calcium and phosphorus levels of their patients; additionally, collecting these data may encourage providers to engage one another about the patient's conditions and care.

Comment: Several commenters asked for clarification on the following points: (1) Are only Medicare patients included in the denominator, (2) are Medicare Railroad and Medicare Advantage (MA) patients included in the denominator, (3) could CMS give an example of an accurate application of the exclusions and/or threshold, (4) if CMS institutes a threshold, would it be rounded, (5) if a patient is excluded from the measure for attestation purposes, must his or her values still be reported in CROWNWeb, and (6) how does CMS plan on counting the number of treatments for home patients.

Response: We will address these questions in turn.

First, a facility treating at least 11 Medicare patients during the performance period is required to monitor serum calcium and serum phosphorus on a monthly basis for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. These patients include Medicare Advantage and Medicare Railroad beneficiaries.

As an example of the application of the exclusions and threshold, assume the following: (i) A facility treats 30 Medicare patients in month X; (ii) patient A is an in-center hemodialysis patient who was treated by the facility seven times during the first two weeks of month X, but the facility failed to obtain a blood draw during this period, and the patient is in the hospital for the next two weeks of month X but the facility monitors the patient's serum phosphorus and calcium by obtaining these values from the hospital; (iii) patient B and C are both in-center hemodialysis patients who were treated by the facility at least seven times during month X, but the facility fails to monitor the serum calcium and serum phosphorus of these patients during

[1] We note that the reporting requirements are somewhat different for CROWNWeb. All patients must be reported for CROWNWeb purposes, even if those patients would not be included in the measure for purposes of the ESRD QIP.

month X; (iv) patient D was visiting the facility and was treated by the facility only 4 times during month X; and (v) the facility monitors the serum calcium and serum phosphorus on a monthly basis for every other (i) in-center Medicare patient who had been treated at least seven times by the facility during month X; and (ii) home hemodialysis Medicare patient for whom the facility submitted a claim during month X. The facility is considered to have monitored the serum calcium and serum phosphorus during month X for every patient except B and C because patient D was only treated four times during the month and the facility obtained the values for patient A from another provider. The facility's monitoring rate for month X is 27/29, or 93.1 percent (rounded to 93 percent). A facility with 30 patients must attest that it monitored on a monthly basis the serum calcium and serum phosphorus for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. Therefore, this facility could not attest that it successfully monitored the serum calcium and serum phosphorus in total for at least 96 percent of its (i) in-center Medicare patients who had been treated at least 7 times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submitted a claim.[2] For purposes of this measure, facilities may round up to a whole percentage point when calculating whether they met the 96 percent threshold.

Finally, for the reasons discussed above, facilities will be required to monitor the serum calcium and serum phosphorus at least once per month for every home hemodialysis patient for whom it submits a claim regardless of the number of treatments during that month.

Comment: Many commenters requested that we revisit various aspects of the PY 2014 ESRD QIP.

Response: The PY 2014 ESRD QIP was finalized on November 1, 2011 (76 FR 70228). Although we requested comment regarding the PY 2014 Mineral Metabolism reporting measure in the proposed rule, we did not propose to reconsider any other elements of the PY 2014 program. Therefore, we consider these comments to be outside the scope of the proposed rule. We refer readers to the 2012 ESRD PPS final rule for more information on the finalized PY 2014 ESRD QIP (76 FR 70228).

For the reasons stated above, we finalize that a facility treating at least 11 Medicare patients during the performance period can attest to meeting the requirements of the PY 2014 Mineral Metabolism reporting measure if it monitors on a monthly basis the serum calcium and serum phosphorus for at least 96 percent in total of all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. We also finalize that a facility treating fewer than 11 Medicare patients during the performance period can attest to meeting the requirements of the PY 2014 Mineral Metabolism reporting measure if it monitors on a monthly basis the serum calcium and serum phosphorus levels for at least all but one of its (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

D. 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 proposed 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 (if the measure raises potential safety concerns). 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 proposed that we would take immediate action to remove the measure from the ESRD QIP and not wait for the annual rulemaking cycle. We proposed that 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.

We proposed 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

[2] Note that, for ease, we provided an example for only one month. However, to make the attestation, a facility must monitor for the duration of the performance period the serum calcium and serum phosphorus levels on a monthly basis for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

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 proposed to continue to use the rulemaking process to adopt changes to a measure that we consider to substantially change the nature of the measure. We stated our belief 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 invited 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.

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

Comment: Commenters requested clarification regarding the removal or replacement criteria for measures, specifically the criteria listed in (2) and (5) and the process for removal or replacement. Commenters suggested that CMS provide illustrative scenarios and consider convening an emergency technical expert panel (TEP) to identify and analyze removal or replacement issues. Commenters also encouraged us to add two criteria for removal or replacement: (i) Negative unintended consequences to the Medicare ESRD system as a whole; and (ii) if data for a measure cannot be collected reliably and accurately or if collecting the data places an undue burden on facilities. One commenter asked that CMS confirm that we will use rulemaking to retire or remove measures from the ESRD QIP. Finally, the commenters stated that some of the measures proposed meet the replacement and removal criteria and suggested that CMS implement only new measures that meet the proposed criteria.

Response: We thank those commenters who provided suggestions regarding the criteria and process for measure replacement or removal from the ESRD QIP. We concur with those commenters who argue in favor of implementing measures that meet the proposed criteria. We do not believe that an emergency technical expert panel (TEP) is an appropriate part of the removal process, as we typically convene TEPs in order to obtain expert stakeholder input as part of the measure development process. These TEPs are convened as needed during the measure maintenance cycle and can provide any necessary comment regarding the clinical appropriateness of implemented measures. Emergency TEPs would also be difficult and expensive to employ quickly, such as in response to public comments in support of measure removal. We will consider the inclusion of additional removal criteria such as those suggested by commenters through future rulemaking, but will finalize the proposed criteria to remain consistent with similar criteria implemented for other quality reporting and pay-for-performance programs, such as the Hospital Inpatient Quality Reporting Program and Hospital Outpatient Quality Reporting Program. The second criterion we proposed, the availability of alternative measures with a stronger relationship to patient outcomes, is intended to allow us to implement new measures in the ESRD QIP that have a stronger association with relevant health outcomes. Such measures may better assess the quality of care provided by dialysis facilities and in such cases, we believe it would be appropriate to reflect this in the ESRD QIP. Our use of the fifth criterion is consistent with this principal, and would be applied in those circumstances where we believe existing measures are not as temporally proximal to health outcomes of interest as are newly available measures. We believe that in such cases, it would be appropriate to remove these measures, rather than simply increase the volume of quality measures for which dialysis facilities are responsible under the ESRD QIP.

Except for measures that raise potential safety concerns, any decisions to remove or replace measures under the ESRD QIP will be made through the rulemaking process. Each year, we will assess whether any measures should be removed or replaced under the ESRD QIP, and we will make appropriate proposals during the rulemaking cycle. Stakeholders will then have the opportunity to provide feedback regarding the proposed removal or replacement of these measures, and the rationale behind our proposals. Any measure removal will then be finalized as part of the ESRD PPS final rule.

We take the suggestion that we implement only new measures that meet the proposed criteria to mean that we should implement only measures that do not meet the proposed removal criteria. We recognize the potential value in taking these criteria into consideration for measure implementation, and believe we do so to the extent practicable. However, we believe that we must take into consideration additional criteria, such as statutory requirements governing the ESRD QIP and emergent public health and safety issues, when determining what measures to propose and finalize for the program. In some cases, it is possible that these issues will take precedence over the criteria proposed for measure removal.

Comment: Several commenters urged us to adopt measure specifications and data definitions that are clear, modifying this information through rulemaking alone. Commenters argued that it is only appropriate to use sub-regulatory processes to aid facilities in interpreting the specifications and definitions, and suggested that we develop a regular and transparent process for collecting and responding to these questions, ideally on a quarterly basis with a schedule set forth in rules.

Response: We thank those commenters who provided feedback to our proposal to update NQF-endorsed measures using a subregulatory process. We concur that measure specifications and data definitions should be clear. However, we believe that using a subregulatory process to make certain types of updates to measures is appropriate. The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate non-substantive updates made by the NQF to the measure specifications we have adopted for the ESRD QIP so that these measures remain up-to-date and clinically relevant. We also recognize that some changes the NQF might make to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process. Therefore, we are finalizing a policy under which we will use a subregulatory process to make non-substantive updates to NQF-endorsed measures used for the ESRD QIP. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis. Examples of non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges,

and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures used in the Hospital IQR Program). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the ESRD QIP. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in the acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus non-substantive would apply to all ESRD QIP measures. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We aim to be as transparent as possible in implementing the ESRD QIP. Occasionally, questions arise related to measures that have been adopted. We plan to publish these questions and answers on a publicly available Web site. We will consider standardizing a timeline for submission of and answers to these questions as the program evolves.

For the reasons discussed above, we are finalizing our proposal regarding continued use of measures in the ESRD QIP unless we remove or replace them. We are also adopting a policy under which we will use a subregulatory process to make non-substantive updates to measures, and will use the rulemaking process to make substantive updates to measures.

1. PY 2014 Measures Continuing for PY 2015 and Subsequent PYs

We previously finalized six measures including one measure with two measure sub-components (see Table 2 below) for the PY 2014 ESRD QIP (76 FR 70228). We proposed to continue to use five of these measures for the PY 2015 ESRD QIP; however, we also proposed 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 proposed to remove the PY 2014 URR Dialysis Adequacy measure. In addition, we proposed to add three new measures of dialysis adequacy, an anemia management reporting measure, and a hypercalcemia clinical measure (Table 3).

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. NQF has since withdrawn its endorsement of the calcium measure.

* 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.

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.

We proposed to continue using two measures and one measure topic adopted in PY 2014 for the PY 2015 ESRD QIP and subsequent payment years of the program. For the reasons stated in the CY 2012 ESRD PPS final rule (76 FR 70262, 70264 through 65, 70269), we proposed 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/Anemia Management-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 requested comment on the proposed continuation of these measures.

The comments we received on these proposals and our responses are set forth below. We will separately discuss each of the measures and the comments received on these measures.

a. Hemoglobin Greater Than 12 g/dL

Comment: Many commenters strongly supported the continuation of this measure, specifically because proper anemia management can prevent patients from developing serious, life threatening conditions. Other commenters, however, asked that we consider removing the measure or reducing its weight since high hemoglobin and ESA overuse no longer pose a realistic concern because of the economic incentives of the ESRD PPS payment bundle and the new clinical evidence and FDA-approved label for ESAs (*http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm).* One commenter noted that the TREAT study and its own research indicate that large ESA doses, rather than high hemoglobin levels, result in adverse effects. Finally, one commenter believes that the Hemoglobin Greater Than 12 g/dL measure leads to confusion because physicians begin increasing ESA dosage only after hemoglobin levels have fallen far below 12 g/dL, resulting in an increase in patients with low hemoglobin levels. The same commenter noted that it is difficult to incentivize clinics to provide proper ESA dosage with the ESRD PPS payment bundle and the Hemoglobin Greater than 12 g/dL measure combined. Finally, one commenter urged us to individualize anemia management measures.

Response: We appreciate feedback relating to the use of the Hemoglobin Greater Than 12 g/dL measure in the ESRD QIP. We recognize that changes in the incentive structure for ESA therapy may have consequences for ESA utilization. We feel, however, that because of the negative clinical outcomes that can result from high hemoglobin levels in the ESRD population, this measure is still important in ensuring that facilities provide quality care.

We also appreciate the need to consider dosage and clinical practice when ascertaining the potential adverse effects of ESA therapy. We have begun to develop additional anemia management measures that account for ESA dose. These measures are focused on utilization of ESAs and transfusion avoidance to further incentivize proper care. We intend to propose to adopt one or more of these measures for the ESRD QIP in future rulemaking.

Finally, we agree that it is important to individualize care for each beneficiary. We believe that the Hemoglobin Greater than 12 g/dL measure both allows facilities discretion to properly manage hemoglobin levels in each patient and prevents adverse patient outcomes associated with hemoglobin levels that are too high. However, we recognize that greater individualization may be possible and are currently working to develop additional anemia management measures that will enhance this aspect of the ESRD QIP.

Comment: Several commenters supported the measure, generally, but asked us to make refinements. One commenter suggested that we measure hemoglobin on a three or 6-month rolling basis rather than monthly because monthly measurement does not provide a comprehensive assessment of the care patients are receiving; studies show that although hemoglobin levels can fluctuate greatly within short periods of time, the mean hemoglobin level can remain in the measure target range. Another commenter stated that, as the measure is currently conceived, facilities cannot act on its results. Because it takes time for hemoglobin levels to change, one commenter recommended excluding patients who have been on ESA therapy for one month or less and patients whose ESA therapy was promptly discontinued once the facility became aware that their hemoglobin levels were over 12 g/dL. Finally, one commenter noted that hemoglobin levels at high altitude facilities are more likely to be greater than 12 g/dL.

Response: We thank the commenters who made suggestions regarding the refinement of the Hemoglobin Greater Than 12 g/dL measure. Addressing the concern commenters raised with the high degree of variability in hemoglobin from month to month, the measure rate is calculated using the average hemoglobin of a patient over 4–12 months. For example, if a patient is treated for 4 months, then we use the average of the 4-month period to calculate the measure rate. If a patient is treated for 5 months, we use the average from that 5-month period and so on. Relevant to concerns raised about the exclusion of patients who have just begun ESA therapy, the measure currently excludes new patients (less than 90 days since ESRD onset), and excludes claims for which there is no evidence of ESA use. We believe these exclusions address the commenters' concerns. Regarding the comment that hemoglobin levels at high altitude facilities are more likely to reach the measure threshold, we do not currently employ risk adjustment for the measure for this or other environmental factors that could conceivably have similar impacts. However, we plan to conduct monitoring and surveillance of our quality measures for issues such as geographical variation.

Comment: One commenter argued that using patients' yearly averages for measures fails to test the actionability of the measures because it is difficult to identify areas of improvement until the end of the year. Instead, the commenter suggests ''per-facility averaging,''—averaging of end-of-month hemoglobin results for each facility's patients, each month, then averaging up to 12 of those facility monthly averages, which this commenter argued allows facilities to know their year-to-date numerators and denominators, fostering ongoing quality incentive and process improvement.

Response: We appreciate the commenter's suggestion regarding per-facility averaging and all feedback to improve the usefulness of our quality measures to facilities. However, we believe that averaging hemoglobin over multiple patients in a facility would be inconsistent with medical guidance, which deals with patient specific situations. We believe that facilities should strive to provide the best care to each patient treated by the facility.

Comment: One commenter requested confirmation that patients who are not

on ESA therapy are not included in the Hemoglobin Greater than 12 g/dL measure.

Response: The measure rate is calculated using claims that include a hemoglobin level and ESA dosing information.

Comment: Several commenters requested that we include a measure in the ESRD QIP that establishes a floor for hemoglobin, specifically noting that, because of the bundle, there may be a perceived financial incentive to underutilize ESAs. They argued that studies have shown that as hemoglobin drops below 10, mortality and hospitalization increase, and that hemoglobin levels affect a patient's quality of life (both empirically and anecdotally). Some commenters stated that we should reinstate the Hemoglobin Greater than 10 g/dL measure that we used in the PY 2012 ESRD QIP, arguing that the measure is reliable and is consistent with the FDA-approved labeling which recognizes the importance of transfusion avoidance and recommends that initiation of ESA therapy be considered when the hemoglobin level falls below 10 g/dL. One commenter argued that patients should be allowed to make decisions about their quality of life and safety, even if that means keeping the hemoglobin level higher than recommended. Other commenters noted that patients with hemoglobin less than 10 g/dL are increasing, as are the rate of transfusions, and increased transfusions can decrease the chances of a successful transplant; in turn, failed transfusions can increase the cost of care since patients with transplants cost less than those on dialysis. One commenter stated that we should specifically consider reinstituting a hemoglobin floor if the United States Renal Data Service information shows that transfusion rates have risen significantly. Other commenters suggested that even if we do not adopt a measure for low hemoglobin, we report hemoglobin levels, transfusion rates, and ESA dosage on DFC and include the Hemoglobin Less than 10 g/dL measure on DFC. Finally, other commenters urged us to continue to monitor and support metrics such as transfusions, quality of life, reactivity to antibodies preventing transfusions, and underutilization of ESAs.

Response: We thank the commenters for bringing to us their concerns about the ESRD PPS payment bundle potentially increasing the risk for underutilization of ESA therapy. As noted in the CY 2012 ESRD PPS final rule (76 FR 70257), we could not at the time identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs, and the state of evidence supporting such a lower bound remains weak. For these reasons, we believe that the rationale for removing the Hemoglobin Less Than 10 g/dL measure from the ESRD QIP measure set remains valid. However, we recognize that the potential for ESA underutilization is an important issue. As noted in the CY 2012 ESRD PPS final rule (76 FR 70257), we will continue to monitor the Medicare ESRD population for evidence of underutilization of ESAs, a rise in blood transfusions, and the replacement of ESA therapy with transfusions. Although we are no longer including the Hemoglobin Less than 10 g/dL measure in the ESRD QIP (and will no longer be publicly reporting it on DFC beginning January 2013), the results will be available via a downloadable file for facilities to provide for continued monitoring of the measure. Finally, we continue to work with stakeholders through a consensus-based measure development process to produce measures capable of addressing ESA underutilization and blood transfusions, while remaining consistent with the existing relevant guidelines and evidence base.

We also appreciate comments encouraging us to move toward implementing quality of life and other patient-centered measures that address anemia management. These measurement domains are important to us and we plan to develop appropriate measures to be implemented in the ESRD QIP during future rulemaking.

For the reasons stated above, we will continue to use the Hemoglobin Greater than 12 g/dL measure for PY 2015 and future years of the ESRD QIP. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-HGB-2015-FR.pdf*

b. Vascular Access Type (VAT) Measure Topic

Comment: Many commenters strongly supported our continued inclusion of the VAT measure topic in the PY 2015 ESRD QIP. Many commenters, however, also expressed concern that the composite measure over-emphasizes fistulae, underemphasizes grafts, and, therefore, promotes inappropriate care in some cases. Commenters noted that fistulae are not suitable for some patients, fistulae take time to mature, and grafts are sometimes the most clinically appropriate. Several commenters asked us to decrease the emphasis on fistulae by developing a graft measure and, in the meantime, weight the catheter measure at ⅔ of the VAT measure topic and the fistula measure at ⅓ of the VAT measure topic. Other commenters urged us to take a ''fistula first, catheter last'' approach that would award some points for patients with grafts. Commenters were also concerned that the fistula standards are too stringent and could cause unintended consequences such as ''cherry-picking'' patients who are not eligible for a fistula. Commenters suggested that we exclude or allow doctors to exclude certain patients from the measure's denominator providing for more individualized care, noting that studies show that facilities are unlikely to ''game'' such an exception.

Response: As discussed in the CY 2011 ESRD PPS Final Rule, we continue to believe that the VAT measure topic and its respective weights incentivize the best care for ESRD beneficiaries (76 FR 70265, 70275). Catheters are undesirable due to their high rate of complications, such as infections, and we discourage their use through the catheter measure. We believe that the preferred type of vascular access is an AV fistula due to lower rates of complications, which we promote through the fistula measure. Although grafts do decrease the risk of infections and complications when compared to catheters, grafts do not decrease these risks as much as fistulae. We, therefore, do not believe that grafts are either beneficial enough to be specifically rewarded or harmful enough to be specifically penalized. Furthermore, we do not believe it is in the best interest of patients to weight the fistula measure more than the catheter measure because our primary goal is to promote fistula use; we believe that both measures are equally important in promoting the best clinical practices with respect to VAT.

We recognize that the catheter measure could incentivize ''cherry-picking'' of patients, leading to access to care issues for patients with catheters. We are actively monitoring access to care and other potential issues associated with ''cherry-picking,'' and it is our intent to engage the community as we monitor these issues.

Comment: One commenter encouraged us to promote fistulae in pediatric patients as well as adults.

Response: We thank the commenter who encouraged the promotion of fistulae use in pediatric patients. The NQF-endorsed fistula measure excluded pediatric patients. Children on chronic dialysis have a fundamentally different psychosocial profile than adults. Fistula use, with its attendant frequent painful needle sticks are less commonly used in

children than adults. In addition, there are technical issues that make fistula creation more difficult in children. We will continue to investigate whether there are measures in existence or that could be developed for the purpose of appropriately addressing vascular access among pediatric patients and may propose to adopt one or more of these measures in future rulemaking.

For the reasons listed above, we will continue to use the VAT measure topic for PY 2015 and future years of the ESRD QIP. The technical specifications for the finalized measures in this measure topic can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Catheter-2015-FR.pdf* and *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Fistula-2015-FR.pdf*.

c. In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)

Comment: Many commenters supported the measure in its entirety. Many commenters supported monitoring patients' experiences, but believe the ICH CAHPS survey, with 57 questions, is too burdensome and lengthy for beneficiaries to complete. These commenters requested that we minimize this burden and suggested that the ICH CAHPS survey be parsed into three parts, with each patient receiving one of these parts and a group of core questions. Commenters also suggested that CMS allow facilities to give patients the survey and allow patients to return surveys via a ''drop-box'' at the facility or by mail to the third-party administrator; commenters believe this approach will improve the response rate as patients are less likely to ignore the survey and one commenter noted that, without such an approach, the experiences of homeless patients will not be recorded.

Response: As we noted in the 2012 ESRD PPS Final Rule, we continue to believe that assessing the experiences of patients is vital to quality care (76 FR 70269 through 70). Patient surveys can, and should, draw a facility's attention to issues that can only be raised by those receiving care. Although commenters may consider the survey to be burdensome to patients, the CAHPS tool went through extensive testing during development including focus groups and one-on-one patient sessions which assessed this burden and created specifications accordingly. Furthermore, we believe that concerns about patient burden can be at least partially mitigated without decreasing the number of questions on the survey or how the survey is administered. For example, as the specifications indicate,[3] patients may take a break during the administration of the survey or take the survey in multiple sittings if they feel that the number of questions is too great to answer at one time. Finally, we do not believe that facilities should be permitted to give patients the survey at the facility and allow patients to submit these surveys via a ''drop box'' or any other method. We believe that patients are much more likely to truthfully respond to the surveys if they are perceived to be in no way connected to the facility; providing the surveys at the facility and allowing patients to return them by any means may lead to the patient to believe that his or her answers can be traced to him or her, and this thought may bias the surveys. Thus, we believe that this survey as it is currently specified is the best method available at this time to measure patient experience.

We thank commenters for bringing to our attention the hardships homeless patients may face in accessing the survey. Although we believe that the survey most accurately represents patients' experiences of care at this time, we will continue to evaluate how we can accurately capture all patient populations, including the homeless.

Comment: One commenter suggested that CMS define a threshold for patients at which a facility would not need to administer the survey.

Response: We recognize that there are many small dialysis facilities for which hiring a third-party administrator to fulfill the ICH CAHPS survey requirements is impractical or prohibitively costly. Therefore, beginning PY 2015, we will exempt any facilities that have treated (whether that patient was visiting the facility or otherwise) 10 patients during the performance period or fewer that are qualified to take the survey. Patients are qualified to take the survey if they are adult, in-center hemodialysis patients. We believe that 11 patients (regardless of the number of times these patients were treated) is an appropriate threshold for applying the measure because it is consistent with the policy that we are finalizing for all measures in which we recognize that facilities with 10 or fewer patients in the denominator of a measure should be exempt from that measure. Although we are not requiring facilities to submit actual ICH CAHPS data at this time, we are considering collecting it in the future. We also intend to use the information collected from reporting measures for purposes of scoring clinical measures based on the same data in subsequent payment years and want to adopt a minimum reporting threshold that we can apply to all measures. For these reasons, we are finalizing that facilities must attest to administering the ICH CAHPS survey if they treat during the performance period at least 11 adult, in-center hemodialysis patients. We also finalize that we will consider a facility to have met the 11 patient threshold unless it affirmatively attests in CROWNWeb that it treated 10 or fewer in-center, adult hemodialysis patients during the performance period. If a facility does not affirmatively attest to having treated 10 or fewer in-center, adult hemodialysis patients during the performance period, we will score it on this measure. Additionally, we are applying this policy to the NHSN Dialysis Event reporting measure, discussed below, because we intend to use the data from that measure to adopt a clinical measure in subsequent payment years. Unlike the ICH CAHPS measure, the NHSN measure applies to both adult and pediatric in-center hemodialysis patients. Therefore, we finalize that a facility must treat at least 11 in-center hemodialysis patients (whether adult or pediatric) during the performance period to be scored on the NHSN Dialysis Event reporting measure. To be considered a facility which has treated 10 or fewer in-center hemodialysis patients (whether adult or pediatric) during the performance period, the facility must make an attestation in CROWNWeb to this effect. If a facility does not make this attestation, we will score it on this measure.

Comment: One commenter expressed concern that patients often do not answer the surveys honestly for fear of retaliation and the validity of the survey should be questioned.

Response: We recognize that patients may feel pressure to answer questions in the survey favorably. We believe, however, this concern is mitigated because under the measure specifications, a third-party must administer the survey. These third-party administrators are not associated with facilities and do not report patient-specific data to the facilities. Therefore, the facility would have no knowledge of patient's answers.

Comment: Several commenters expressed concern about CROWNWeb's ability to provide an adequate reporting system for this measure.

Response: CROWNWeb was launched nationally in June of 2012, and we recognize that some facilities may still be familiarizing themselves with the

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

new system. As discussed, facilities are not required to report ICH CAHPS data to CROWNWeb or any other system; they are only required to make an attestation that they administered the surveys according to the specifications. The attestations for the ICH CAHPS measure for PY 2015 are not due until the end of January 2014. We have no reason to believe that the attestation function will not be ready by the end of January 2013, the PY 2014 deadline. We believe that by this time, facilities' transition period should have ended, and facilities will be able to successfully submit their attestations. Therefore, because the attestations should be ready in CROWNWeb by January 2013 for the PY 2014 ESRD QIP, they should also be available in CROWNWeb for the PY 2015 program.

Comment: Many commenters noted that the ICH CAHPS measure's third-party administration requirement imposes significant costs on facilities and that facilities should be allowed to include these costs in their cost reports.

Response: Facilities may report allowable operating expenses in their Medicare cost reports. We believe that it is consistent with this payment policy for facilities to include the ICH CAHPS costs on their cost reports because they are allowable operating expenses.

Comment: Several commenters urged us to adopt the ICH CAHPS measure as an outcome measure rather than a reporting measure. One commenter believes that, if we cannot implement the measure as an outcome measure for PY 2015, we should do the following in order to facilitate our adoption of an ICH CAHPS outcome measure as soon as possible: (i) Develop a standardized protocol and quality assurance guidelines for survey administration that are more detailed than the AHRQ requirements; (ii) contract with an experienced organization that can provide oversight for the ICH CAHPS program; and (iii) approve survey vendors. Another commenter argued that the survey should be limited to questions about the facility rather than the physician.

Response: Currently, we are not able to include the ICH CAHPS survey as an outcome measure because we do not possess data from which we can set performance standards. We believe that it is important to adopt an outcome-based measure as soon as possible, and we are diligently working to ensure that it is a part of the program as soon as possible. To that end, we will be working to set up a survey vendor approval program; we believe that the specifications are appropriately detailed, but we will continue to assess whether they should be refined before we propose to adopt this survey as an outcome-based measure. Regarding the survey questions, the majority of the survey is limited to questions about the facility. Only seven of the 58 core questions are about the patients' nephrologists. There are 22 questions about the staff at the facility (not including the doctor), three about the center, and nine about treatment; the remaining questions capture demographic information. The continuous care received by dialysis patients makes them keenly aware of their primary doctors' involvement. To the extent that the questions are about the physician, we believe that they are appropriate because they are targeted at the nephrologist who is most involved in the patient's dialysis care.

Comment: Commenters requested that we develop new measures of patient's experiences. One commenter argued that a measure should be developed that evaluates a patient's experience during each dialysis session because each experience can vary, and further argued that this type of evaluation would allow facilities to better assess why patients do not stay for entire treatments or miss treatments. Many commenters requested that we develop a CAHPS measure for home hemodialysis and peritoneal dialysis patients. Commenters also suggested that we make the responses to the surveys public.

Response: We remain dedicated to developing and adopting measures of patient experiences of care in the ESRD QIP, specifically those patients who are treated at home. At this time we cannot operationally make the responses to the ICH CAHPS survey public because, as noted above, we do not possess the data; however, we will consider making these surveys public in future years if facilities are required to submit their ICH CAHPS data to CMS.

For the reasons discussed above, we are finalizing the ICH CAHPS reporting measure for use in the PY 2015 ESRD QIP and future years of the program. We are also finalizing that the measure applies to facilities that treat a minimum of 11 in-center, adult hemodialysis patients during the performance period. We will consider a facility to have met the 11 in-center, adult hemodialysis patient threshold unless it affirmatively attests in CROWNWeb to having treated 10 or fewer adult, in-center hemodialysis patients during the performance period. If a facility does not make the attestation, we will score it accordingly. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/ICHCAHPS-2015-FR.pdf.*

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

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. Therefore, we proposed 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 subsequent payment years of the ESRD QIP.

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

Hospital Acquired Infections (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 HAIs outcome, HHS agencies, including CMS and the Centers for Disease Control and Prevention (CDC) are working together 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 proposed 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 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 proposed 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 proposed 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 proposed that the performance period for the PY 2015 ESRD QIP would be CY 2013. We proposed that facilities must report dialysis event data monthly to the NHSN for this measure. We also proposed that facilities be granted a ''grace period'' of one month to report these data. 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 patients in-center. For purposes of the NHSN Dialysis Event reporting measure, we determine whether a facility treats patients in-center 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 proposed 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 proposed 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 NHSN Dialysis Event reporting measure that we proposed 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 proposed to retain the measure and expand the reporting period for PY 2015 and future payment years of the program. We requested comment on this proposal, and noted that the technical specifications for this measure are located at *http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNDialysisReporting-2015-NPRM.pdf.*

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

Comment: Many commenters supported the expansion of the NHSN Dialysis Event reporting measure, stating that monitoring the number of patients with access-related infections for an entire year will help the community better understand ways to reduce infection rates. Some commenters expressed concern with certain aspects of the measure. Several commenters expressed their concern about the burden of this measure, specifically highlighting the burden of manual data-entry and the staff hours demanded for this entry and oversight; one commenter noted that NQF criteria related to feasibility favor electronic collection and data collected during the course of care. Commenters argued further that manual data entry affects reliability, further affecting the baseline calculations for future measures. Many commenters suggested a batch download system. Some commenters noted that the CDC intends to make a Clinical Document Architecture (CDA) system available for batch entries, but expressed concern that the CDC CDA system will be available for individual facilities only (rather than for an entire corporation); others stated that they did not believe the CDA system will be ready for data entry by the end of CY 2012. Commenters also stated that the NHSN system is yet another Web site to which ESRD facilities must report, reducing time staff can spend caring for patients. Finally, some commenters support the expansion of the measure, but only if the required monthly reporting is at the facility rather than the patient level.

Response: We do not believe that this measure is unnecessarily burdensome. Monitoring vascular access infections following uniform definitions and utilizing the comparative rate data to evaluate and improve performance is part of providing good patient care. Although enrollment and training can be time-consuming, approximately 90 percent of all hemodialysis centers have already enrolled in NHSN. Furthermore, we believe that any burden a facility may face is outweighed by the importance of this measure since infections can often lead to serious complications, including death. Further to help decrease the burden, the CDC began allowing facilities to report to NHSN through imported CDA files on September 14, 2012. Using this function, any individual with Administrative Rights for a facility will be able to import that facility's specific CDA files that meet NHSN's formatting requirements. This includes large dialysis organizations that have given Administrative Rights to a single person for purposes of the entire (or some portion of) the organization. However, at this time each facility's files must be submitted separately. Because we are aware that large dialysis organizations (as well as many other dialysis companies) have given Administrative Rights to a single representative of the organization, we recognize that they will eventually be able to submit CDA data for a number of individual facilities, from a single central location, all through a single batch submission process. This batch data submission process is expected to be available in August 2013. Finally, the monthly reporting required by the NHSN is at the facility level. Facility-level review of the data in NHSN is expected, whether the data are reported by facility staff or by a corporate representative. We believe that facilities have a direct role in preventing infections by collecting the NHSN Dialysis Event data, actively assessing their data, and regularly feeding back this information to clinical staff to improve practices.

Comment: One commenter argued that the NHSN Dialysis Event reporting measure will not improve care because the system is not efficient and is not correlated to CROWNWeb. Many commenters urged us to synchronize NHSN and CROWNWeb data

requirements. Commenters also requested that CMS continue to use the same reporting schedule for PY 2015 as it will for PY 2014, allowing facilities to report quarterly with all data being required by March 31, 2014. Commenters noted that quarterly reporting is important because this timeframe will allow facilities ample time to submit data correctly, stating that some infections take more than a month to identify and capture. One commenter recommended that we modify the requirements of this provision to allow a facility to report a full 12 months of data by January 31, 2014. Other commenters urged us to ensure that the NHSN Dialysis Event reporting measure allows the NHSN system to remain a surveillance system.

Response: We disagree with the comment that the NHSN Dialysis Event reporting measure will not improve care. Requiring facilities to report through the NHSN will allow us to monitor and better understand the causes of infections. Additionally, as we stated in the proposed rule (77 FR 40971 through 72), we intend to use the information gathered by this reporting measure to adopt a clinical measure in future years; this measure will encourage facilities to decrease the circumstances which lead to infections. Although we intend to use data from the NHSN to adopt a clinical measure, we will work with the CDC to ensure that the ESRD QIP does not unnecessarily limit the surveillance purposes of the NHSN system.

Commenters are correct in that the NHSN Dialysis Event reporting measure data is not correlated to CROWNWeb. We recognize that CROWNWeb and the NHSN are two distinct systems which require reporting. At this time, we do not require infection reporting in CROWNWeb. We believe that it is more beneficial for both facilities and CMS to require infection reporting through the NHSN. The NHSN is a well-established 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; it is used by many other types of providers to report infections. We believe that NHSN's history and wide-spread surveillance make it the best mode of reporting dialysis events at this time.

We do not agree with commenters' suggestions to extend the reporting timeline for the PY 2015 NHSN Dialysis Event reporting measure. The NHSN system recommends monthly reporting, and we believe it is important to adhere to the NHSN requirements as much as possible. However, to maximize data completeness and accuracy, facilities will be allowed to add to and modify the reported data until the performance period reporting deadline. Data for the entire performance period must be reported by April 15, 2014. We chose April 15, 2014 because this date allows facilities a full quarter after the performance period to review their data for completeness and accuracy. After consulting with the CDC, we believe that such a timeframe will maximize the reliability of the data and allow facilities to report any infections that developed during the performance period but that are identified after the performance period has ended.

Comment: One commenter is concerned with the proposed expansion of this measure if NHSN data is not validated or audited for completeness. This commenter expressed specific concern that there could be surveillance bias in interpreting submitted data.

Response: We recognize that bias exists because some facilities may be more likely to identify and report dialysis events than others. Varying degrees of completeness of the data could lead to inaccurate comparisons between facilities. The CDC and CMS are beginning to formulate a strategy to validate data for purposes of the ESRD QIP; we are committed to rigorous validation to identify inaccuracies and ensure reliability of the data.

Comment: One commenter suggested that CDC standardize and clarify data definitions to ensure ''apples-to-apples'' comparisons and allow corporate oversight of data entered into the system for verification and reliability purposes. Another commenter stated that it does not support the adoption of a future NHSN Dialysis Event clinical measure because facility policies and procedures and physician practices vary widely with respect to the circumstances under which blood cultures are obtained and results are reported; this commenter requested that reporting be standardized before the measure is adopted.

Response: The CDC develops protocols, definitions, and criteria for the purposes of standardizing reporting, and expects that all NHSN users strictly adhere to the protocol guidance for data that are reported into NHSN. The dialysis event surveillance reporting protocol is available on CDC's NHSN Web site and includes data definitions (*http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf*). Users may contact the NHSN help desk (*NHSN@cdc.gov*) for clarifications to these data definitions. We will continue to work with the CDC to monitor these concerns while we consider adopting a measure based on NHSN data for future years of the program.

Comment: One commenter requested clarification regarding whether facilities are required to report infections occurring in the dialysis unit only, exempting the facilities for infections that result from care in other environments.

Response: The measure specifications, which are available at (*http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf*), provide that positive blood cultures occurring within one calendar day after a hospital admission must also be reported. For further clarification on reportable event definitions and considerations surrounding attribution, please contact the NHSN help desk (*NHSN@cdc.gov*).

Comment: One commenter asked us to confirm that, as long as the census data is reported every month, the facility may attest to having met the requirements for the NHSN measure.

Response: For the reasons discussed above, we finalize that a facility may attest for purposes of being exempt from reporting for the NHSN dialysis event measure if it treats fewer than 11 in-center hemodialysis patients during the performance period. If a facility treats 11 or more in-center hemodialysis patients, we will score the facility based on whether it reported data to the NHSN.

Comment: One commenter urged us to develop a measure which targets the cause of the infections. Another commenter suggested that CMS consider adding NHSN dialysis specific indicators, perhaps in stages, such as local access site infection, access-related bloodstream infection, and vascular access infection to the NHSN surveillance data.

Response: We thank commenters for these suggestions. We acknowledge that preventing and monitoring infections is crucial to patient care. We will continue to work with the dialysis community to include robust infection measures in the ESRD QIP.

Comment: Many commenters support our proposed transition of the NHSN Dialysis Event reporting measure to a clinical measure using the NQF-endorsed measure #1460. Some commenters urged us to adopt the clinical measure in PY 2015. Other commenters, however, suggested that we allow sufficient time to ensure that NHSN data can be reported without additional burden to providers. One commenter suggested that, once the measure is adopted as a clinical measure, we interpret the rate of positive blood cultures against the

facility's rate of empiric antibiotic treatment, since some facilities treat empirically rather than through taking blood cultures.

Response: We thank commenters for supporting our proposal to adopt the NQF-endorsed infection measure for future years of the program. We are unable to adopt the NQF-endorsed clinical measure for PY 2015 because we have not yet gathered data on which we can base performance standards. For purposes of the ESRD QIP, facilities began reporting to the NHSN during 2012; to receive full points on the measure for PY 2014, facilities need only to report three months of data. We do not believe it is appropriate to base performance standards on three months of data for purposes of an infection measure because infections can vary by season. We believe that using a 12-month period for setting these standards will prove more accurate. Because we are requiring 12 months of data for the PY 2015 ESRD QIP, we believe we can use this information to adopt standards for a clinical measure in future years. Additionally, we agree with the commenters who believe that it may be necessary for facilities to become more familiar with the NHSN system before we adopt a clinical measure.

We thank the commenter who suggested that we interpret the rate of positive blood cultures against the facility's rate of empiric antibiotic treatments to account for facilities that might treat patients empirically for infection without drawing cultures. The NHSN collects information on IV antimicrobial starts, in part, for this reason. Providers are expected to adhere to standards of clinical practice, which include obtaining blood cultures prior to antibiotic administration for suspected bloodstream infections.

Comment: One commenter stated its support for the adoption of an MRSA standardized infection rate clinical measure.

Response: We thank the commenter for providing this suggestion and will take it into consideration in future measure development and rulemaking.

For the reasons stated above, we finalize the NHSN Dialysis Event reporting measure as proposed except for the following; a facility must treat at least 11 in-center hemodialysis patients (both adult and pediatric) during the performance period to be scored on the NHSN Dialysis Event reporting measure, as noted above. To be considered a facility which has treated 10 or fewer in-center hemodialysis patients during the performance period, the facility must make an attestation in CROWNWeb to this effect. If a facility does not make this attestation, we will score it accordingly. Additionally, we recommend that facilities report monthly to the NHSN. Data for the entire performance period must be reported by April 15, 2014. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNDialysisReporting-2015-FR.pdf.*

b. 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 for us 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 proposed 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 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 proposed 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 noted, 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 did not propose 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, we proposed that 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 laboratory 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 proposed 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 stated our belief that 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 requested comment on these proposals. We also requested 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 proposed 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 stated our belief that 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; we noted that 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 proposed 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 noted 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 requested comment on these proposals to expand the Mineral Metabolism reporting measure.

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

Comment: Many commenters generally supported this measure, but requested that we make modifications to our proposed exclusions. These commenters suggested that we exclude, for all of the reporting measures, the following patients: (i) Beneficiaries who are regularly treated at the facility and who fit into one of these categories: (a) Beneficiaries who die within the applicable month; (b) beneficiaries that receive fewer than 7 treatments in a month; and (c) beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. Commenters stated that these exclusions are consistent with our own measures reported on DFC. Additionally, commenters stated that these exclusions seek to hold facilities accountable only for those beneficiaries to whom they regularly give care and for whose care they can affect. Another commenter, however, stated that we should not implement other commenters' suggestions that we exclude beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; this commenter stated that it is the responsibility of the facilities to educate patients on the importance of making and keeping appointments. Additionally the commenter argued that ''good faith'' is too vague; commenter requested that, if we did adopt this exclusion, we clearly define a ''good faith effort.''

Response: Upon further review, we agree with commenters who believe that the exclusions should be modified. We recognize that treating a patient twice may not provide enough time to effectuate quality patient care. We agree with the commenters who suggested that an in-center hemodialysis patient should be excluded if treated by a facility fewer than seven times during the month, regardless of whether the patient is officially admitted to that facility. With seven treatments, we believe that a facility should have had adequate opportunities to draw blood necessary to report serum calcium and phosphorus levels. We also believe that the threshold of seven will discourage unnecessary testing of in-center hemodialysis patients by facilities because they will know that, since in-center patients are typically treated three times per week, a patient must have been treated by the facility for at least two weeks to be included; thus, the facility need not feel pressure to draw blood for every patient for the first few visits of the month. Based on these considerations, we will not finalize our proposal to exclude only in-center patients who have been treated fewer than two times by the facility during the claim month. Instead, we will exclude any in-center patient who is treated by the facility fewer than seven times during the reporting month.

We do not believe that it is necessary to specifically exclude transient patients from this measure because, as noted, any patient that is treated by the facility at least seven times during the applicable reporting month is present at the facility for enough time that the facility should be held accountable for that patient. Likewise, for the same reasons mentioned above, we do not believe we need to separately exclude patients who are deceased at the end of the reporting month. Provided that the patient is treated by the facility at least seven times during that month, the facility should be able to draw blood necessary to report serum calcium and serum phosphorus levels even if that patient is deceased at the end of the month.

We continue to believe that facilities should be required to report the serum calcium and phosphorus levels of home dialysis patients irrespective of whether those patients attend a monthly appointment. We believe that it is incumbent upon a facility to make home dialysis patients aware that they must attend monthly appointments to be properly treated. In addition, since the mechanisms that cause cardiovascular and bone disease do not differ between home and in-center hemodialysis patients, we believe that the inclusion of home dialysis patients in the Mineral Metabolism reporting measure is appropriate. Therefore we will finalize our proposal that we will include any home hemodialysis patient for which a facility submits a claim with respect to the reporting month in this measure.

We also believe it is important to include transplant patients until they are officially discharged from a facility; regular monitoring can help ensure that a transplant remains effective and that the facility is continuing to provide the best care possible.

We believe it is important to monitor serum calcium and serum phosphorus levels in adult and pediatric patients alike because improper bone mineral metabolism management can lead to serious, negative outcomes, including death, in both populations. Although we are aware that specific target values for calcium and phosphorus have not been set for the pediatric population, we still believe that this measure will lead to

better observation of mineral metabolism in these patients if one or both of these values are unusually high or low. Additionally, we believe that the inclusion of pediatric patients in this measure is consistent with current guidelines on the frequency of mineral metabolism testing as reported in KDIGO guidelines chapter 3 ''Diagnosis of CKD–MBD: biochemical abnormalities.'' Thus, we believe that this measure is appropriate for both adult and pediatric patients.

For the reasons stated above, we finalize that facilities must report in CROWNWeb the serum calcium and serum phosphorus levels on a monthly basis for (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

Comment: Several commenters encouraged us to not adopt a percentage reporting threshold because it would not distinguish between beneficiaries legitimately excluded and those that were merely missed. Other commenters requested that we use both exclusions and a threshold; one commenter suggested a threshold of 90 percent or an allowance of two patients to ensure that small facilities are not disproportionally affected. Another commenter stated that requiring 98 percent reporting may make it difficult for patients to travel because dialysis facilities may encourage them otherwise to ensure compliance with the measure. One commenter requested that we provide guidance regarding the standardization of blood-draws so that data can be reliable before we implement a reporting threshold.

Response: We agree with the commenters who argued that, even with exclusions, there are circumstances in which facilities cannot report the serum calcium and serum phosphorus levels for every patient at least once per month. For example, a facility may wait to draw blood from a patient because it believes that the patient will be treated for the entirety of the month, but learns that the patient has been hospitalized unexpectedly for all or part of the applicable month. Therefore, we believe that we should not require an attestation of 100 percent monitoring. Based on data from the CROWNWeb pilot, we believe that facilities are generally able to report serum calcium and serum phosphorus for approximately 96 percent of their patients. As commenters have argued, the information in CROWNWeb, however, was voluntarily reported which may mean that the data is biased toward facilities that value reporting; additionally, the data from the CROWNWeb pilot was mainly supplied by LDOs that may be more likely to have more resources and corporate policies that require reporting compliance. Furthermore, such a high percentage requirement may disadvantage small facilities. For example, if a facility has 10 patients, failure to report for one patient will drop that facility's reporting rate to below 90 percent.

Taking all of these issues into consideration, we finalize a normative reporting threshold for this measure; facilities will be required to report at the rate of the 50th percentile of all facilities in 2013 for each month of the performance period in order to gain 10 points on the measure. However, if the 50th percentile of all facilities in 2013 is greater than 97 percent, facilities will only be required to report monthly for 97 percent, in total, of their (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. This floor ensures that facilities are not penalized as long as they improve by one percent above the reporting rates in the CROWNWeb pilot; that is, facilities know that, provided they reach 97 percent for each month of the performance period, they will meet the requirements of the measure. We believe that it is important to adopt a reporting rate of 97 percent in PY 2015 to ensure continued improvement. We believe that this methodology fairly balances the concerns that the reporting in CROWNWeb is skewed with our desire to encourage continued improvement in the community.

We are concerned that small facilities may be disproportionately impacted by the reporting threshold because, for example, a facility with 10 patients could fail to report for only one patient and, therefore, fail to meet the threshold. As we have stated, we intend to use the information collected from reporting measures for purposes of scoring clinical measures based on the same data in subsequent payment years. Therefore, we will not require a facility to report this measure if it treats fewer than 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. If a facility does not treat at least 11 of these patients during the performance period, it will be required to attest to this fact via CROWNWeb. If a facility does not make the attestation, we will score it accordingly.

Comment: Some commenters did not support including this measure in PY 2015. One commenter argued that it is inappropriate to adopt this measure because it is not-NQF endorsed, nor. One commenter stated that it is inappropriate to adopt this measure under the exception set forth in the statute for measures which are not NQF-endorsed; this commenter stated that the NQF process ensures that measures have gone through a rigorous evaluation process, including reliability and validity. Some commenters argued that this measure should be deferred because we have not articulated the intent of the data collection or explained the measure for which we intend to ultimately use these data. Several commenters do not support this measure because facilities already collect these data so the measure is unlikely to improve care, and they requested that we adopt a measure based on outcomes. One commenter does not support adoption of this measure because, it contends, Kidney Disease: Improving Global Outcomes (KDIGO) has not indicated that serum calcium and serum phosphorus must be reported on a monthly basis. Further, the commenter argues that although it is customary to measure serum calcium and phosphorus monthly, there is no evidence that it indicates quality care.

Response: KDIGO recommends monthly measurements (see Table 13 on internet document titled ''Kidney Disease Improving Global Outcomes Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD–MBD)'' at *http://www.kdigo.org/guidelines/mbd/guide3.html#chap31*)). KDIGO also emphasizes the importance of following trends versus single measurements, thus supporting relatively frequent measurements (for example, monthly). There is evidence that calcium and phosphorus levels may be associated with clinical outcomes. Monthly measurements will serve to identify elevated levels of serum calcium and phosphorus and trigger therapeutic interventions, thus contributing to high quality care. Because of these important considerations, and for the reasons stated above, we believe that it is important to adopt this measure even though it is not NQF-endorsed. We disagree that it is inappropriate to adopt a measure not endorsed by NQF under the exception set forth in the statute. We believe the exception language was intended for such a circumstance where an endorsed measure is not available for implementation to address key issues described in the statute, such as mineral

metabolism. We will continue to work toward the development and implementation of appropriate, NQF-endorsed measures to support the ESRD QIP.

Comment: Many commenters noted that it is impractical for facilities to obtain lab values from other providers because other providers are not required to measure these data, do not share data with dialysis facilities, and, even if facilities could obtain these data, they could not be sure that the lab values were consistent or reported under the same standards. Finally, these commenters stated that CROWNWeb does not permit facilities to submit data obtained from other providers if the lab result is outside the admission or discharge date.

Response: We recognize that it may be difficult for facilities to coordinate with hospitals and other care providers in order to obtain lab values. Therefore, we are not mandating facilities to do so. In the CY 2013 ESRD PPS proposed rule (77 FR 40969), we stated that facilities may obtain lab values from other providers. This proposal was specifically designed to afford facilities more flexibility in acquiring and reporting serum calcium and serum phosphorus values. As discussed previously in this preamble, facilities are highly encouraged to coordinate with other providers, but the ESRD QIP does not mandate them to do so. We believe that the commenters' concerns about inconsistent lab data are mitigated by the requirement that the lab must be accredited. Finally, the commenter is right in that CROWNWeb does not allow facilities to submit data obtained from other providers if the lab result is outside the admission or discharge date. As long as the patient is treated at least seven times by the facility during the applicable reporting month, however, the facility will be required to report the patient's serum phosphorus and calcium levels regardless of whether the patient also has blood drawn elsewhere (for example, as a result of a hospitalization) during the month.

Comment: Many commenters encouraged us to monitor, in addition to phosphorus and calcium, serum levels of parathyroid hormone (PTH), arguing that proper bone mineral management must take all three factors into account. Commenters also encouraged us to adopt measures in all of these areas.

Response: We thank those commenters who advocated the monitoring of PTH. We recognize the important role played by parathyroid hormone in mineral metabolism in the ESRD population, and will pursue avenues by which we may monitor serum levels of parathyroid hormone in the future.

As explained above, we are modifying our proposed exclusions and finalizing that any facility must report serum calcium and serum phosphorus levels for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim least once per month via CROWNWeb at the lesser of the 50th percentile of facilities in 2013 or 97 percent per month to receive 10 points on the measure. We also finalize that we will only apply this measure to facilities with at least 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. Facilities who treat less than 11 of these patients during the performance period must attest to this fact in CROWNWeb. If they do not make this attestation, we will score them accordingly. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Reporting-2015–FR.pdf.*

3. New Measures for PY 2015 and Subsequent PYs 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 proposed 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 related to hemoglobin and ESA dosages for all patients.

a. 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 through 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 proposed to remove the URR Hemodialysis Adequacy measure. In its place, we proposed 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, we stated that 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 proposed 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) meet the modality specific Kt/V threshold. Performance on the measures is expressed as a proportion of patient-months meeting the measure threshold. The technical specifications for these measures can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/PediatricHemodialysisAdequacy-ktv-2015-NPRM.pdf; http://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 requested comment on these proposals. The comments we received on these proposals and our responses are set forth below.

i. Adult Hemodialysis Adequacy

Comment: The majority of commenters strongly supported the adoption of this measure and the removal of URR as a measure of dialysis adequacy, stating that the measure is more accurate and used more widely by the dialysis community. Other commenters, however, stated that URR is a more appropriate measure of dialysis adequacy because Kt/V is dependent upon many factors, including mid-week sampling, accurate urine collection, and dialysis

prescriptions, whereas URR needs only pre- and post-blood draws. One commenter did not support a Kt/V measure because it only promotes ''adequacy'' rather than optimal health, urea is not associated with toxicity, it does not take into account ultrafiltration, and it is only a point in time measurement. Some commenters supported the adoption of Kt/V as a measure of dialysis adequacy for hemodialysis patients, but requested that we delay implementation until PY 2016 so that we can ensure the data we are using to calculate achievement thresholds, benchmarks, and performance standards were calculated using consistent methodology. One commenter suggested that we include Kt/V in PY 2015, but calculate rates for performance standards, benchmarks, and thresholds based on data from January 1, 2012–June 30, 2012 since these dates would include only data that were calculated using the NQF-endorsed formulae. Finally, one commenter stated that we should request raw data from facilities and calculate Kt/V to ensure consistency.

Response: We thank those commenters who supported the implementation of these measures. We note that the published literature suggests there is insufficient evidence to support the superiority of alternative measures of small solute clearance over spKt/V. The KDOQI Clinical Practice Guideline for Methods for Measuring and Expressing Hemodialysis Dose (CPG 2) also state that ''the delivered Kt/V determined by single-pool urea kinetic modeling continues to be preferred as the most precise and accurate measure of dialysis'' (page 12, KDOQI 2006 Update). Furthermore, the minimum delivered hemodialysis dose for both adult and pediatric patients, spKt/V>=1.2, was endorsed by NQF in 2007. Regarding concerns about the use of consistent methodology in the calculation of performance standards, beginning in January 2012, the measure specifications for adult and pediatric hemodialysis Kt/V state that single-pool Kt/V be measured using Daugirdas II or Urea Kinetic Modeling. We anticipate that these specifications will provide valid and consistent spKt/V values.

We thank the commenter for the suggestion of utilizing data from January 1, 2012–June 30, 2012 to set achievement thresholds, benchmarks, and performance standards. We believe, however, that whenever possible, these values should be based on a full year of data since these data, although not necessarily calculated using the same NQF-endorsed methodology, represent any changes that may occur as a result of seasonality. Additionally, utilizing this timeframe will enable us to post the numerical values of the performance standards as soon as they are available in December 2012 or January 2013.

We thank the commenter for the suggestion of collecting raw data rather than calculated spKt/V values. At this time, we are not operationally able to request these elements on claims. We will consider this suggestion in future years of the program.

Comment: Several commenters supported the measure but requested that we refine it to specify that the calculated spKt/V include estimates of residual renal function (RRF) to avoid incentivizing improper, longer dialysis sessions for these patients; one commenter recommended that, consistent with KDOQI guidance, RRF be included in spKt/V only if the urine collection used to measure it was within the previous 90 days. Commenters also requested that we exclude patients dialyzing four or more times per week or overnight and include patients with Kt/V less than 2.5 since many patients achieve these values.

Response: Consistent with the 2006 KDOQI Clinical Guidelines for hemodialysis adequacy, we do not find published, medical evidence to support the inclusion of RRF in defining the minimum target spKt/V. Additionally, effective January 2012, the Medicare claims processing instructions specifically state that the reported spKt/V should not include RRF. We currently exclude patients dialyzing four or more times per week from the adult HD measure because this exclusion was NQF-endorsed.

According to the measure specifications, overnight dialysis patients are included in the HD spKt/V measure unless they are dialyzing less than two or greater than four times per week, or if they are in the first 90 days of ESRD treatment. We do not currently have the ability to identify patients who are receiving thrice weekly in-center nocturnal hemodialysis and do not have a measure specific to this population. We are currently working with stakeholders to develop adequacy measures to address frequent, home, and nocturnal hemodialysis patients for future years of the ESRD QIP.

Finally, patients with spKt/V less than 0.5 or greater than 2.5 are excluded from the Kt/V adult hemodialysis dialysis adequacy measure. Patients with HD spKt/V values greater than 2.5 are excluded from the measure calculation as these values are considered implausible for most hemodialysis patients.

Comment: Commenter stated that spKt/V does not reflect patients on short daily, frequent, and nocturnal dialysis and should be updated accordingly. Another commenter requested that we develop a spKt/V measure for home dialyzers.

Response: We are currently working with stakeholders to develop adequacy measures to address other members of the ESRD population (i.e. frequent, home, and nocturnal hemodialysis patients) for future years of the ESRD QIP.

Comment: One commenter requested that we specify that the lab draw for this measure should be done mid-week to better reflect patients' actual conditions.

Response: Under the measure specifications for the Kt/V adult hemodialysis adequacy measure, facilities are required to report the last spKt/V measurement of the month. The NQF-endorsed measures for minimum dialysis adequacy for both pediatric and adult patients do not adjust for the day of the week; a minimum target value of spKt/V greater than or equal to 1.2 should be achieved regardless of when this is measured. We appreciate your suggestion and will take it under consideration during our ongoing measure maintenance.

Comment: One commenter stated that ''dialysis adequacy'' is a misnomer because it does not provide a full picture of dialysis adequacy. Instead, the commenter suggests it be called a measure of ''urea removal,'' encouraging stakeholders to develop measures that are more comprehensive of dialysis adequacy. Another commenter asked us to recognize that ''adequacy'' is not synonymous with optimal levels.

Response: ''Dialysis adequacy'' is used in the ESRD QIP to represent the quantification of urea removal by dialysis, one widely accepted measurement of adequacy of this treatment. We recognize there are other aspects of dialysis adequacy, and we are currently working with stakeholders to develop additional measures for future years of the ESRD QIP. Additionally, we emphasize that these minimum spKt/V target levels may not be optimal levels for all patients. Therefore we encourage clinicians to consider targeting higher spKt/V targets on an individual patient basis as clinically indicated.

ii. Peritoneal Dialysis Adequacy

Comment: Many commenters supported the adoption of this measure and asked us to finalize the measure along with the formula and methodology for its calculation. One commenter explicitly asked us to finalize a methodology for obtaining

dialysate, blood, and urine sampling. Other commenters, however, did not support the measure, stating that we have not yet specified a consistent reporting methodology. These commenters suggested that we finalize this measure as a reporting measure only for PY 2015, define a methodology for calculating the values in the final rule, and use data from CY 2013 for purposes of adopting this measure as a clinical measure in future years. One commenter stated that we should request raw data from facilities and calculate Kt/V to ensure consistency. Finally, some commenters stated that they did not support the measure.

Response: We thank the commenters who supported the adoption of this measure. There is more than one method that may be used by facilities to calculate PD Kt/V. Methods for reporting PD Kt/V on Medicare claims were specified prior to the start of data collection in July 2010 and are based on measure specifications endorsed by the National Quality Forum in 2007. Measurement of peritoneal dialysis Kt/V is based on timed (24 hour) dialysate collection to measure urea clearance (k). Time (t) is specified in the definition (week or per week). The only component of Kt/V measurement in peritoneal dialysis that is formula-based is the estimation of total body water (V). V is estimated from either of two formulae (Watson or Hume) predictive equations that are based on patient anthropometric and demographic information. We will consider the standardization of estimating total body water as part of our annual ongoing measure maintenance process, but we note that we believe it is appropriate to adopt this measure without this standardization because the Watson and Hume formulae yield substantially similar results. Moreover, NQF approved the measure with the specification to use the Watson or Hume formula to estimate ''V.'' We choose to collect reported Kt/V, rather than the data elements for Kt/V, due to the limitations of collecting data on Medicare claims and to minimize burden on facilities.

Comment: One commenter supported the use of Kt/V as a measure of dialysis adequacy for peritoneal dialysis patients, but suggested that we refine it in the final rule. This commenter stated that we need to: (i) Clarify in the technical measure specifications that a patient is only included in the measure population if he/she has been on peritoneal dialysis for 90 days or more so that a patient transferring from hemodialysis to peritoneal dialysis will not be immediately counted in the measure; and (ii) exclude patients in the first month they are eligible to be included in the denominator if no Kt/V measurement is taken until the fourth month since the measure specifies Kt/V need only be measured once every 4 months. One commenter noted that a monthly measurement period for the measure is problematic because Kt/V is assessed throughout the month in home training clinics; this commenter suggested that there be a 30-day window from the time of the adequacy measure to adjust the prescription and repeat the adequacy measure.

Response: We thank commenters for their feedback regarding the exclusion criteria for Kt/V for adult peritoneal ESRD patients. To the first point, patients are excluded from this measure if they are in the first 90 days of treatment for ESRD. If a patient changes from hemodialysis to peritoneal dialysis during a month, the patient would be included in both the HD and PD Kt/V measure calculations. The 2006 KDOQI Clinical Practice Guidelines for peritoneal dialysis adequacy (Guideline 2.1.2) state ''the total solute clearance (residual kidney and peritoneal, in terms of Kt/V) should be measured within the first month after initiating dialysis therapy and at least once every 4 months thereafter.'' While this measure is consistent with the guideline, we acknowledge that a patient may be included in the PD Kt/V measure calculation in the same month their modality changed to PD. However, after switching from hemodialysis to peritoneal dialysis, peritoneal dialysis clearance typically is not measured right away or even in the same month as the PD catheter insertion, as the peritoneal membrane is in a state of flux and its membrane transport characteristics are unstable for a few weeks. In several clinical scenarios it may not be appropriate to measure PD Kt/V within the first several weeks after initiation of peritoneal dialysis. Therefore, we believe that the PD unit personnel will not have measured PD adequacy in the 30 days following the transition from HD to PD. With regard to the comment on excluding patients from the denominator for the first month if no measurement is taken until the fourth month, we use the data reported in conjunction with Medicare dialysis facility claims value code D5: Result of last Kt/V reading and occurrence code 51: Date of last Kt/V reading. The claims reporting instructions indicate that for PD patients this should be within the last 4 months of the claim date of service. All monthly claims with valid PD Kt/V values will be used in the calculation. In response to the monthly measurement period comment, for PD patients, facilities are only required to report Kt/V once every 4 months.

Comment: One commenter urged us to develop a pediatric peritoneal dialysis adequacy measure in collaboration with stakeholders.

Response: We are currently working with stakeholders to develop a pediatric peritoneal dialysis adequacy measure as part of a consensus-based measure development process, and we will consider implementing such a measure through future rulemaking.

iii. Pediatric In-Center Hemodialysis Adequacy

Comment: Several commenters supported the adoption of a Kt/V hemodialysis adequacy measure for pediatric patients even if we do not adopt the adult Kt/V measures. Other commenters, however, argued that we should not finalize the pediatric in-center hemodialysis adequacy measure because (i) the measure does not exclude RRF patients; and (ii) the measure applies to 4 times per week hemodialysis. These commenters believe that adoption of the proposed measure would, in effect, raise the pediatric dialysis dose above the adult dialysis dose in a substantial number of children who either have a significant RRF or are treated with dialysis four days a week; they caution that we should avoid incentivizing improper, longer dialysis sessions for these patients. Some commenters urged us to harmonize the adult and pediatric spKt/V hemodialysis adequacy measures, specifically regarding the required number of dialysis sessions for inclusion in the measure and the inclusion of RRF. Another commenter stated that we should consider changing the measure so that it is based on weekly dose. Other commenters stated, generally, that spKt/V is not appropriate for pediatric patients and encouraged us to work with stakeholders to develop a suitable pediatric dialysis measure.

Response: We thank the commenters who supported the implementation of the spKt/V hemodialysis adequacy measure for pediatric patients and those who provided feedback for its implementation. The measure methodology was developed through a consensus-based process incorporating the input of a Technical Expert Panel and was endorsed by NQF in 2011. The pediatric hemodialysis adequacy measure differs from the corresponding adult adequacy measure in that the measure applies to patients receiving four dialysis treatments a week.

Analysis of 2007 claims data suggest that in 5.6 percent of patient-weeks, dialysis sessions occurred four times per week for pediatric patients. Given that this is a significant proportion, the TEP concluded that these patients should be included in this measure. As seen in Table 4 below, there were three or four dialysis sessions in approximately 88 percent of patient-weeks. Based on these results, the TEP concluded that by defining the denominator as hemodialysis patients receiving dialysis three or four times weekly, the measure will be applicable to most pediatric hemodialysis patients.

TABLE 4—DIALYSIS SESSIONS PER PATIENT WEEK AMONG ALL HD PEDIATRIC PATIENTS < 20 YEARS OLD

Sessions per week	Number of patient-weeks	Percent
1	211	2.6
2	614	7.5
3	6712	82.2
4	533	6.5
5	60	0.7
6	36	0.4
7	3	0.04

N=312 patients with first Medicare dialysis claim on or before January 1, 2007.

With regard to the incorporation of RRF in the calculation of adequacy, the TEP did not agree that RRF should be added to the measure description for several reasons: (i) Published studies evaluating dialysis adequacy in the pediatric population do not include residual renal function; (ii) RRF changes continuously with age in the pediatric population; and (iii) RRF is difficult to measure among pediatric patients. Neither the NQF-endorsed measure specifications nor the KDOQI guidelines support measuring spKt/V in pediatric patients based on a weekly dose. Furthermore there is no evidence to support a minimum target value for a weekly Kt/V dose. We will continue to consider other measurements of dialysis adequacy for the pediatric population; at this time, we believe that this measure is the most suitable.

For the reasons stated above, we are adopting the Kt/V measure topic as proposed. The technical specifications for each of the finalized measures in this measure topic can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/HemodialysisAdequacy-ktv-2015–FR.pdf* (adult hemodialysis), *http://www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysisAdequacy-ktv-2015–FR.pdf* (adult peritoneal dialysis), and *http://www.dialysisreports.org/pdf/esrd/public-measures/PediatricHemodialysisAdequacy-ktv-2015–FR.pdf* (pediatric in-center hemodialysis).

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 ensuring normal calcium levels in the blood. Therefore, we proposed 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 also proposed 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 proposed to adopt this measure not only for PY 2015, but also subsequent payment years, we also proposed that, beginning with the PY 2016 program, we would measure hypercalcemia beginning in January of the applicable performance period. This would allow us to have a 3-month rolling average for all months in the performance period. We proposed 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 proposed 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.*

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

Comment: Several commenters supported this measure, noting that it is consistent with KDIGO guidelines and is especially necessary given that we will include oral-only drugs in the bundle beginning in PY 2014; some commenters specifically argued that that there is sufficient validity and reliability of the data collected in CROWNWeb to establish an appropriate clinical measure for PY 2015, and noted that this measure is in keeping with Congress' intent to include a measure of bone mineral metabolism in the ESRD QIP. Other commenters, however, stated their belief that, despite its NQF-endorsement, the measure is not aligned with clinical standards, is contrary to KDIGO guidelines, and does not advance the aims of the National Quality Strategy. Additionally, several commenters, both those supporting and opposing the measure, argued that it is inappropriate to use CROWNWeb data to define performance standards, achievement thresholds, and benchmarks because the data underrepresents small- and mid-sized dialysis organizations, does not account for the differences in reporting which may exist when data are voluntarily reported (and data were voluntarily reported in the CROWNWeb pilot), was submitted with the understanding that it was test data and would not be used by CMS programs, and because it suffers from serious data collection problems, a lack of definitions, and a lack of reporting requirements in CROWNWeb. Many commenters suggested that we adopt this measure as a reporting measure only for PY 2015. Several other commenters believe that the proposed hypercalcemia measure is only appropriate if we include similar clinical measures for serum phosphorus, parathyroid hormone (PTH), and other mineral metrics because a hypercalcemia measure alone represents a piecemeal approach to bone and mineral metabolism that will not be sufficient to ensure quality care for ESRD patients and may even incentivize

inappropriate care. Finally, commenters recommended that CMS monitor secondary parathyroid hormone and not include oral-only drugs in the bundle until such measures and monitoring are in place.

Response: Commenters rightly state that the performance standards, achievement thresholds, and benchmarks for the proposed Hypercalcemia measure were not calculated using data from all facilities. Because it is possible that these calculations could contain a systemic bias, and we have no effective means of addressing that bias in the ESRD QIP as this time, we will not finalize a clinical measure for hypercalcemia, as discussed above, until valid data from all facilities are accessible for the purpose of establishing performance standards, achievement thresholds, and benchmarks. We are not finalizing a clinical Hypercalcemia measure at this time. We do, however, continue to believe that hypercalcemia is an important indicator of bone mineral metabolism, and we intend to use this measure in subsequent payment years.

Comment: One commenter stated that, generally, we should not use data from CROWNWeb for the ESRD QIP until the validity of CROWNWeb data is confirmed. Commenters also urged us to find solutions for the CROWNWeb issues which the community has been experiencing in order to ensure that, as measures increasingly rely on CROWNWeb data, there is no question as to the data's validity.

Response: We thank the commenters who expressed concern regarding the use of CROWNWeb data for the ESRD QIP. Given the potential risk to validity of ESRD QIP clinical measures calculated using CROWNWeb data, we will not finalize the proposed clinical measure for hypercalcemia that depends on those data, as noted above.

Comment: One commenter urged us to exclude patients who have hypercalcemia for reasons other than ESRD treatment (for example, medication and malignancy) from the Hypercalcemia measure. The commenter requests confirmation that the Hypercalcemia measure includes all patients rather than just Medicare patients, and is concerned with CMS' move to include the total facility population in the measure collection process. One commenter seeks clarification regarding whether a lower or higher rate is desirable for the Hypercalcemia measure.

Response: We thank the commenters for raising these issues with the Hypercalcemia measure, and we will incorporate them in discussions during future rulemaking, when the Hypercalcemia measure is considered as a measure for the ESRD QIP in future payment years.

For the reasons discussed above, we will not finalize the Hypercalcemia measure for use in the PY 2015 ESRD QIP or subsequent years until indicated otherwise in rulemaking.

c. 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 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 the effect of the ESRD PPS. We believe that it is important that we continue monitoring hemoglobin levels in patients to ensure that anemia is properly treated, and we, therefore, proposed 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 hematocrit [4] 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 facility.

We stated in the proposed rule that 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 proposed to adopt an Anemia Management reporting measure for the PY 2015 ESRD QIP, and future payment years of the program. For this measure, we proposed 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 proposed 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 stated that 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 proposed 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

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

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 did not propose 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 proposed 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 requested comment on this proposal. We also requested 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-approved ESA labeling 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 changes to ESA labeling 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 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 labeling 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. A 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 noted 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 proposed to adopt an Anemia Management reporting measure for the PY 2015 ESRD QIP and subsequent payment years. We provided the technical specifications for this measure, at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2015–NPRM.pdf.* We requested public comment on these proposals.

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

Comment: Some commenters supported the measure, stating that they believe this measure will allow us to closely monitor the underutilization of ESAs and the increase in transfusions. Commenters also stated that they believe that this measure will assist in explaining and monitoring timely ESA discontinuation and studying the potential effect of altitude on patients. Many commenters supported this measure, but requested that we make modifications to our proposed exclusions. These commenters suggested that we exclude, for all of the reporting measures, the following patients: (i) Beneficiaries who are regularly treated at the facility and who fit into one of these categories: (a) beneficiaries who die within the applicable month; (b) beneficiaries that receive fewer than 7 treatments in a month; and (c) beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. Commenters stated that these exclusions would be consistent with our own measures reported on DFC; commenters also stated that these exclusions seek to hold facilities accountable only for those beneficiaries to whom they regularly give care and for whose care they can affect. Another commenter, however, stated that we should not implement other commenters' suggestions that we exclude beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; this commenter stated that it is the responsibility of the facilities to educate patients on the importance of making and keeping appointments. Additionally this commenter argued that ''good faith'' is too vague; commenter requested that, if we did adopt this exclusion, we clearly define a ''good faith effort.'' Another commenter stated that peritoneal dialysis patients do not need to be seen at a facility once per month and the measure should be accordingly revised.

Response: Consistent with the Mineral Metabolism reporting measure, we agree with commenters who believe that the exclusions should be modified. We recognize that treating a patient twice may not provide enough time to effectuate quality patient care. We agree with the commenters who suggested that an in-center hemodialysis patient should be excluded if treated by a facility fewer than seven times during the month, regardless of whether the patient is officially admitted to that facility. With seven treatments, we believe that a facility should have had adequate opportunities to draw blood necessary to report hemoglobin/hematocrit. We also believe that the threshold of seven will discourage unnecessary testing of in-center hemodialysis patients by facilities because they will know that, since in-center patients are typically treated three times per week, a patient must have been treated by the facility for at least two weeks to be included; thus, the facility need not feel pressure to draw blood for every patient during the first few visits of the month. Based on these considerations, we will not finalize our proposal to only exclude in-center patients who have been treated fewer than two times by the facility during the claim month. Instead, we will exclude any patient who is treated by the facility

fewer than seven times during the reporting month.

We do not believe that it is necessary to specifically exclude transient patients from this measure because, as noted, any patient that is treated by the facility at least seven times during the applicable reporting month is present at the facility for enough time that the facility should be able to measure that patient's hemoglobin/hematocrit. Likewise, for the same reasons, we do not believe we need to separately exclude patients who are deceased at the end of the reporting month. Provided that the patient was treated by the facility at least seven times during that month, the facility should be able to draw blood necessary to obtain hemoglobin/hematocrit values even if the patient is deceased at the end of the month.

Additionally, we do not agree that facilities should not be held accountable for drawing blood from home dialysis patients who fail to attend a monthly appointment. We believe that it is incumbent upon a facility to make home dialysis patients aware that they must attend monthly appointments to be properly treated. Therefore, we will finalize our proposal that we will include any home hemodialysis patient for which a facility submits a claim with respect to the reporting month in this measure.

Finally, we believe it is important to include transplant patients until they are officially discharged from a facility; regular monitoring can help ensure that a transplant remains effective and the facility is continuing to provide the best care possible.

For the reasons stated above, we will modify our proposals for the exclusions for this measure and finalize that, for the PY 2015 ESRD QIP, facilities must report hemoglobin/hematocrit at least once per month via claims for (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. If the facility administers an ESA to these patients, it must also report the HCPCS code and corresponding unit for that patient. We will interpret an empty HCPCS field to mean that no ESA was administered.

Comment: Several commenters encouraged us to not adopt a percentage reporting threshold because it does not distinguish between beneficiaries legitimately excluded and those that were merely missed. Other commenters requested that we use both exclusions and a threshold; one commenter suggested a threshold of 90 percent or an allowance of two patients to ensure that small facilities are not disproportionally affected. Another commenter stated that requiring 98 percent reporting may make it difficult for patients to travel because dialysis facilities may encourage them otherwise in order to ensure compliance with the measure. One commenter requested that we provide guidance regarding the standardization of blood-draws so that data can be reliable before we implement a reporting threshold.

Response: We agree with the commenters who argued that, even with exclusions, there are circumstances in which facilities cannot report the hemoglobin/hematocrit and ESA dosage, as applicable, for every patient at least once per month. It is possible that these exclusions alone may hold a facility responsible for a patient who was technically treated by the facility but who did not receive actual treatment from the facility during the applicable month. For example, a facility may wait to draw blood from a patient because it believes that the patient will be treated there for the entirety of the month, but learns that the patient has been hospitalized unexpectedly for all or part of the applicable month. Therefore, we believe that we should not require facilities to report for 100 percent of their patients. Based on data from CROWNWeb, we believe that facilities report hemoglobin/hematocrit and ESA dosage for approximately 99 percent of their patients on a monthly basis. We believe it is appropriate to assume that a similar percentage was reported via claims. Although, as commenters have argued with regard to the Mineral Metabolism reporting and the Hypercalcemia measures, this information in CROWNWeb was voluntarily reported which may mean that the data is biased toward facilities that value reporting; additionally, the data from the CROWNWeb pilot was mainly supplied by LDOs that may be more likely to have more resources and corporate policies that require reporting compliance.

Taking all of these issues into consideration, we finalize a normative reporting threshold for this measure; facilities will be required to report at the lesser of the 50th percentile of all facilities in 2013 or 99 percent, in total, of their (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. This floor ensures that facilities are not penalized as long as they report at a high rate that is consistent with CROWNWeb data; that is, facilities know that, provided they reach 99 percent for each month of the performance period, they will meet the requirements of the measure. We believe that this methodology fairly balances the concerns that the reporting in CROWNWeb is skewed with our desire to encourage continued excellence in the community.

We are concerned that small facilities may be disproportionately impacted by the reporting threshold because, for example, a facility with 10 patients could fail to report for only one patient and, therefore, fail to meet the threshold. As we discuss below, we believe that 11 cases is an appropriate minimum for purposes of scoring clinical measures. As we have stated, we intend to use the information collected from reporting measures for purposes of scoring clinical measures based on the same data in subsequent payment years. Therefore, we will not require a facility to report this measure if it treats less than 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; or (ii) home hemodialysis Medicare patients for whom the facility submits a claim. If a facility does not treat at least 11 of these patients during the performance period, it will be required to attest to this fact via CROWNWeb. If a facility does not make the attestation, we will score it accordingly.

Comment: Several commenters do not support this measure because facilities already collect these data so the measure is unlikely to improve care. Some of these commenters asked us to require facilities to report this information separate from the ESRD QIP on at least one monthly claim to ensure anemia is properly treated.

Response: As we noted in the proposed rule (77 FR 40974), we believe that this measure will discourage underreporting of ESAs and hemoglobin. Currently, facilities may report a value of 99.99 as default hemoglobin for claims that do not include an ESA. Since the bundle includes ESAs, it may not be financially beneficial for a facility to report an ESA, especially if a patient's hemoglobin is greater than 12—negatively affecting its Hemoglobin Greater than 12 g/dL measure score. Additionally, we are concerned that the 99.99 value will be overutilized and will not allow us to properly monitor hemoglobin levels across the ESRD population. If we are able to closely and accurately monitor ESA dosage and hemoglobin, we believe we will be able to improve care by using this information to monitor the effects of the bundle and the ESRD QIP on beneficiaries; we also believe we may

utilize these data in the future to develop an anemia management clinical measure.

Comment: Many commenters noted that it is impractical for facilities to obtain lab values from other providers because other providers are not required to measure these data, do not share data with dialysis facilities, and, even if facilities could obtain these data, they could not be sure that the labs were consistent or reported under the same standards. Additionally, one commenter argued that hemoglobin levels from other facilities will be of little use without further information regarding why the patient was at that facility. One commenter agreed that hemoglobin/hematocrit values can be supplied by another provider provided the labs are evaluated by an accredited facility.

Response: We recognize that it may be difficult for facilities to coordinate with hospitals and other providers in order to obtain lab values. We, however, are not mandating facilities to do so. In the proposed rule (77 FR 40974), we stated that facilities may obtain lab values from other providers. This proposal was specifically designed to afford facilities more flexibility in acquiring and reporting hemoglobin and hematocrit values, as well as ESA dosage. Facilities are highly encouraged to coordinate with other providers, but this measure does not mandate them to do so. We believe that the commenters' concerns about inconsistent lab data are mitigated by the requirement that the lab must be accredited. Further, we do not believe that data from another provider will be of little use. We can use these values to monitor hemoglobin and hematocrit levels of ESRD patients, as well as ESA dosage; additionally, collecting these data may encourage providers to engage one another about the patient's conditions and care.

Comment: One commenter noted that hemoglobin values on claims are from the prior month; therefore the 99.99 is used for the claim in the first month of a patient's dialysis or if a patient had a transplant. The commenter requested clarification on what it should report in these circumstances. Other commenters argued that 99.99 should be available without penalty to facilities because in some instances, it is appropriate. One commenter supported disincentivizing 99.99 reporting in order to stop facilities from not reporting patients with high hemoglobin.

Response: The commenter is correct in that the Erythropoietin Monitoring Policy (2006) [5] requests that the hemoglobin/hematocrit reading reported on claims be defined as ''the most recent reading taken before the start of this billing period. For patients beginning dialysis, use the most recent value prior to the onset of treatment.'' We recognize that, for some patients, specifically those new to dialysis, this hemoglobin/hematocrit values may not be available. Therefore, we will not require a facility to report a hemoglobin/hematocrit value for a patient if that patient has been on dialysis for less than one month (including when dialysis is resumed after a transplant); facilities may report the default value without being penalized in this circumstance. We remind facilities that if an ESA is reported on a claim, the facility must also report a hemoglobin/hematocrit level, regardless of whether that patient is new to dialysis (CR 7460).

Comment: One commenter asked us to include Omontys, an ESA new to the market, in this measure. Other commenters generally requested that we monitor new ESAs and their effects on hemoglobin levels.

Response: We intend to monitor ESA dosage for all ESAs used by dialysis facilities. Using HCPCS codes, a facility must indicate which ESA it administered, including Omontys.

Comment: One commenter noted that it supports the reporting of hemoglobin, but not hematocrit because the data set should be standardized to require only hemoglobin reporting.

Response: Facilities can report either hemoglobin or hematocrit on claims. Either will count for the purpose of this measure. (For the Hemoglobin Greater than 12 g/dL measure, hematocrit values are changed to hemoglobin by dividing by 3). As of 2011, only 14 percent of facilities reported hemoglobin, while 70 percent reported hematocrit. We believe that requiring 70 percent of all facilities to alter their reporting method would generate undue burden on the dialysis facility community, for relatively little gain, as we have an established method for incorporating both hemoglobin and hematocrit into the measure calculation.

Comment: Some commenters asked us to state the purposes of the anemia management reporting measure with more specificity. Some commenters requested that we clarify how we intend to report and make publicly available hemoglobin/hematocrit levels and ESA dosages. Commenters asked us to clarify the plans for the use of the information and how we will account for patient weight in our analyses.

Response: We believe that the anemia management reporting measure emphasizes the importance of anemia management for the ESRD population and will support efforts to establish more meaningful, evidence-based clinical measures of anemia management in the future. We intend to publicly report the anemia management reporting measure rates in the same manner that we use to publicly report other measure rates under the ESRD QIP but will not score facilities based on those rates. Facilities will be able to preview the reporting data to be publicly reported before we post it on DFC. At present, the Anemia Management reporting measure does not take patient weight into account, but we will consider whether this type of adjustment is appropriate for future years of the ESRD QIP. We would also like to clarify that we will use HCPCS codes that indicate ESA administration and their corresponding units for assessing whether an ESA was administered. We will interpret an empty HCPCS field to mean that no ESA was administered.

Comment: One commenter supports this measure but suggests that the data be captured in CROWNWeb since hemoglobin levels are only reported on claims with ESA doses.

Response: The commenter is correct that CROWNWeb only requires a hemoglobin/hematocrit if an ESA is entered.

Since January 1, 2012, however, facilities have been required to report hemoglobin/hematocrit on claims regardless of whether an ESA dose was administered (CR 7460). Facilities are expected to report the anemia management reporting measure on their claims.

Comment: One commenter supports the measure but only for patients with hemoglobin less than 10 g/dL. It is more likely, the commenter argues, that one will identify a patient with a low hemoglobin (even if that patient is not on ESAs) if a new reporting measure is instituted. The commenter believes that reporting hemoglobin for patients not on ESAs who have a hemoglobin greater than 12 g/dL is not necessary because these patients are not at risk for the complications that arise from targeting high hemoglobin levels using ESAs.

Response: It is our intention to use the data we collect from this reporting measure to develop an anemia management clinical measure and monitor anemia management trends. In order to better understand the ESRD population as a whole and collect a

[5] *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM4135.pdf.*

robust data set, we believe it is important to collect hemoglobin/hematocrit levels for patients regardless of their values or if an ESA was administered. Using this information, we can, among other things, assess trends across the entire population and use these data for measure development and monitoring purposes.

As explained above, we are modifying our proposed exclusions and finalizing that a facility must report hemoglobin/hematocrit and ESA dosage (via HCPCS codes and their units) for the lesser of the 50th percentile of facilities in 2013 or 99 percent, in total, of its (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. We will interpret an empty HCPCS field to mean that no ESA was administered. We also finalize that we will only apply this measure to facilities with at least 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. Facilities who treat less than 11 of these patients during the performance period must attest to this fact in CROWNWeb. If they do not make this attestation, we will score them accordingly. Additionally, we will not penalize facilities for using the default 99.99 value for a patient in his/her first month of treatment at that facility. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2015-FR.pdf.*

4. Measures Under Consideration for Future PYs of the ESRD QIP

In addition to the PY 2015 ESRD QIP, we noted in the proposed rule that we are 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 stated that we intend to adopt these measures for future payment years of the ESRD QIP, possibly beginning with the PY 2018 program. We notified facilities of our intent and solicited 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 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 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 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 these 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 DFR 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 ESRD QIP, but did not finalize the proposal, in part, because commenters voiced concerns regarding the accuracy of the co-morbidity 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 co-morbid 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 these data not only for reporting the measure rates on DFC at present, but also for calculating the measures if we adopted them for use 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 requested comment regarding the feasibility of adopting these measures for future payment years of the ESRD QIP.

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

Comment: Although most commenters agreed that measures for hospitalization are important for quality reporting purposes, many commenters strongly opposed that the SHR measure be included in the ESRD QIP in subsequent payment years. These

commenters argued that the SHR measure is a measure over which facilities have little control because patients often follow the advice of their primary care physician or visit a hospital without consulting the facility to receive treatments that could be furnished in the outpatient setting. Commenters expressed concern that the measure could lead to cherry-picking, disincentivize appropriate hospitalization, and is not transparent enough for facilities to make improvements in this area because of they are confused about the risk-adjustment methodology. Other commenters stated that the measure needs further refinement and validation, specifically regarding risk adjustment for frail patients such as those in nursing homes, cultural factors, socioeconomic factors, and health factors specific to the ESRD population. Commenters asked that these adjusters be made public. One commenter believes that this measure would create a bias for facilities on the basis of location. Some commenters suggested that, instead of implementing this measure, CMS consider a coordinated care model. Other commenters requested that we adopt a pilot for this measure wherein only aggregate data is reported until the measure can be further assessed and validated. Several commenters suggested that we implement an SHR measure focused on admissions that could have been prevented by interventions from dialysis facilities; one commenter suggested that the SHR measure be modified to calculate a ''risk-adjusted standardized hospitalization ratio for dialysis access-related infections and fluid overload,'' since these are elements facilities can control.

Response: We thank commenters for these opinions. We will take these comments into consideration as we further assess the appropriateness of adopting the SHR measure for the ESRD QIP.

Comment: Many commenters strongly supported the consideration of SHR for future years of the ESRD QIP. One commenter requested that we implement the measure as soon as possible. Commenters also supported reporting measure rates on DFC beginning in CY 2013. One commenter supports the addition of SHR data to DFC as long as a caveat is included explaining that dialysis facilities can influence but do not control hospitalization rates. This commenter also requested that the ''expected,'' ''better than expected,'' and ''less than expected'' categories remain on DFC. One commenter argued that there is not enough data on SHR to report rates on DFC.

Response: We thank the commenters who supported the future consideration of the SHR for implementation. We intend to begin public reporting of the SHR on DFC as of January 2013 to indicate the relative performance of facilities. We believe that dialysis facilities own partial responsibility for the rate at which their patients are hospitalized, in particular when that rate is substantially higher than at other peer facilities and may not be explained by variation in the illness of patients. We do acknowledge that care provided by dialysis facilities is not the sole determinant of the hospitalization of ESRD patients and this measure would not support the assertion that they are. The SHR is only shown for patients with at least 5 patient years at risk, which corresponds to approximately 10 expected hospitalizations. The confidence interval for the SHR will also be reported on DFC to show the uncertainty in the value due to random variation, which will help to address the issue of limited data for the SHR. We appreciate these suggestions and will take them into consideration as we further assess the appropriateness of adopting the SHR measure for the ESRD QIP.

Comment: Some commenters strongly support using the 72x claims as indicators of risk factors for facilities and patients. One commenter suggested that this information could be used in creating an access to care measure/adjustment in the future. Other commenters, however, believe that reporting comorbidities on the 72x claim could be a huge administrative burden for facilities, including time associated with validating that the data they submit on these claims is valid.

Response: We recognize that reporting co-morbidities on 72x claims could be burdensome to some facilities. We believe, however, that this information is valuable, specifically in the context of future measure development. We will continue to assess the best means available for risk-adjustment for both the SHR and SMR measures, taking both the benefits of the information and the burden to facilities into account, should we propose to adopt these measures in future rulemaking.

Comment: One commenter argued that SHR is not a measure whereby facilities can make meaningful improvement because the measure's rates cannot be calculated in real-time; the commenter asked that claims be made available to the facility in a timely manner if the measure is adopted so that they can become aware of hospitalizations and other co-morbidities and calculate their SHR in real-time.

Response: We will consider this suggestion if we decide to propose to adopt the SHR measure for the ESRD QIP in future rulemaking.

Comment: One commenter noted that the SHR measure should be at least a two to three year measure as 1 year of data is not sufficient for an accurate assessment.

Response: We recognize that the NQF-specifications call for a measurement period that is longer than 1 year, and we continue to assess how to implement such an extended measure period effectively in the ESRD QIP if we propose to adopt the SHR measure in future rulemaking.

Comment: Many commenters opposed the use of SMR in future years for reasons similar to that of SHR. Commenters expressed concern that the measure could lead to cherry-picking and is not transparent enough for facilities to make improvements in this area because of they are confused about the risk-adjustment methodology. Other commenters stated that the measure needs further refinement and validation, specifically regarding risk adjustment for frail patients such as those in nursing homes, cultural factors, socioeconomic factors, and health factors specific to the ESRD population. Commenters asked that these adjusters be made public. One commenter believes that this measure would create a bias for facilities on the basis of location. Another commenter argued that the measure should only account for catheter/dialysis complications and should not include ''sudden deaths.'' One commenter stated that literature suggests that the measure is invalid in small facilities and only valid in large facilities when averaged over several years. Some commenters suggested that, instead of implementing this measure, CMS consider a coordinated care model. Other commenters requested that we adopt a pilot for this measure wherein only aggregate data is reported until the measures can be further assessed and validated.

Response: We thank the commenters who shared concerns and provided suggestions regarding the future consideration of the SMR for implementation in the ESRD QIP. We will continue to consider these suggestions as we decide whether to propose to adopt the SMR measure. In the DFR, we limit reporting to facilities with at least 3 expected events for the time period. Similarly, we only calculated SHR based on at least 5 patient years at risk, which corresponds

to approximately 10 expected hospitalizations. We incorporated these limitations on the measures to account for potentially imprecise estimates resulting from small facility size.

Comment: One commenter stated that the SMR measure should not be adopted until CMS can articulate how it fits into the ESRD QIP's strategic vision.

Response: While we recognize that the ESRD population is at high risk for mortality by definition, we believe that mortality rates are susceptible to the quality of care provided by dialysis facilities. We believe the SMR may help distinguish the quality of care offered by dialysis facilities as determined by mortality, a key health care outcome used to assess quality of care in other settings, such as hospitals. We believe the SMR may also fill an important gap in the ESRD QIP by assessing the outcome of all ESRD care provided at the dialysis facilities, rather than individual processes of care. For these reasons, we will continue to consider the inclusion of the SMR in future rulemaking cycles.

Comment: Many commenters strongly supported the consideration of SMR for future program years, noting that death is the most important measurement of negative outcomes. One commenter requested that we implement the measure as soon as possible. One commenter suggested that the measure specifically focus on patients within their first 90–120 days of dialysis since these patients are generally more likely to die. Commenters also supported reporting measure rates on DFC beginning in CY 2013.

Response: We thank commenters for their support of this measure. At this time, we do not believe it should be included in the PY 2015 ESRD QIP due to the concerns voiced by other commenters. We will consider the measure's assessment of patients in their first months of dialysis for future rulemaking. Finally, we will begin reporting the SMR measure rates on DFC in 2013 and are attempting to address potential shortcomings pointed out by commenters that we described in the CY 2012 ESRD PPS final rule (76 FR 70267) prior to proposing the measure for ESRD QIP.

Comment: One commenter argued that SMR is not a measure whereby facilities can make meaningful improvement because the measure's rates cannot be calculated in real-time; the commenter asked that claims be made available to the facility in a timely manner if the measure is adopted so that they can become aware of hospitalizations and other co-morbidities and may calculate their SMR in real-time.

Response: We will consider this suggestion if we decide to propose to adopt the SMR measure for the ESRD QIP in future rulemaking.

Comment: One commenter noted that the SMR measure should be at least a two to three year measure as 1 year is not sufficient for an accurate assessment.

Response: We recognize that the NQF-specifications call for a measurement period that is longer than 1 year, and we continue to assess how to implement this measurement period effectively in the ESRD QIP if we decide to propose to adopt the SMR measure.

Comment: One commenter requested clarification regarding whether the facility's rates would be compared to current or past national averages when assessing the number of expected deaths.

Response: The SMR measure estimates the relative death rate ratio for a facility, as compared to the national death rate. The relative death rate ratio and the national results are all determined during the same (current) time period.

In response to comments, we will continue to consider the SMR and SHR measures for future years of the program. We will, as proposed, begin displaying the rates/ratios for these measures on DFC beginning in early 2013.

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 patients by ESRD 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 requested comment on these potential areas of future measurement and welcomed suggestions on other topics for measure development.

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

Comment: We received suggestions for many future measures. These included: (i) A CAHPS/experience of care measure for home dialysis and pre-dialysis patients; (ii) a measure assessing catheter access site infections; (iii) a measure for adequate serum albumin; (iv) a measure promoting immunizations; (v) measures assessing iron management; (vi) patient fluid management measures; (vii) measures incentivizing home hemodialysis; (viii) an NHSN measure for home patients that includes peritonitis; (ix) measures that specifically monitor nursing sensitive indicators; (x) a measure that tracks which modalities a facility offers; (xi) a measure that tracks whether a facility exceeds the average percentage of patients between 18 and 54 who are employed; (xii) a measure that tracks whether facilities have shifts after 5:00 p.m.; (xiii) an emergency department use measure; (xiv) a measure on transplantations/referrals; (xv) a measure on dialysis adequacy for frequent dialyzers; (xvi) measures on phosphorus and PTH; (xvii) a composite measure which takes into account the interdependability of calcium, phosphorus, and parathyroid hormone in bone mineral metabolism; (xviii) measures assessing quality of life; and (xix) palliative care measures.

Response: We thank the commenters for your comments regarding measure implementation. We will take these suggestions into consideration during future measure development and rulemaking.

Comment: Some commenters specifically requested that we broaden the use of pediatric measures in the ESRD QIP. These commenters recommended that we (i) develop (a) a dialysis adequacy measure for peritoneal pediatric patients and (b) a CAHPS/experience of care measure for pediatric patients; and (ii) consider the following NQF-endorsed measures: (a) Measure 1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients; (b) Measure 1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients; (c) Measure 1425: Measurement of nPCR for Pediatric Hemodialysis Patients; (d) Measure 1433: Use of Iron Therapy for Pediatric Patients; and (e) 1424: Monthly hemoglobin measurement for Pediatric Patients.

Response: We thank the commenters for suggesting additional measures relevant to the pediatric portion of the ESRD population for future consideration in the ESRD QIP. We recognize the importance of assessing the quality of care furnished to pediatric ESRD patients. To this end, we are adopting in this final rule a measure of pediatric hemodialysis adequacy for PY 2015. We will consider whether it is appropriate to propose to adopt

additional pediatric measures for the ESRD QIP.

Comment: Some commenters specifically discouraged us from considering certain measures for future ESRD QIP adoption. These included (i) a quality of life measure, because no research shows that facilities can improve this aspect of patient life and patients often refuse to take surveys; and (ii) measures on electronic information exchange because it is unclear what these measures would entail or how they could be carried-out.

Response: We appreciate the comments and will take them into consideration during future measure development.

Comment: Many commenters supported a measure on transfusions if this measure assessed transfusions that are within the control of ESRD facilities. One commenter suggested that, before the measure is adopted, we wait to see the results of studies looking at when transfusions are and are not within a facility's control. One commenter requested clarification regarding where CMS accesses transfusion data, whether the information shows the underlying reason for the transfusion, and the timeframe for CMS' access and analysis of the data.

Response: We appreciate the comments and will take them into consideration during future measure development.

Comment: Commenters also discussed the general principles CMS should embrace in future years of the program. Commenters encouraged us to work with the kidney care community to adopt a strategic vision for the ESRD QIP, specifically the criteria and process for the adoption of measures and domains. One commenter requested that CMS and other stakeholders agree on the timeline and process for future measure development. Commenters also urged us to provide the criteria used to select measures, recommending the NQF selection criteria, and engage the Measures Application Partnership in identifying measures to include in the program and their weighting. In selecting measures, commenters stated that every measure should (i) have a verified entity responsible to maintain and update it at least once every three years; and (ii) be fully and clearly specified and tested for reliability and validity. Commenters also recommended that we phase measures into the program, requiring reporting of the measure outside of the ESRD QIP for at least 1year, and once a measure is added, we score facilities based on the lesser of the facility's performance or the national performance rate, at least for the first year. One commenter stated that all future measures should be NQF-endorsed before they are adopted. Another commenter noted that NQF-endorsement does not mean a measure is appropriate for the ESRD QIP.

Response: We remain dedicated to a transparent, consensus-based measure development process that offers multiple opportunities for input from stakeholders. The measure development process that we currently use includes using Technical Expert Panels and public comment periods, seeking NQF endorsement, providing measures to the Measures Application Partnership for feedback, and the rulemaking process in which we respond to stakeholder comments. We encourage continued engagement by the kidney care community in this process, both in prioritizing additional measures, supporting ongoing measure development, and providing feedback for currently implemented measures.

At present, we analyze all clinical measures for validity and reliability, and NQF endorsement is a key consideration we take into account when deciding whether to propose to adopt clinical measures. Where endorsed measures are not available to address key issues relevant to the ESRD population, we intend to consider unendorsed measures until such endorsed measures are available. We agree that clinical measures should be fully specified at the time they are proposed.

We believe that, generally, it is helpful to both the ESRD QIP community and CMS to phase-in measures as the commenter suggests. We do not entirely understand the comment stating that we should score facilities based on the lesser of the facility's performance or the national performance rate. We take this to mean that we should use a scoring methodology similar to PY 2012 and PY 2013 for new measures. At this time, we believe the objectives of the program are best served by scoring facilities using the achievement and improvement scoring methodology for the reasons discussed below.

Comment: Some commenters support additional measures but requested that they be implemented no sooner than PY 2018 since CROWNWeb has just launched and data collection would likely be through CROWNWeb.

Response: We recognize that CROWNWeb is a new data collection system and plan to take that into consideration while developing and implementing ESRD QIP measures in the future.

Comment: In designing future years of the ESRD QIP, commenters urged us to focus on the most important measures because adding measures could dilute each measure's weight in the calculation of the Total Performance Score.

Response: We acknowledge the commenter's concern and note that we will seek to balance appropriateness of the measures, importance of the measures, and parsimony as we consider what measures to implement through future rulemaking.

Comment: Some commenters made broad suggestions about measure adoption in the future, suggesting that we use a phased approach for measure implementation whereby the measures would be reported outside of the ESRD QIP for 1 year prior to adoption of the measure in the ESRD QIP; commenters argued that this reporting period will allow us to set a proper baseline for clinical measures.

Response: We thank commenters for their suggestions. In general, we seek to collect at least 1 year of data through claims or CROWNWeb before adopting a measure for the ESRD QIP. However, we make this assessment on a case-by-case basis because of the importance of timely implementation of some measures (for example, measures that directly affect patient safety). We will continue to consider these issues as the ESRD QIP evolves.

Comment: One commenter encouraged us to improve the program by maintaining a reasonable number of measures in order to reduce administrative costs and publicly reporting quality measures on DFC.

Response: As the ESRD QIP evolves from year-to-year, we seek to continuously evaluate the effectiveness of the measure set, burden to providers, and clarity for beneficiaries.

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 the ESRD QIP, and we requested comment regarding our use of such a measure in future payment years.

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

Comment: Commenters made many suggestions with regard to a 30-Day Readmissions measure. Some commenters did not support the adoption of this measure for the ESRD QIP, arguing that facilities cannot always control hospitalization, and suggested that facilities would be better suited to use this type of measure in a coordinated care setting. One commenter encouraged us to adopt this measure in place of an SHR measure because a 30-Day Readmission measure is more likely to increase care coordination and less likely to encourage cherry-picking. One commenter suggested that a 30-Day Readmission measure include a grace period of 10–14 days for which the facility would not be held responsible, preventing facilities from being penalized if the patient received low-quality care in the hospital, and limiting the possibility that facilities could turn away patients who have recently been hospitalized. This commenter also pointed out that the hospital 30-Day Readmissions measure does not include ESRD patients and argued that hospitals should be held responsible for readmissions during the grace period the commenter suggests. One commenter requested that the community be able to review the findings of the Hospitalization TEP that CMS held in May 2012 before this type of measure is adopted.

Response: We appreciate the comments regarding our consideration of a 30-day readmission measure and will take them into consideration in future rulemaking. We note that it is our policy to make publicly available the results of measure development TEPs through *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html.*

b. Efficiency

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

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

Comment: We received many comments regarding our proposal of developing and adopting an efficiency measure in future years. Several commenters noted that an efficiency measure is not necessary because of the bundled payment. Many commenters asked that, if such a measure is developed, it be case-mix adjusted for nursing home residents, homeless patients, and drug and alcohol abuse to discourage cherry-picking. One commenter cautioned us to explore the unintended consequences which may result from this measure, and another commenter requested that we engage in more studies defining ''efficiency'' before we adopt a measure.

Response: We thank our commenters for their input regarding the consideration of an efficiency measure for implementation in the ESRD QIP. We will take these suggestions into account as we develop measures for future years of the ESRD QIP.

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 requested comment on developing such a measure or adjustments to measures, specifically with regard to access to care issues.

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

Comment: Many commenters provided feedback on a possible access to care measure. Some commenters encouraged the development of such measures. Many of these commenters suggested that, instead of creating a measure to assess access to care, we develop comorbidity adjustments for quality measures that would ease facilities' concerns about treating these patients. Commenters who serve aging patients with multiple comorbidities believe there needs to be further consideration for facilities caring for these types of patient populations. Other commenters noted that present and future measures should exclude homeless patients, nursing home patients, and patients with comorbidities of drug/alcohol abuse and mental health issues to protect access to care for these patients. Several commenters believe that care coordination is important but is not practical due to data timing issues and knowledge of staff; these commenters suggested that CMS fund additional staff and technology prior to implementing care coordination measures. One commenter suggested that we analyze the following factors when assessing access to care: (i) Miles traveled to facility; (ii) time required to commute to facility; and (iii) method of transportation/responsible party.

Response: We thank the commenters for expressing interest in addressing the issue of access to care. We are sensitive to the particular role access to care can play for ESRD patients, and the limitations encountered in collecting relevant data. Clinical measures assessing mortality and hospitalization in the ESRD population were proposed in the PY 2014 ESRD QIP, and we have incorporated risk adjustment for comorbidities in the specifications for these measures, but it is not clear to us how effectively this risk-adjustment can address problems with access. Factors such as distance traveled are not captured by claims data. We believe that exclusion of the suggested groups (homeless, nursing home patients, etc.) from quality measures may protect access for these groups, but would fail to adequately address issues for quality of care in those patients who are most at risk for poor health outcomes. We are also concerned that such exclusions may excuse facilities from taking steps toward more effective coordination of care. We respectfully disagree that care coordination is not practical. Rather, we believe it is a vital element of care for a population that is by definition at particular risk for transitions into and out of care settings such as acute care hospitals. It is particularly important for those patients who reside in long-term care facilities such as nursing homes, or who must seek care for chronic conditions related to mental health issues or drug/alcohol abuse to receive care that is coordinated since these individuals often receive extensive care from various types of providers.

6. Scoring Background and General Considerations 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 in the proposed rule (77 FR 40976), we proposed to adopt a scoring methodology for the PY 2015 ESRD QIP that is nearly identical to the PY 2014 ESRD QIP.

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

Comment: Several commenters supported our proposal to use the PY 2014 scoring methodology in the PY 2015 ESRD QIP.

Response: We thank commenters for their support. We will finalize our proposals to use the PY 2014 scoring methodology for use in the PY 2015 program with the modifications discussed below. We believe that these modifications improve the efficacy of the program for the reasons discussed.

7. 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 allow facilities a period of time to preview and ask questions regarding these scores before they are published and impact payment. We 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 proposed to establish CY 2013 as the performance period for all of the measures. We requested comments on this proposal.

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

Comment: Commenters supported our proposal to use CY 2013 as the performance period for the PY 2015 ESRD QIP; some commenters specifically supported a performance period that allows us to set standards before the performance period begins. Some commenters, while supporting this performance period, cautioned us against using data from CROWNWeb from this period since CY 2013 will be the first full year CROWNWeb is implemented.

Response: We thank commenters for their support. We note that, because we are not finalizing the Hypercalcemia measure, we are no longer using data from CROWNWeb for purposes of scoring any clinical measure for the PY 2015 ESRD QIP. For purposes of the PY 2015 ESRD QIP, we will be using CROWNWeb to collect data only for the Mineral Metabolism reporting measure. We believe that this is appropriate since facilities will only be required to report data, but will not be scored based on these data for PY 2015. We believe that CROWNWeb is sufficiently implemented to allow successful reporting for CY 2013. We will continue to assess the appropriateness of CROWNWeb data for inclusion for purposes of clinical measures in the ESRD QIP.

Comment: Many commenters asked us to shorten the data lag between the performance period and the payment reduction/public reporting of the data so that the data can remain relevant. Commenters suggested that CROWNWeb could be used to reduce these data lag.

Response: For PY 2015, we have determined that data derived from claims is the most appropriate source on which to score facilities on clinical measures because this source is the most complete and representative of the greatest number of facilities. Because claims take more time to compile and calculate than other data sources to ensure reliability, there is a lag between the time when the claims are submitted for processing and the time that the claims become available to calculate ESRD QIP measure rates. We also believe it is important to allow facilities a period of time to review their scores before the payment adjustments take place. We are considering how we might be able to shorten this timeline in the future. We believe that CROWNWeb will be valuable in this effort once it has been successfully launched for a period of time, and we are confident that the data submission and validity issues have been resolved.

Comment: One commenter suggested that we consider employing rolling 12-month performance periods with payment updated quarterly.

Response: At this time, we are not able to implement a rolling 12-month performance period that is updated on a quarterly basis because we do not have the systems or resources in place to calculate scores, answer inquiries, and provide Performance Score Certificates more than once per year. We will, however, continue to consider this suggestion as the ESRD QIP evolves.

For the reasons stated above, we finalize CY 2013 as the performance period for the PY 2015 ESRD QIP as proposed.

8. Performance Standards for the PY 2015 ESRD QIP

Similar to the PY 2014 ESRD QIP, we proposed 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. Clinical Measure Performance Standards

With respect to the seven proposed clinical measures, we proposed 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 proposed to set the performance standards based on the national performance rate (that is, the 50th percentile) of facility performance in CY 2011. We noted that 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 stated our concern 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 recognized that stakeholders might prefer that we base performance standards on data as close in time to PY 2015 as possible.

We stated that 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 proposed CY 2011 as the basis for the performance standards (that is, the national performance rates). We did, 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 noted that we do not possess data for the entirety of CY 2011, the year on which we proposed 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 stated that we do have data on which we can base performance standards. We noted that 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 these data via CROWNWeb piloting since July 2008. Additionally, we compared the serum calcium values reported by facilities in 2010 as part of a clinical data reporting program called ELab,[6] to values that have been voluntarily reported by facilities in 2010 through CROWNWeb, and the values are significantly similar. We stated our belief that these similarities will also extend to data reported in 2011. Therefore, we proposed 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 stated in the proposed rule that 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 proposed 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 proposed 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 stated that we understand that stakeholders may be concerned about the nuances of the data and we invited public comment on this proposal.

We noted that if, after consideration of the comments, we decided to not adopt the adult, hemodialysis Kt/V measure for PY 2015, we would continue to use URR as a measure of hemodialysis adequacy for this population. We also noted that the NQF-endorsed measure for Kt/V measure for peritoneal dialysis adequacy does not specify the body surface area formulae or the total body water formulae 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 we solicited comments on the inclusion of the peritoneal dialysis Kt/V adequacy measure. We proposed that, were we to retain the URR measure for adult hemodialysis, we would still adopt the Kt/V peritoneal dialysis measure. We proposed that these measures would still comprise a Dialysis Adequacy measure topic and would be scored in the same manner as we proposed for the Kt/V measures, below.

Even with the challenges outlined above, we believed that the advantages of adopting the Kt/V hemodialysis measure for PY 2015 outweigh the disadvantages. Therefore, we proposed Kt/V as the measure for hemodialysis adequacy for PY 2015, but we specifically solicited comments regarding whether we should continue to use URR for adult hemodialysis patients for PY 2015.[7]

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 proposed to calculate performance standards based

[6] *http://www.esrdnet11.org.*

[7] Note 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 proposed 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.

on the data from CY 2011 discussed above, but we invited comment on an alternative 6 month period beginning on or after the date on which uniform reporting began, January 1, 2012.

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

Comment: Many commenters agreed with our proposal to use CY 2011 as the comparison period for purposes of calculating the performance standards because this period will allow facilities to view these standards when the final rule is published. Others, however, expressed support for using data from July 1, 2011–June 30, 2012 to calculate the performance standards because this period is closest in time to the performance period. Some commenters did not have a preference for the comparison period, but requested that we be consistent in the time periods we choose. Many commenters suggested that, regardless of the time period, we do not use CROWNWeb data to calculate performance standards because the data in CROWNWeb from this time period is largely from large dialysis organizations (LDOs).

Response: Although we appreciate that July 1, 2011–June 30, 2012 is closer in time to the performance period, we believe that it will be more beneficial to facilities if they are familiar with the performance standards against which their performance will be evaluated before the performance period begins. We will continue to evaluate whether it will be feasible in the future to adopt performance standards using data from a period closer in time to the performance period and also make those standards public before the beginning of the performance period. Additionally, as we stated above, we will not be finalizing the Hypercalcemia measure for PY 2015. All of the other clinical measures we are adopting for PY 2015 are claims-based, and we can set the performance standards for those measures without using CROWNWeb data.

Comment: One commenter expressed concern that the standards are too rigid and we expect perfection.

Response: We believe that the standards that we are setting are appropriate. It is the past performance of facilities nationally which determine the performance standards; thus, ESRD facilities have demonstrated their ability to achieve these standards. Additionally, to avoid a payment reduction, facilities need only meet the minimum Total Performance Score. As discussed below, a facility need not have a perfect score on all, or any, of the measures to meet this minimum. Furthermore, we believe it is important to incentivize the best care possible.

For these reasons, we finalize our proposal to establish performance standards for the PY 2015 ESRD QIP clinical measures at the 50th percentile of national performance during CY 2011. The numerical values for the performance standards are set forth below in Table 5.

b. Performance Standards

TABLE 5—FINALIZED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2015 ESRD QIP CLINICAL MEASURES

Measure	Performance standard %
Hemoglobin > 12 g/dL	1
Vascular Access Type	.....
% Fistula	60
% Catheter	13
Kt/V	.....
Adult Hemodialysis	93
Adult, Peritoneal Dialysis ..	84
Pediatric Hemodialysis	93

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 proposed to substitute the PY 2014 performance standard for that measure. We stated our belief that the ESRD QIP should not have lower standards than previous years. We requested comments on this proposal.

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

Comment: One commenter did not support our proposal to keep performance standards at least as high as they were the previous year and suggests that we, instead, investigate why a performance standard would drop. Another commenter agreed with our proposal and stated that the only reason that performance standards should be lower than they were the previous year is if we discover a major technical issue with the previous year's standards, such as that the performance standards were miscalculated.

Response: We believe it is important to encourage improvement as the ESRD QIP evolves to ensure that beneficiaries continue to receive quality care at achievable levels. Therefore, we will finalize our proposal to utilize previous years' performance standards if they are higher than those of the next year. The performance standards for the measures used in previous years of the ESRD QIP (the Hemoglobin Greater than 12 g/dL measure and the Vascular Access Type measure topic) have not declined. Therefore, for PY 2015, we will use the performance standards in the above table. If we discover that performance on any of the measures is declining in future years, we also intend to investigate the precipitating causes and modify the ESRD QIP as necessary to ensure high quality care for beneficiaries.

c. Performance Standards for the 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 proposed 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 proposed that this attestation must be completed in CROWNWeb by January 31, 2014.

For the NHSN Dialysis Event reporting measure, we proposed 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 proposed that the performance standard for that facility would also include completion of these requirements.

For the Mineral Metabolism reporting measure, we proposed to set the performance standard as successfully reporting serum phosphorus and calcium values for all qualified patients for 12 months.

For the Anemia Management reporting measure we proposed to set the performance standard as successfully reporting hemoglobin or hematocrit and ESA dosage (if applicable) for all qualified patients for 12 months.

We requested comment on these proposals. We did not receive any comments on these proposals. We will, therefore, finalize the reporting measure performance standards as proposed.

9. Scoring for the PY 2015 ESRD QIP 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 proposed to use a similar methodology for purposes of scoring facility 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 proposed 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 proposed to define the achievement threshold for each of the proposed clinical measures as the 15th percentile of national facility performance during CY 2011. We stated our belief 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 proposed 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 proposed that, for the proposed Kt/V Dialysis Adequacy measures and the proposed Hypercalcemia measure, we would use the same data we proposed above to calculate the performance standards for purposes of calculating the achievement thresholds and the benchmarks for these measures. We requested comment on these proposals.

In determining an improvement score for the clinical measures, we proposed that facilities would receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed 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 proposed to base the improvement threshold on data from CY 2012 rather than CY 2011 (the period of time we had proposed to use to calculate the performance standards, achievement thresholds, and benchmarks) because, as we explained 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. Rather than proposing to adopt a policy under which no facility could receive an improvement score on these measures, we proposed to use data from CY 2012 to calculate the improvement thresholds. Additionally, we stated our belief that 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. We requested 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 to not 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 proposed to calculate improvement thresholds based on data from CY 2012, we also requested comment regarding use of these alternative periods for purposes of calculating the improvement thresholds.

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

Comment: One commenter stated that, to foster continued improvement, we should consider raising the achievement threshold over time to a level greater than 15 percent.

Response: We believe that, at this time, it is appropriate to set the achievement threshold at the 15th percentile so that lower-performing facilities are incentivized to provide high quality care; if the thresholds are set too high, it is possible that a facility would not be incentivized to perform well because the cost to meet the achievement threshold would be so high that it would outweigh the overall loss of revenue resulting from the ESRD QIP payment reduction. Although we do not believe we should award low-performing facilities a large number of points, we do believe it is important to set the standards to incentivize all facilities to perform better.

Comment: One commenter suggested that we rename the achievement threshold the ''Statistical Performance Floor'' because ''achievement'' seems misleading if the floor is set at the 15th percentile. This commenter also recommended that the facility performance rate be renamed the ''Facility's Current Year Performance Rate,'' the benchmark be renamed the ''Exceptional Performance Rate'' since it is at the 90th percentile, and the performance standard be renamed the ''National Average/Median Performance Rate in the Base Year.''

Response: One of the ways we can make the ESRD QIP transparent is by seeking to achieve consistency from year-to-year, provided there is not a contravening interest. Changing the terminology of the achievement threshold, performance rate, performance standards, and benchmark could unnecessarily confuse both facilities and beneficiaries. Additionally, we seek to harmonize CMS' value-based purchasing programs as much as possible, and we use these naming conventions across programs.

Comment: Several commenters argued that we are creating inconsistencies between the Conditions for Coverage (CfCs) and the ESRD QIP; these commenters specifically argued that the CfCs state that a facility cannot be penalized for patient non-compliance, but many of the ESRD QIP measures effectively penalize facilities for patient non-compliance. The commenter suggested that we make allowances for patient noncompliance in the ESRD QIP's design; one commenter specifically recommended that we should require only 90 percent compliance from patients that visit the facility at least seven times per month to reconcile the CfCs and the ESRD QIP.

Response: We do not believe that we are creating inconsistencies between the CfCs and the ESRD QIP, nor do we believe that the ESRD QIP penalizes facilities for patient non-compliance. Although patients' compliance with the plan of care is a factor in some of the

measures, the quality of care is largely controlled by the facility's treatment of patients. Additionally, to the extent that patient non-compliance may be a factor, facilities are not required to obtain perfect results for every patient. To avoid a payment reduction, as we explain below, a facility need only meet the performance standards (that is, the 50th percentile of national performance) for each clinical measure during the comparison period (for PY 2015, this will be CY 2011) and score half of the possible points for the reporting measures.

Comment: Commenters agreed with our proposal to use the facility's rate in CY 2012 to calculate improvement thresholds.

Response: We thank the commenters for their support.

Comment: One commenter suggested that the improvement threshold be renamed the ''Facility's Base Year Performance Rate'' since the improvement threshold does not represent a gain or level of improvement.

Response: As noted above, we believe it is important to use consistent terminology from year-to-year to ensure transparency and comprehension in both the ESRD QIP and across CMS' VBP programs.

For the reasons discussed above, we finalize our proposed definitions of the achievement thresholds, benchmarks, and improvement thresholds. We have calculated the numerical values for the achievement threshold and benchmarks based on data from CY 2011; we will calculate the numerical values for the improvement thresholds based on individual facilities' data from CY 2012. The numerical values for the achievement thresholds and benchmarks for the PY 2015 ESRD QIP clinical measures are set forth below in Table 6.

TABLE 6—FINALIZED NUMERICAL VALUES OF ACHIEVEMENT THRESHOLDS AND BENCHMARKS FOR THE PY 2015 ESRD QIP CLINICAL MEASURES

Measure	Achievement threshold (percent)	Benchmark (percent)
Hemoglobin > 12 g/dL	5	0
Vascular Access Type:		
% Fistula	47	75
% Catheter	22	5
Kt/V:		
Adult Hemodialysis	86	97
Adult, Peritoneal Dialysis	63	94
Pediatric Hemodialysis	83	97

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 proposed 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 requested comments on this proposal.

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

Comment: One commenter did not support our proposal to keep achievement thresholds and benchmarks at least as high as they were the previous year and suggests that we, instead, investigate why these values would drop. Another commenter agreed with our proposal and stated that the only reason that performance standards should be lower than they were the previous year is if we discover a major technical issue with the previous year's standards, such as that the performance standards were miscalculated.

Response: We believe it is important to encourage improvement as the ESRD QIP evolves to ensure that beneficiaries continue to receive quality care at achievable levels. Therefore, we will finalize our proposal to utilize previous years' achievement threshold and benchmarks if they are higher than those of the next year. The achievement thresholds and benchmarks for the measures used in previous years of the ESRD QIP (the Hemoglobin Greater than 12 g/dL measure and the Vascular Access Type measure topic) have not declined. Therefore, for PY 2015, we will use the performance standards in the above table. If we discover that performance on any of the measures is declining in future years, we also intend to investigate the precipitating causes and modify the ESRD QIP as necessary to ensure high quality care for beneficiaries.

a. Scoring Facility Performance on Clinical Measures Based on Achievement

We proposed to award between 0 and 10 points for each of the clinical measures. As noted, we proposed 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 proposed to base the score on where a facility's performance falls relative to the achievement threshold and the benchmark for that measure. We proposed 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 * ((Facility's performance period rate—achievement threshold)/(benchmark—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. Scoring Facility Performance on Clinical Measures Based on Improvement

We proposed 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 proposed 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 * ((Facility performance period rate—Improvement threshold)/(Benchmark—Improvement threshold))]—.5, with all scores rounded to the nearest integer, with half rounded up.

We note that if the facility's score is equal to or greater than the benchmark, it would receive 10 points on the measure per the achievement score methodology discussed above.

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

Comment: One commenter requested clarification on whether (i) a facility can earn points if its performance rate is below the improvement threshold but above the achievement threshold and (ii) a facility can earn points if its performance rate is below the achievement threshold but above the improvement threshold. A commenter also requested clarification regarding whether, when scoring improvement, we multiply the ((Facility performance period rate—Improvement threshold)/(Benchmark—Improvement threshold))] by 10 before or after we subtract 0.5. Likewise, this commenter requested clarification for the achievement scoring on whether we multiply the ((Facility's performance period rate—achievement threshold)/(benchmark—achievement threshold))] by 9 before or after we add 0.5.

Response: It is possible for a facility to earn achievement points even if that facility did not improve during the performance period as long as that facility's performance period rate exceeds the improvement threshold. Likewise, a facility can earn improvement points even if its measure rate during the performance period is below the achievement threshold provided that facility improved during the performance period. Additionally, the 0.5 is added or subtracted, for achievement and improvement respectively, as the last step in the equations.

For the reasons stated above, we will finalize the proposed methodology for scoring measures on achievement and improvement.

c. 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 the measures. The criteria that would apply to each reporting measure are discussed below.

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

(i) 0 points for meeting the reporting requirements for less than 6-consecutive months during the performance period;

(ii) 5 points for meeting the reporting requirements for at least 6-consecutive months during the performance period; and

(iii) 10 points for meeting the reporting requirements for all 12 months of 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, therefore, 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 requested comment regarding whether the proposed 6-consecutive month reporting requirement will improve quality more than a non-consecutive month reporting requirement. We also proposed, 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 proposed 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 proposed 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 proposed 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 proposed that the facility would be required to comply with the ICH CAHPS reporting measure.

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

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

Comment: Several commenters requested that we award points for partial or non-consecutive reporting of data. Other commenters recommended that we modify our scoring of the NHSN Dialysis Event, Anemia Management, and Mineral Metabolism reporting measures to allow facilities to gain points for non-consecutive reporting on a point scale of 0–10. Commenters suggested that two should be subtracted from the number of months for which the dialysis facility successfully meets the reporting requirements (rounding negative scores to zero), meaning that a facility would have to report two months of data before receiving points on the measure. Commenters argued that this approach will encourage facilities to consistently report even if consecutive reporting is not possible. One commenter argued that facilities should be required to report for all months in order to receive any points on this measure; alternatively, this commenter urged us to require facilities to report consecutive months of data.

Response: We thank commenters for these suggestions. The NHSN participation requirements state that facilities must report at least 6 months of data during a calendar year to the

dialysis event module to maintain active status in the NHSN. We believe it is important to align the scoring requirements for the NHSN dialysis event reporting measure for the ESRD QIP with the NHSN requirements, which are intended to improve the quality of the data submitted to the NHSN. Furthermore, we believe the severity of bloodstream infections and other vascular access-related infections among dialysis patients warrants more extensive monitoring in order to prevent future events. We will, therefore, require a minimum of 6 months of NHSN Dialysis Event reporting before awarding facilities points. We believe that facilities should receive credit for reporting non-consecutive months for this measure; we agree with commenters that this approach will encourage reporting because, even if a facility misses a month or many months, it can still receive points on the measure. Additionally, NHSN requirements allow non-consecutive reporting, but strongly encourage regular monthly reporting. We also agree with the commenters who stated that facilities should be awarded points on an incremental scale to incentivize reporting as much as possible. Therefore, we will begin awarding points for 6 months of reporting, and will not require consecutive monthly reporting during the performance period. Additionally, we will award incremental points for reporting more than 6 months of data. We will award points to facilities as follows:

(i) 0 points for reporting less than 6 months of data;

(ii) 5 points for reporting 6 months of data; and

(iii) 10 points for reporting 12 months of data.

(iv) If the facility reports more than 6 but less than 12 months of data, we will award incremental points using the following formula:

$$\frac{\text{Number of Months Facility Successfully Reports}}{12} \times 10$$

We will round the result of this formula (with half rounded up) to generate a measure score from 5–10 points; as noted, facilities will earn points for reporting non-consecutive months.

As we discuss below, because of the time it takes to train and enroll in the NHSN Dialysis Event module, we do not believe that it is feasible for all facilities receiving a CCN in the performance period to report at least 6 months of data. We will not apply the 6 month minimum requirement on these newly opened facilities, as we believe this requirement would place significant undue burden on these facilities to report data during their initial year of operation starting up their care delivery and administration. Therefore, the NHSN Dialysis Event reporting measure will not apply to any facility receiving a CCN on or after January 1, 2013.

For the Mineral Metabolism and Anemia Management reporting measures, we believe that it is beneficial to encourage less than 6 months of reporting so that we can receive data from as many facilities as possible and use this data to develop a robust clinical measure in these areas. We believe that the Anemia Management and Mineral Metabolism reporting measures should also allow facilities to receive credit for reporting non-consecutive months because we believe that this approach will encourage reporting even if a facility fails to report for a month or more. We agree with commenters that a facility should be required to report at least two months before it is awarded points. Two months of reporting translates to reporting at a rate roughly equal to our achievement threshold for clinical measures—15 percent. We have determined that this threshold is an appropriate marker for where a facility should start earning achievement points on the clinical measures, and we believe it should also apply to these reporting measures. Additionally, as we discuss below, we will apply the scoring methodology for the Anemia Management and Mineral Metabolism reporting measures to facilities that receive a CCN during the first 6 months of the performance period. Taking all of these elements into consideration, we are finalizing a scoring methodology that will allow facilities to score points on the Mineral Metabolism and Anemia Management reporting measures provided that they receive a CCN before July 1, 2013. In order to score above a zero on these measures, a facility must report at least three months of data.

Therefore, we finalize that facilities receiving a CCN before July 1, 2013 will score 0–10 points on the Anemia Management and Mineral Metabolism reporting measures using the following formula:

$$\left(\frac{\text{Number of Months Facility Successfully Reports}}{\text{Number of Months in the Performance Period Facility has CCN}} \times 12\right) - 2$$

We will round the result of this formula (with half rounded up) to generate a measure score from 0–10, and we will allow facilities to earn points using the same formula for reporting non-consecutive months.

Additionally, we finalize the ICH CAHPS measure scoring as proposed.

10. 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 had proposed to include in the PY 2015 ESRD QIP as well as the National Quality Strategy priorities.

a. 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 proposed 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 proposed 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 proposed 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 stated that 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 proposed 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 proposals to calculate measure topic scores, we provided 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 50/60; assume that this rate leads to a score of 6. For PD patients, Facility Y's Kt/V measure rate is 4/7. 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 requested comment on the proposed method of weighting individual measure scores to derive a measure topic score.

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

Comment: Some commenters supported our proposals for weighting measure topics. Some commenters, however, raised concerns that, given the small number of pediatric patients relative to adult patients, combining the adequacy measures might result in a score that does not accurately reflect the quality of care provided to pediatric patients treated in adult dialysis facilities. Other commenters suggested that the measure topics should be weighted consistently across facilities to allow meaningful comparisons between facilities; these commenters requested that we modify the weighting so that each measure is weighted based on clinical relevance, importance, and the number of patients in a ''typical'' facility's population.

Response: We disagree with the commenters' statement that combining the adequacy measures might not reflect the quality of care given to certain patients. The weighting scheme ensures that emphasis on each measure in the Kt/V measure topic is proportionate to the number of patients that facility treats. If we were to weight the measure topics consistently across facilities or base the weight on clinical relevance or the typical facility, the scoring methodology would not equally weight the quality of care provided to each, individual patient. That is, one patient's results could count for more points than another patient's results, perhaps incentivizing better care for only certain ESRD populations. It is the goal of the ESRD QIP to provide the best care for every patient, and we believe the proposed weighting for measure topics meets this goal. Therefore, we are finalizing the methodology of weighting measure topics as proposed.

b. Weighting the Total Performance Score

In the proposed rule we stated our belief 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 stated our belief that, while the reporting measures are valuable, the clinical measures value actual patient outcomes and therefore justify a higher combined weight. We did, 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 proposed 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 proposed to equally weight the reporting measures for which a facility receives a score as 20 percent of the Total Performance Score. We requested 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 did, however, revisit our policy of including any facility that receives a score on one measure, whether that measure is a clinical or reporting measure, and we proposed a different approach for PY 2015. We stated our belief that 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 discussed below) from the performance period, but lacks sufficient data (11 cases, as discussed below) to calculate the improvement threshold, we proposed to only calculate its achievement score, because it would not be possible to calculate its improvement score. We requested 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 proposed that all Total Performance Scores be rounded to the nearest integer, with half being rounded up, and we requested comment on this proposal. For further examples regarding the proposed measure and Total Performance Score calculations, we refer readers to the figures below.

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

Comment: Many commenters supported our proposed scoring methodology. Commenters specifically supported our proposal to require a facility to have a score for both a clinical and a reporting measure to receive a Total Performance Score. One commenter stated that, because of the importance of preventing HAIs, we should weight the reporting measures at 50 percent of the Total Performance Score. Some commenters stated their belief that we should maintain the 90/10 Total Performance Score weighting because clinical outcomes are more important than simply tracking and relaying information.

Response: We believe, at this time, that it is appropriate to weight all of the clinical measures topics equally and all of the reporting measures equally in order to equally incentivize quality in all of these areas of care. We do, however, agree with the commenter that noted that because of the importance of reporting measures, such the NHSN Dialysis Event measure which tracks HAIs, we should give greater weight to the reporting measures in calculating the Total Performance Score. As stated above, we are not finalizing the Hypercalcemia clinical measure due to our lack of consistent baseline data. Instead, we will collect calcium data through the Mineral Metabolism reporting measure until we have baseline data that is robust enough to support a clinical measure's adoption. Because of our need to collect data from not only LDOs, as we did in the CROWNWeb pilot, but all types of dialysis facilities, our decision to not finalize the Hypercalcemia measure, and the importance of collecting HAI data through the NHSN Dialysis Event reporting measure, we believe it is appropriate to weight the reporting measures more than we had proposed. We continue to believe, however, that clinical outcomes should constitute the majority of the Total Performance Score. Therefore, we finalize that, for the PY 2015 ESRD QIP, each clinical measure/measure topic will be equally weighted to comprise 75 percent of the Total Performance Score, and the reporting measures will be equally weighted to comprise 25 percent of the Total Performance Score.

c. Examples of the PY 2015 ESRD QIP Scoring Methodology

Below, we provide examples to illustrate the scoring methodology for the PY 2015 ESRD QIP. 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

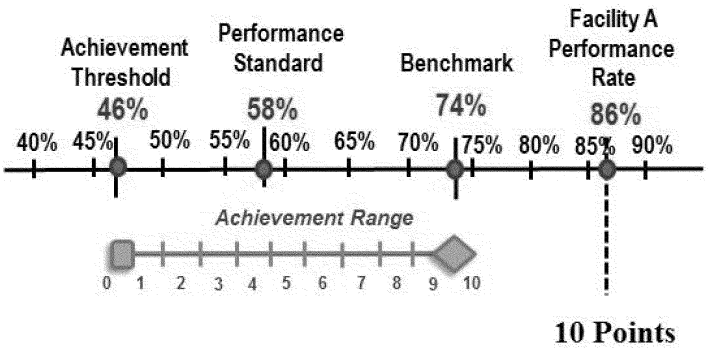
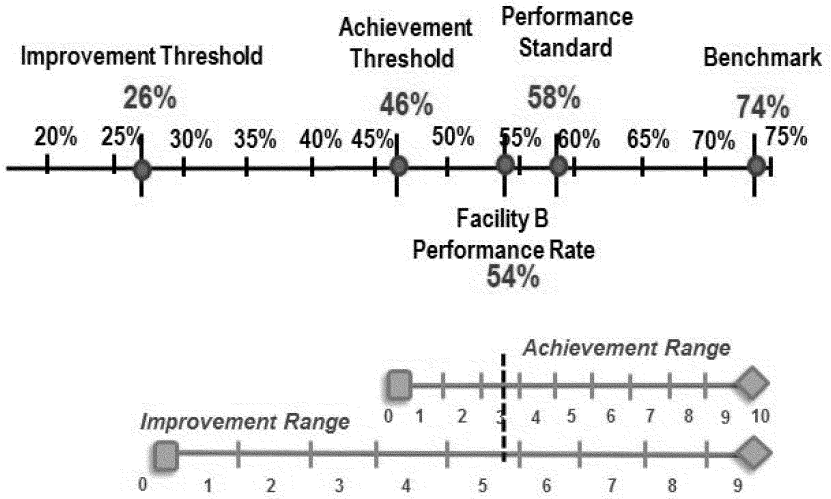


Figure 2 shows the scoring for another facility, Facility B. As illustrated below, the facility's performance on the example clinical measure improved from 26 percent in CY 2012 to 54 percent during the performance period. The achievement threshold is 46 percent, the performance standard is 58 percent, 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.

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

The result of this formula for this example is [9 * ((54 − 46)/(74 − 46))] + .5, which equals 3.07 and we round to 3.

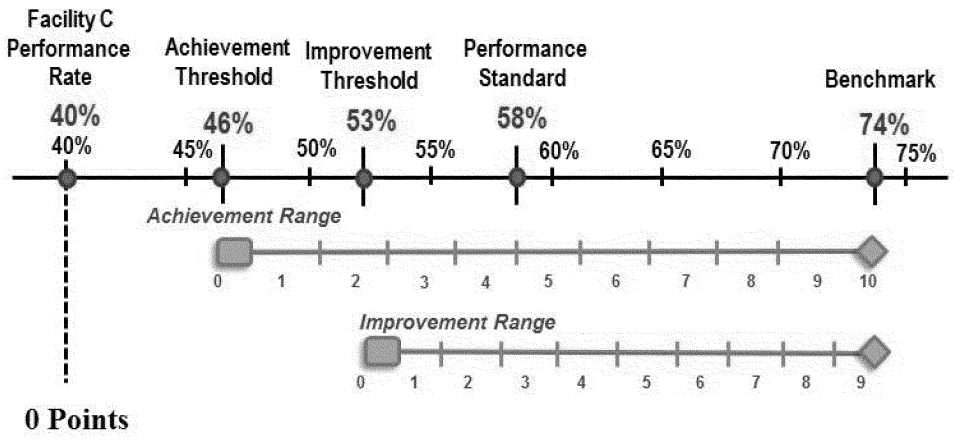
Likewise, to calculate the improvement score, we employ the improvement formula discussed above.

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

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 improvement threshold (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 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:

Total Performance Score = [(.25 * Hemoglobin Greater Than 12g/dL Measure) + (.25 * Kt/V Dialysis Adequacy Measure Topic) + (.25 * Vascular Access Type Measure Topic) + (..0625 * NHSN Dialysis Event Reporting Measure) + (.0625 * ICH CAHPS Survey Reporting Measure) + (.0625 * Mineral Metabolism Reporting Measure) + (.0625 * 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 Vascular Access Type measure topic, the facility's Total Performance Score would be calculated as follows:

Total Performance Score = [(.375 * Hemoglobin Greater Than 12g/dL Measure) + (.375 * Kt/V Dialysis Adequacy Measure Topic) + (.0625 * NHSN Dialysis Event Reporting Measure) + (.0625 * ICH CAHPS Survey Reporting Measure) + (.0625 * Mineral Metabolism Reporting Measure) + (.0625 * 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:

Total Performance Score = [(.25 * Hemoglobin Greater Than 12g/dL Measure) + (.25 * Kt/V Dialysis Adequacy Measure Topic) + (.25 * Vascular Access Type Measure Topic) + (.125 * Mineral Metabolism Reporting Measure) + (.125 * 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. Minimum Data for Scoring Measures for the PY 2015 ESRD QIP

We proposed to only score facilities on clinical measures for which they have a minimum number of cases during the performance period. We assessed how reliable each 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 proposed 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. Minimum Data for Scoring Clinical 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 developed and proposed a new methodology to make favorable adjustments to the clinical measure rates of facilities with very small numbers of patients. We also proposed a case minimum [8] for clinical measures to protect patient privacy, which we believe could be compromised if the

[8] For clarification purposes, as in previous years, a ''case'' refers to a patient that is included in the measure.

publicly reported data for a facility is based on a small patient population.

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 proposed 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 sought public comment on this proposal.

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 developed and proposed 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, we proposed that if a facility reports at least 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 proposed 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 proposed 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

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

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

- $\text{Let } w_i = 1 - \frac{n_i}{c} \text{ if } n_i < C, \text{ and } w_i = 0 \text{ if } n_i \geq C,$

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 (that is, for the PY 2015 ESRD QIP, the fistula measure and the Kt/V Dialysis Adequacy measure topic):

o 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 (that is, for the PY 2015 ESRD QIP, the Hemoglobin Greater Than 12g/dL and catheter measures):

o The new score is: $t_i = x_i - w_i * SE(x_i)$. (If $t_i < 0\%$, we set $t_i = 0\%$).

We stated our belief that 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 sought public comment on this methodology and the proposed adjustment threshold. While one model is presented above, we invited 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 stated our belief 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 noted that we will continue to assess reliability based on the measures and scoring methodology for that payment year.

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

Comment: Many commenters supported our proposal to use an adjustment for measure rates, especially because aging patients and patients with comorbidities can negatively affect a small facility's score. Commenters also supported our proposal to use the adjuster for measures with 11–25 cases. Other commenters did not support the proposed adjustment because it is overly complicated, could mislead patients, and could make low-volume facilities appear better than high-volume facilities when they are not, in fact; these commenters suggested that we raise the case minimum to at least 25 cases instead of employing the proposed adjustment methodology. Some commenters expressly stated that the proposed case minimum is not sufficient; other commenters argued that the proposed case minimum should be lowered because the proposal could preclude participation from many low-volume facilities, specifically pediatric facilities.

Response: Were we to set the case minimum at 26 rather than 11, we estimate that an additional 520, or an additional 10 percent of, facilities would be excluded from the program. Although lowering the case minimum would include even more facilities, we do not believe it is appropriate to do so because of not only reliability but also privacy concerns. As we stated in the proposed rule (77 FR 40984), we believe the adjustment balances the competing concerns of reliability, privacy, and inclusion.

Although it can be difficult to understand the adjustment methodology, we do not believe that this concern alone should prevent us from finalizing it as proposed. The adjustment will result in no harm to any facility; although a facility may not be able to predict its Total Performance Score if some of its measures are subject to the adjustment, the facility will know that the adjuster will not negatively affect its score. It could continue to predict its minimum score and use this score as a baseline for assessing whether or not it will receive a payment reduction. Additionally, we believe that the argument that the adjuster could allow smaller facilities to seem better than they are is of little concern. Although the adjuster will affect the measure score, it will not affect the measure rate. The rates that are displayed to the public will be shown without an adjustment. Thus, a beneficiary could continue to meaningfully compare facilities, regardless of the number of patients these facilities serve.

Comment: Some commenters requested that, if we adopted the proposed adjustment, we publish tables with the values of *sw* to make the ESRD QIP as transparent and predictable as possible.

Response: The *sw* values represent the within facility variation. It is specific to each facility and, because it will be based on 2013 data, it cannot be derived until the end of the performance period. Therefore, we are not able to publish the *sw* values at this time.

Comment: Some commenters encouraged us to continue to conduct analyses to determine the appropriate reliability of measures and the minimum case number for future years of the program. Some commenters suggested that, if we are concerned with reliability and minimum case numbers, we employ longer performance periods spanning multiple years. Commenters also encouraged us to align the ESRD QIP minimum case number with other VBP programs.

Response: We will continue to study the reliability of measures and the Total Performance Score. We have and will continue to consider using longer performance periods on a measure-by-measure basis. Although we strive to align the VBP programs as much as possible, each program has unique measures which may necessitate different minimum case numbers. We will continue to look for harmonization as much as is appropriate.

For the reasons stated above, we finalize the case minimum and adjustment for clinical measures as proposed.

b. 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 proposed to modify the reporting measure minimum data requirement from that of PY 2014.

For PY 2015, we proposed 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 stated our belief that it is not appropriate to require it to do so in order to receive a full 10 points on the reporting measures. Instead, we proposed 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 proposed 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 proposed 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 proposed to round down to calculate the number of months for which it must report to receive 5 points. Finally, we proposed 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, we proposed that it must report data from April 1, 2013–December 31, 2013 (or 9 months of data). In order for it to receive 5 points, we proposed that it must report half of the months for which it is open, consecutively. For the example facility to receive 5 points, it would need to report 4.5 months of data. Since we proposed to round down, this facility

would be required to report 4 months of data to receive 5 points.

We realized 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 stated our belief that it is appropriate to reduce payment for a 1-year period based on less than 6 months of performance. Therefore, we proposed to exclude facilities receiving a CCN on or after July 1, 2013 from the requirements of the reporting measures. Because we finalized, 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 requested comment regarding these proposals. We also elicited 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.

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

Comment: Commenters supported our proposals regarding the reporting measures' minimum data requirements for new facilities; specifically, commenters supported our proposal to exempt facilities receiving a CCN after June 30, 2013 from the reporting measures. Some commenters suggested that a facility that receives a CCN between January 2013 and June 2013 should be required to begin reporting on the first day of the third month after the facility receives a CCN to allow the facility to deploy its IT system and enroll in CROWNWeb and NHSN.

Response: Consistent with our change to allow facilities to score 0–10 incremental points on the Anemia Management and Mineral Metabolism reporting measures, we will finalize changes to our proposed scoring methodology for these measures for facilities receiving a CCN between January 1, 2013 and June 30, 2013. Facilities receiving a CCN between January 1, 2013 and June 30, 2013, will be able to score points in proportion to their overall rate of monthly reporting on the Anemia Management and Mineral Metabolism reporting measures. As we noted above, we believe it is important to require a minimum threshold for facilities to earn points on this measure. Thus, we finalize that a facility receiving a CCN after January 1, 2013 but before June 30, 2013 can score points on the Mineral Metabolism and Anemia Management reporting measures using the following formula:

$$\left[\frac{\text{Number of Months Facility Successfully Reports}}{\text{Number of Months in the Performance Period Facility has CCN}} \times 12\right] - 2$$

We will round the result of this formula (with half rounded up) to achieve a measure score from 0–10.

For purposes of the Anemia Management and Mineral Metabolism reporting measures, we do not agree with commenters that facilities should be required to report the first day of the third month after they receive their CCN. A facility with a CCN may submit claims to Medicare. If a facility is submitting claims, it should be reporting hemoglobin and ESA levels. It should also be reporting in CROWNWeb. Therefore, we do not believe it is necessary to allow facilities more time on these measures, and we finalize that facilities must begin reporting for these measures on the first day of the month after they receive their CCN.

As we have previously noted, we believe that a facility needs a period of time after it receives its CCN to ensure that its systems are in place to report to the NHSN system. As we explained above, we are requiring facilities to report 6 non-consecutive months of data to receive points on the NHSN Dialysis Event measure. Because of the time required to enroll and train in the NHSN system, we do not believe it is equitable to require facilities receiving a CCN during the performance period to comply with this measure. Therefore, we are finalizing that a facility that receives a CCN during the performance period will be not be scored on the NHSN Dialysis Event reporting measure.

For the ICH CAHPS measure, we believe that facilities receiving a CCN before July 1, 2013 should be able to hire a third-party administrator in time to administer the ICH CAHPS survey. Although it may take some time for facilities to put this administrator in place, it can begin doing so before it receives a CCN. Therefore, we finalize our proposals that, to earn 10 points on the ICH CAHPS reporting measure, a facility receiving a CCN between January 1, 2013 and June 30, 2013 must attest that it successfully administered the survey during the time for which it had a CCN during the performance period.

We also finalize that facilities receiving a CCN after June 30, 2013 will be exempt from the Mineral Metabolism, Anemia Management, and ICH CAHPS reporting measures. For the NHSN Dialysis Event reporting measure, facilities will be exempt if they receive a CCN on or after January 1, 2013.

12. 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 proposed to retain the same approach as in PY 2014. We discuss the methodology for deriving the performance standards for the measure topics, above. We requested 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 requested 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. Accordingly, we proposed 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 (76 FR 70281), 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, the facility will still be incentivized to strive for, and attain, better performance rates in order to reduce the amount of its payment reduction. We requested comments on the proposed payment reduction scale.

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

Comment: Commenters agreed with our proposal to use the PY 2014 payment reductions scale for the PY 2015 ESRD QIP. Some commenters, however, supported placing more emphasis on the reporting measures in calculating the minimum Total Performance Score since these are the measures over which facilities have the most control. Some commenters suggested that we base payment reductions on actual impact rather than projections of impact, setting tiers of reductions by percentage of facilities we wish to be in each tier. Another commenter urged us to create a more individualized approach to payment reductions because high quality care is markedly different from patient to patient.

Response: At this time, we do not believe it is in the best interest of the program to base payment reductions on actual impact and the percentage of facilities to which we wish to provide payment reductions. Regardless of the impact, we believe that facilities that do not meet the performance standards for each of the clinical measures should face a payment reduction. Were we to base reductions on percentages, the result could be that some high performing facilities receive a payment reduction. Our current payment reduction scale allows every facility to avoid a payment reduction provided that they meet the minimum Total Performance Score.

We agree that it is important to provide individualized care to patients. We believe that the program, incentivizes facilities to furnish individualized care within a certain range of established, clinical acceptable guidelines.

Finally we agree with the commenters that requested we place more emphasis on the reporting measures when calculating the minimum Total Performance Score. We specifically believe that this approach is appropriate now that we have weighted the reporting measure to comprise 25 percent of the Total Performance Score. Were we to continue to score the reporting measures at zero when calculating the minimum Total Performance Score, by increasing the weight of the reporting measures, we would be decreasing the minimum Total Performance Score. This result is contrary to our belief stated in this final rule that the reporting measures should be afforded more importance. Therefore, we will finalize the alternative approach we requested comment on in the proposed rule to include the reporting measures in the minimum Total Performance Score at 50 percent of the total points a facility could have received had it met all of the reporting requirements. As noted above, it is possible to gain a total of 40 points from the reporting measures; thus, we will include half, or 20 of these points, in our calculation of the minimum Total Performance Score. We believe this approach is consistent with our methodology for the clinical measures since we calculate the clinical measure component of the minimum Total Performance Score as the score a facility would have received if it had reached the 50th percentile for all clinical measures.

Comment: One commenter suggested that the 2 percent payment reduction be revisited since such a small percentage will not be a worthwhile incentive as new measures are added. Several commenters expressed concern that the ESRD QIP works as a penalty system and suggested that the ESRD QIP provide incentives as well as penalties, and on balance, be budget-neutral. One commenter suggested that the payment reductions be returned to the penalized facilities for use only to improve care in the areas where they failed to meet quality standards.

Response: Section 1881(h) of the Act does not provide us with the authority to issue bonus payments to facilities based on their performance under the ESRD QIP, to make reductions of more than 2.0 percent, or to redistribute the payment reductions to the originally penalized facilities.

For the reasons stated above, we finalize our proposals for calculating payment reductions except that we will include reporting measures in calculating the minimum Total Performance Score. The reporting measure component of the minimum Total Performance Score will equal the score a facility would have received if it is awarded half of the maximum points it could have received on the reporting measures (that is, 5 points on each measure). Based on this approach, the minimum Total Performance Score is 60 points. Facilities failing to meet this minimum will receive payment reductions in the amounts indicated in Table 7 below.

TABLE 7—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2015

Total performance score	Reduction (%)
100–60	0
59–50	0.5
49–40	1.0
39–30	1.5
29–0	2.0

13. 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 proposed 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 proposed 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 proposed 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 proposed 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 noted our intent 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 are incorrect beyond a certain threshold. In future years, we stated our intention to propose more detailed procedures regarding our data validation process that may result in penalties. We requested comment on our data validation proposals for PY 2015 and the methods we are considering for PY 2016.

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

Comment: Many commenters supported our proposal to have a data validation pilot program that would result in no payment reductions. Some commenters suggested that we continue the pilot until we can evaluate the data from the program, and some commenters suggested that we should share the results of the pilot with the dialysis community before the official program is launched. One commenter requested that, before the pilot program begins, we define the errors being sought and publish these for public comment. Another commenter stated that, before data validation efforts are initiated, CMS should provide clear specifications, data definitions, and reporting requirements because it would be inappropriate to penalize facilities when clarification questions or reporting issues have not been resolved. Commenters also recommended that CMS include the initial data validation in the routine Comprehensive Error Rate Testing (CERT) request for RACs (Recovery Audit Contractors), but cautioned against paying auditors on a contingency fee.

Response: We thank commenters for their support of the pilot data validation program. At this time, we are still finalizing the processes and procedures for the pilot. We will provide this information before the pilot program begins on a publicly available Web site. We will consider the commenters' suggestions as we continue this process. Additionally, as discussed in the sections of this rule outlining the measures, we believe that the specifications, data definitions, and reporting requirements are clear and transparent. If it becomes apparent that there is some significant confusion as to any of these elements, we will clarify these them using the most appropriate means.

Comment: One commenter stated that it does not believe it is appropriate for CMS to develop a data validation measure for the ESRD QIP. This commenter argued that CMS must first explain the scope of accuracy and errors (for example, does it include missing values, transcriptional errors) that CMS requires. Other commenters requested that, before payment is tied to validation, CMS should publish for comment the relationship of errors to payment reductions (with some accorded more weight than others depending on their scope and type) and allow the dialysis community to review the results of the pilot.

Response: We thank commenters for these suggestions. We believe that ensuring data accuracy of reported data is an important component to ensure accurate performance scores and corresponding payments. We continue to consider whether and how we will tie payment to any data validation issues. We will publish any future proposals in rulemaking for public comment.

Comment: Some commenters expressed concern with the burden data validation may place on facilities. One commenter is concerned that producing records within 60 days is too monetarily burdensome and suggests a 120 day period. Another commenter requested that we limit the number of document requests based on provider size and resources and reimburse facilities for data requests. One commenter suggested that the requested data sample be a percentage of patients rather than a fixed number so that small facilities are not disproportionally affected. One commenter asked that the requested records be as current as possible so that they can be easily accessed by facilities that many have data storage protocols. Another commenter specifically noted its support for HAI data validation, but stated its concern that we underestimated the burden on facilities; this commenter requested that we provide more detail on the validation process, specifically the facilities' responsibilities, and encouraged us to partner with NHSN and state and public health partners in developing a standardized process for the validation of HAI data.

Response: We do not believe that our proposals place an undue burden on facilities. We proposed to request only ten records, and we will provide the facility 60 days to produce these records. We do not believe that collecting such a small amount of documentation in such a great deal of time should pose problems for facilities. As we explain later in this rule, we estimate that it will take each facility only 2.5 hours to comply with the requests for these records and will cost approximately $83.08 per facility. We do not believe that 2.5 hours in the span of 2 months (or 2.5 minutes per day) is too little time to comply with these requests nor do we believe it warrants an additional 60 days for compliance. Further, we do not agree that we should request a percentage of documents from facilities rather than a fixed number. If a facility is large, asking for even one percent of its records could prove to be a large burden. Alternatively, requesting that a small facility provide even 10 percent of its records would not provide our data contractor with enough information to assess the validity of the data. By requesting 10 records from each facility, we can ensure a similar burden (2.5 hours and approximately $83.08) for each facility and an analysis of its validity based on the same volume of information.

As noted above, at this time, we are still finalizing the processes and procedures for the pilot. We will provide further information on a publicly available Web site. As we finalize these procedures, we intend to engage various stakeholders to encourage the development of a

standardized process for the validation of data, including data from the CDC for HAIs.

Comment: One commenter requested that we specify a data validation appeals process.

Response: We will consider proposing a data validation appeals process in future rulemaking. Because the proposed program is a pilot and will not have any impact on payment, we do not believe an appeals process is necessary at this time.

Comment: One commenter believes that the various technological resources facilities have should be taken into account when evaluating data validity. This commenter encouraged us to evaluate manual/electronic medical records (EMR) data entry in CROWNWeb.

Response: We will consider commenter's suggestion when we evaluate the data in the pilot program. We will specifically consider if there are variations in the accuracy of data because of the mode of data entry.

Comment: One commenter encouraged us not to implement a payment reduction until all facilities have been asked to submit medical records for purposes of data validation at least one time. Another commenter stated that each facility should have the opportunity to identify data transmission/download errors without the risk of payment penalty.

Response: We thank commenters for the suggestions and will consider them as our pilot program advances.

For the reasons stated above, we finalize our pilot data validation program as proposed, and we will specify the processes and procedures of this pilot on *http://www.dialysisreports.org.*

14. 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 proposed 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 stated our belief that these proposals are the most operationally efficient and will allow facilities the most certainty when they change ownership. We proposed to apply these rules beginning with the PY 2014 ESRD QIP, and we requested public comment on these proposals.

The comments that we received and our responses to these comments are set forth below.

Comment: Many commenters strongly supported our proposals for scoring transferred facilities. One commenter expressed concern that the proposals will change the marketplace in ways that are not yet known.

Response: We thank commenters for their support. We realize that this proposal may impact how dialysis facilities are acquired in the future. However, we believe that creating rules around how we will treat transferred facilities for purposes of the ESRD QIP will create a marketplace that is more predictable. Therefore, we finalize these rules for transferred facilities as proposed.

15. 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 proposed that these requirements generally apply to PY 2015 and subsequent payment years. However, we proposed to make some modifications, as outlined below, to these requirements and that these modifications 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 pubic 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 proposed 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 that 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 proposed 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 5 days of us making these certificates available for download from *www.dialysisreports.org* in accordance with section 1881(h)(6)(C) of the Act (76 FR 637). We proposed 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 5 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 proposed 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 proposed that facilities be required to post their Performance Score Certificates (PSCs) 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 in PY 2014, we proposed 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 proposed 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 proposed 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.

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

Comment: Commenters supported our proposal to allow facilities until the first business day after January 1 to post certificates. Most commenters agreed with our proposal to require facilities to post both English and Spanish versions of the PSC beginning in PY 2014, stating that the additional burden is very small; one commenter argued that Spanish versions of the PSC are not necessary in all locations and recommended that individual facility administrators determine whether posting a PSC in Spanish is necessary or beneficial based upon the population that the facility serves. Another commenter suggested not only requiring a Spanish PSC but also developing Spanish-language materials explaining the PSCs.

Response: We agree with commenters that the burden of posting a Spanish as well as an English PSC is very little and far outweighs the benefits it could convey upon beneficiaries. We do not agree that it is appropriate for facility administrators to determine whether posting the Spanish PSC is necessary. A facility that does not furnish services to native Spanish speaking patients in 1 year could begin to do so during the next year. As the ESRD QIP evolves, we seek to make the program as transparent as possible for all beneficiaries.

Comment: Some commenters believe that the ESRD QIP should be clearer, and we should develop and make public guidance documents for patients and clinics. These commenters also suggested that we hold open door forums specifically for patients so that they do not interpret the quality of care information incorrectly.

Response: As we noted above, we seek to make the program as transparent as possible, specifically to beneficiaries. We intend to continue to assess the modes and efficacy of our communications to beneficiaries. We will take these comments into account as we do so.

Comment: Some commenters requested that we make available on our Web site individual measure scores (including the numerator and denominator) and the Total Performance Scores; commenters stated that these scores should be organized by facility and state to facilitate choice in care. One commenter requested that this information be published in both English and Spanish. One commenter encouraged us to create a ''one-stop-shop'' for quality information on the internet.

Response: Since the PY 2012 program, we have made aggregate information on measure scores and Total Performance Scores available on *http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDQualityImproveInit/index.html*. This information includes numerators and denominators for each clinical measure, the scores for each measure, and Total Performance Scores for every facility. The information is organized in alphabetical order by state and facility. We will consider publishing this information in Spanish in future years. Additionally, we seek to align the ESRD QIP with CMS' other VBP program; we continue to assess how information across programs should be presented, and we will considering creating a ''one-stop-shop'' for information related to CMS' programs. At present, a great deal of information on these programs can be found here: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html*.

Comment: One commenter believes that the NHSN measure should be included in DFC because it is key to patient safety.

Response: We thank comments and will consider the appropriateness for inclusion of this measure on DFC in future Web site releases.

Comment: One commenter requested that we confirm that there is consistency in measures reported in DFR, DFC, PSR, and for ESRD QIP purposes.

Response: We thank the commenter for its inquiry regarding the consistency of measures reported through DFR, DFC, the Performance Score Reports (PSR), and for ESRD QIP purposes. There are some differences in the measure descriptions between DFR, DFC, and QIP because each serves its own purposes; the measure rates for the ESRD QIP that are posted on DFR, DFC, and in the PSR are the same. For example, for DFR/DFC, the denominators for the Kt/V measures include out of range values, whereas the ESRD QIP Kt/V measure denominators do not. We seek to align reporting mechanisms as much as possible, but, in some cases, we believe that it is appropriate to present this information differently.

Comment: One commenter recommended that we timely monitor quality data and intervene if trends indicate a decrease in the quality of care.

Response: We are committed to monitoring and evaluating the impacts of the ESRD QIP.

Comment: One commenter urged us to prioritize the development and implementation of a single system to which facilities would report their data in order to simplify reporting and minimize unnecessary burdens on providers, particularly staff members otherwise providing direct care to patients.

Response: We continue to evaluate our reporting systems; we seek to minimize provider burden as much as possible, and we will continue to evaluate ways in which we can do so as the program moves forward.

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

A. Background

In accordance with section 1861(v)(1) of the Act and current regulations at 42 CFR 413.89, 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 additional guidance on the standards governing bad debt reimbursement.

Prior to the passage of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96), under section 1861(v)(1)(T) of the Act and § 413.89(h)(1) of our regulations, Medicare payments for allowable bad debt amounts for hospitals were reduced by 30 percent for cost reporting periods beginning on or after October 1, 2001. Likewise, under section 1861(v)(1)(V) of the Act and § 413.89(h)(2) of our regulations, Medicare payments for allowable bad debt amounts for patients in skilled nursing facilities (SNFs) that were not dual eligible individuals beginning with cost reporting periods beginning on or after October 1, 2005, were reduced by 30 percent. Section 413.89(h)(2) 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), end stage renal diease (ESRD) facilities, swing bed hospitals, as defined at 42 CFR 413.114(b), and patients that are dual eligible individuals in SNFs, Medicare paid 100 percent of allowable bad debt amounts. Additionally, 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. Although Medicare previously paid ESRD facilities 100 percent of allowable bad debt amounts, these payments were capped at the facility's reasonable cost in accordance with § 413.178(a). In the proposed rule, we proposed to maintain the cap on bad debt reimbursement to an ESRD facility up to the facility's unrecovered costs. We also proposed to apply the bad debt reduction percentages mandated by section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. No. 112–96), prior to applying the cap up to the ESRD facility's unrecovered costs.

B. Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 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 (section 1861(v)(1)(T)) and SNFs (section 1861(v)(1)(V)). Section 3201(b) of Public Law 112–96 also 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) Public Law 112–96 defined ''providers'' as those providers not previously described in subsections 3201(a) or (b), suppliers, 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 Final Rule

1. Self-Implementing Provisions of Section 3201 Public Law 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 the proposal to maintain the cap on bad deb reimbursement for ESRD facilities, as discussed below.

Comment: We received comments from commenters suggesting that the bad debt reduction percentages be implemented in single digit percent reductions instead of the double digit percent reductions, as mandated by section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012.

Response: While we appreciate the concerns of the provider community regarding bad debt payments to providers eligible to receive bad debt, the percent reductions of bad debt payments are statutorily mandated by section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 and do not provide for discretion. Therefore, we are codifying 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 will 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 will 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 will 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 will 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 8 below:

TABLE 8—SUMMARY OF MEDICARE BAD DEBT REIMBURSEMENT BY PROVIDER TYPES FOR COST REPORTING PERIODS THAT BEGIN DURING FY 2013, 2014, 2015 AND SUBSEQUENT YEARS

Provider type	Allowable bad debt amount during FY 2012 (percent)	Allowable bad debt amount during FY 2013 (percent)	Allowable bad debt amount during FY 2014 (percent)	Allowable bad debt amount during FY 2015 & subsequent FYs (percent)
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

2. ESRD Bad Debt Cap and Remove and Reserve § 413.178

In the proposed rule, we proposed to maintain the cap on bad debt reimbursement up to an ESRD facility's unrecovered costs. Bad debt payments are made under section 1861(v)(1)(A) of the Act to prevent non-Medicare patients from subsidizing Medicare patients and vice-versa, also known as the anti-cross subsidization principle. The cap at an ESRD facility's unrecovered costs for bad debt reimbursement was originally implemented to assure that the combination of the composite rate payment and the bad debt payment did not exceed the ESRD facility's total allowable costs of providing services to Medicare beneficiaries, as well as to avoid violating the anti-cross subsidization principle. Thus, by applying the cap, an ESRD facility would not be paid for bad debt amounts that exceeded its unrecovered costs under the composite rate payment system implemented in 1983.

Comment: We received comments from commenters suggesting the maintenance of the cap on bad debt reimbursement to ESRD facilities up to the facilities' unrecovered costs was inconsistent with the bad debt reimbursement policies for all other types of providers eligible to receive bad debt reimbursement and was also inconsistent with Federal court rulings.

Response: After careful consideration of the policy implications of removing the cap on bad debt reimbursement at an ESRD facility's unrecovered costs, we have decided to eliminate the cap. The elimination of the cap on bad debt reimbursement to ESRD facilities will allow ESRD facilities to claim bad debts at an amount exceeding unrecovered costs incurred under a prospective payment system. In addition, removal of the cap on bad debt reimbursement to ESRD facilities complies with the order of the D.C. Circuit Court in *Kidney Center of Hollywood, et al.* v. *Shalala,* 133 F.3d 78 (D.C. Circuit 1998), and will allow us to apply our bad debt policies consistently across all the types of providers eligible to receive bad debt payments. Therefore, we believe the removal of the bad debt reimbursement cap at an ESRD facility's unrecovered cost, is an equitable and reasonable policy choice with respect to bad debt reimbursement to ESRD facilities.

We are eliminating the cap for ESRD facilities for cost reporting periods beginning on or after January 1, 2013, the effective date of this final rule. With this change, ESRD facilities will be reimbursed for bad debt reduced as outlined in the proposed changes to § 413.89(h)(3), described above. However, because the new bad debt reductions for ESRD facilities become effective October 1, 2012, and the removal of the cap on bad debt reimbursement to ESRD facilities will not be effective until January 1, 2013, for cost reporting periods beginning between October 1, 2012 and December 31, 2012, the cap on bad debt reimbursement to ESRD facilities will be calculated with both the required bad debt reductions and the cap on bad debt reimbursement to ESRD facilities. For illustrative purposes only, the following examples present the interaction of the application of the cap on ESRD bad debt payments until January 1, 2013 and the ESRD bad debt reduction effective October 1, 2012:

Example (A), for cost reporting periods beginning before October 1, 2012, only the cap applies as follows:

1. Unrecovered costs = $100.00
2. Aggregate Gross bad debt = $110.00
3. Bad debt amount of $110.00 is capped at the unrecovered costs of $100.00, therefore, the facility receives $100.00.

Example (B), for cost reporting periods beginning between October 1, 2012 and December 31, 2012, the 12 percent reduction applies up to the facilities' unrecovered costs as follows:

1. Unrecovered costs = $100.00
2. Aggregate Gross bad debt = $110.00
3. Bad debt amount of $110.00 is reduced by 12 percent (bad debt reduction in FY 2013) which equals $96.80. Since the reduction is less than the cap, the facility receives $96.80.

Example (C), for cost reporting periods beginning on or after January 1, 2013 and before October 1, 2013, only the 12 percent reduction applies:

1. Unrecovered costs = $100.00
2. Aggregate Gross bad debt = $110.00
3. The $110.00 bad debt amount is reduced by 12 percent (bad debt reduction in FY 2013). The facility receives $96.80 with no cap applied.

We are moving current regulations text at § 413.178(a) to proposed § 413.89(h)(3). The revised regulation text will remove the bad debt cap for ESRD facilities, and include the bad debt reduction percentages applicable to ESRD facilities in accordance with 1861(v)(1)(W).

We are removing current paragraphs (b), (c), and (d)(1) of § 413.178 since these provisions already are set out at § 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 moving the bad debt exception provision applicable to ESRD facilities discussed at § 413.178(d)(2) to proposed § 413.89(i)(2). For consistency, we are also moving the current general bad debt exception set out at § 413.89(i) to new paragraph § 413.89(i)(1).

We are removing and reserving § 413.178.

3. Technical Corrections

We are making 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. Changes to Medicare Bad Debt Policy

In this rule, we are conforming existing regulations text found at § 413.89(h) to the self-implementing provisions of section 3201 of Public Law 112–96. Previously, bad debt reimbursement to an ESRD facility was capped up to the facility's reasonable costs under § 413.178(a). In this final rule, we are moving the current provision at § 413.178(a) to § 413.89(h)(3), and adding ESRD facilities to the list of facilities to which § 413.89 ''Bad debts, charity, and courtesy allowances,'' applies. We are also eliminating duplicate provisions in § 413.178 and reserving § 413.178 for future use. In addition, we are making a technical correction to § 417.536(f)(1) to clarify Medicare bad debt reimbursement policy.

1. 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 clarifying that the limits on bad debt payments are reductions to amount of allowable bad debt.

We are revising § 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 are adding a new § 413.89(h)(1)(v), which will 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 are revising § 413.89(h)(2) to add paragraphs (h)(2)(i) and (h)(2)(ii). Paragraph (h)(2)(i) will 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 years 2006 through 2012 for a patient that was not a dual eligible individual. Paragraph (h)(2)(ii) will set forth the reduction in reimbursable bad debt payments for SNFs and swing bed hospitals, for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years, for a patient that was a dual eligible individual.

We are revising § 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 and subsequent fiscal years. We are also revising § 413.89(h)(3) to set forth the applicability of the cap on bad debt reimbursement to ESRD facilities for cost reporting periods beginning between October 1, 2012 and December 31, 2012.

We are adding 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 are eligible to receive reimbursement of bad debt for cost reporting periods beginning during fiscal year 2013, fiscal year 2014, and subsequent fiscal years.

2. Rationale for Removing 42 CFR 413.178

Previously, § 413.178(a) stated that CMS will reimburse each ESRD 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 reimbursements will be eliminated and the new reductions in bad debt reimbursements will be applied, as discussed above.

We are revising § 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.

We are also removing and reserving § 413.178, since the revised provisions already are set out at § 413.89, in Chapter 3 of the PRM Part I, and in the Medicare cost report instructions in the PRM Part II. We are moving the current general bad debt exception at § 413.89(i) to new paragraph § 413.89(i)(1) in order to move the ESRD facilities' bad debt exception provision previously discussed at § 413.178(d)(2) to new paragraph § 413.89(i)(2).

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

In this final rule, we are revising 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) will reference 42 CFR 413.89 instead of the outdated reference to § 413.80. In addition, we are revising the 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 are set out at § 413.89, in 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 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

B. Requirements in Regulation Text

We did not propose and therefore are not finalizing any changes to regulatory text for the ESRD PPS in CY 2013.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final 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. We are soliciting public comment on each of these issues.

1. ESRD QIP

a. Display of Certificates for the PY 2015 ESRD QIP

Section III.D.15 of this final rule discusses a disclosure requirement for the PY 2014 and PY 2015 ESRD QIP. As stated earlier in this final rule, section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis care providers and facilities 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 had 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 5,726 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 954 hours (10/60 hours *5,726 facilities). According to the Bureau of Labor Statistics, the mean hourly wage of a registered nurse is $33.23.[9] Since we anticipate nurses (or administrative staff) will post these certificates, we estimate that the aggregate cost of this requirement will be $31,701 ($33.23/hour × 954 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 5 minutes to answer each patient's 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 8,704 hours (1.52 hours/facility × 5,726 facilities). The total estimated annual burden for both displaying the ESRD QIP certificates and answering patients' questions about the certificates is 9,658 hours (8,704 hours + 954 hours). While the total estimated annual burden associated with both of these requirements as discussed is 9,658 hours, we do not believe that there will be a significant cost associated with these requirements because we are not requiring 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 $320,935 ($33.23/hour × 9,658 hours).

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

As stated above in section III.D.2.a of this finalrule, we finalized a measure requiring facilities to reporting dialysis events to the NHSN for he PY 2015 ESRD QIP. Specifically, we will require facilities to submit 12 months of dialysis event data to the NHSN to receive 10 points on the measure. The burden associated with this requirement for existing facilities is the time and effort necessary for facilities to submit 12 months of data in order to receive the maximum number of points. According to our most recent data, 5,525 facilities treat adult in-center hemodialysis and/or pediatric in-center hemodialysis patients and are, then, eligible to receive a score on this measure; therefore, we estimate that approximately 5,525 facilities will submit the required data. Based on data previously collected, we further estimate that the average number of dialysis events is 0.008 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 397,800 (0.09 events/patient/month × 75 patiens/facility × 5,525 facilities × 12 mohths) for the PY 201 ESRD QIP performance period. We estimae it will require 10 minutes to collect and submit data on these events, and the estimated burden for submiting 12 mohths of data will be 66,300 hours (397,800 dialysis events × 10/60 minute). If the dialysis events were distributed evenly across all 5,525 facilities, the reporting would result in an additional 12 hour (66, 300 hours/5,525 facilities), burden for each facility at a cost of $399 ($33.23/hour × 12 hours) per facility. Again, we estimate the mean hourly wage of a registered nurse is $33.23, and we anticipate nurses (for administrative staff) will be responsible for this reporting. In total, we believe that the cost for all ESRD facilities to comply with the reporting requirements associated with NHSN Dialysis Event reporting measure will be approximately $2.2 million ($399 × 5,525 facilities= $2,204,475) per year.

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

As stated above in section III.D.1.c of this final rule, we finalized 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 5,523 facilities treat adult, in-center hemodialysis patients and are, therefore, eligible to receive a score on this measure. We estimate that all 5,523 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 5 minutes to submit the attestation each year. The estimated total annual burden on facilities is 88,829 hours ((16 hours × 5,523 facilities) + ((5/60 minutes) × 5,523 facilities) which is equal to $2,952,818 (88,829 hours × $33.23), or $534 per facility ($2,952, 818/5,523). Again, we estimate the mean hourly wage of a registered nurse is $33.23, and we anticipate nurses (or administrative staff) will be responsible for this reporting. 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

[9] This hourly wage is absent any fringe benefits.

would be taken per facility.[10] Interviewers from each facility would spend a total of approximately 37.5 hours per year with patients completing these surveys (30/60 minutes * 75 minutes) or $1,247 (37.5 hours × $33.23) for an estimated annual burden of 207,113 hours (37.5 hours * 5,523 facilities) which is equal to $6.9 million (207,113 hours × 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 $1,781 ($534 + $1,247) for each facility, or $9.9 million ($1,781 × 5,523 facilities =$9,836,463) across all ESRD facilities.

d. Data Validation Requirements

Section III.D.13 of this final rule outlines the data validation processes we are finalizing. We will 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. Because we anticipate that the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records, we only estimate the burden of retrieving and submitting the necessary records. 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 will be 1,875 hours (750 facilities × 2.5 hours) at a total of $62,307 (1,875 hours × $33.23/hour) or $83.08 ($62,307/750) per facility in the sample. Again, we estimate the mean hourly wage of a registered nurse is $33.23, and we anticipate nurses (or administrative staff) will be responsible for providing this information.

The comments we received on this analysis are set forth below.

Comment: One commenter believes that the underlying premise for the CAHPS burden analysis is incorrect. This commenter stated that if the average facility serves 75 patients, it would survey at most 75 patients per year.

Response: We believe that this assumption is a good approximation for this analysis. We realize that facilities may have more than 75 patients or less than 75 patients. Across the ESRD population, however, we believe 75 patients per facility is accurate. According to the ICH CAHPS specifications, if a facility has less than 200 patients, it must draw a census of patients from this facility. Therefore, if the average facility has 75 patients, we believe it would survey at most 75 patients.

Comment: One commenter expressed concern that responding to questions from patients about the Performance Score Certificates (PSCs) could consume too many staff hours.

Response: We recognize that patients may have questions about the PSCs. The ESRD QIP is designed not only to incentivize care, but also to stimulate discussion about the quality of dialysis care. Therefore, we believe that these questions and answers are important in promoting the goals of the program and improvement in care in that they promote patient awareness and understanding of the care they are receiving. Additionally, we believe that these questions will be answered during the course of usual patient care. We will continue to monitor the burden these questions may place upon facilities.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionAct of1995/PRAL/list.asp#TopOfPage.*

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–1352–F]; 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. The removal of the cap on bad debt reimbursement to ESRD facilities will result in fewer collection of information requirements for ESRD facilities.

VI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We examined the impacts of this final 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 final rule.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis items and services in CY 2013, implements the third year of the ESRD PPS transition, and makes several policy changes and clarifications to the ESRD PPS. These include 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 final rule would result in ESRD facilities not receiving appropriate payments in CY 2013.

This final rule also implements the QIP for PY 2015 and beyond by establishing measures, a scoring system, 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 final rule also implements the reduction percentages of bad debt reimbursement required by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012. This final rule also removes the cap on bad debt reimbursement to an ESRD facility up to the facility's unrecovered costs. Section 3201(c) of The Middle Class Tax

[10] 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. Faculties with fewer than 200 patients are required to survey all 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.

Extension and Job Creation Act of 2012 adds a new subparagraph—1861(v)(1)(W) to the Act and applies 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 final revisions to the ESRD PPS will result in an increase of approximately $250 million in payments, from Medicare, 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 requirements related to the ESRD QIP for PY 2015 will cost approximately $12.4 million and the predicted payment reductions will equal about $12.1 million to result in a total impact from the proposed ESRD QIP requirements of $24.6 million.

In section IV of this final 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 the CY 2013 proposed rule (77 FR 40988) 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.

Fiscal year	Medicare program savings from reductions in bad debt
2013	240 million.
2014	600 million.
2015	900 million.
2016	1.06 billion.
2017	1.14 billion.
2018	1.21 billion.
2019	1.30 billion.
2020	1.39 billion.
2021	1.49 billion.
2022	1.59 billion.
Aggregate FY Total Savings.	10.92 billion.

Additionally, in section IV of this final rule, we discuss the removal of the cap on bad debt reimbursement to ESRD facilities. We estimate the removal of this cap will result in a cost to the Medicare program in the amount of $170 million from 2013 through 2022.

Fiscal year	Medicare program cost resulting from cap removal
2013	10 million.
2014	20 million.
2015	10 million.
2016	10 million.
2017	20 million.
2018	20 million.
2019	20 million.
2020	20 million.
2021	20 million.
2022	20 million.
Aggregate FY Total Cost.	170 million.

B. Detailed Economic Analysis

1. CY 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

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 final rule, we used the June 2012 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.C of this final 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 fourth 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 3.0 percent, 0.2 percent, 1.4 percent and 1.0 percent, respectively, for the first quarter of 2013 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 8 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 final rule, the growth from 2011 to 2012 is 0.7 percent and the growth from 2011 to 2013 is −1.1 percent.

TABLE 9—PRICE INCREASES FROM 2011 TO 2012 AND 2011 TO 2013 OF FORMER SEPARATELY BILLABLE PART B DRUGS

Separately billable drugs	Total growth 2011 to 2012 (percent)	Total growth 2011 to 2013 (percent)
EPO	−0.3	5.0
Paricalcitol	−31.6	−36.5
Sodium_ferric_glut	−24.8	−33.3
Iron_sucrose	−14.7	−14.2
Levocarnitine	12.2	−2.3
Doxercalciferol	−68.3	−68.5
Calcitriol	64.6	15.7
Vancomycin	−12.4	−15.4
Alteplase	15.5	24.4
Aranesp	6.5	12.3
Daptomycin	11.5	19.0
Ferumoxytol	−7.8	−4.3
Weight for others	−8.1	−4.6

Table 10 below shows the impact of the estimated CY 2013 ESRD payments compared to estimated payments to ESRD facilities in CY 2012.

TABLE 10—IMPACT OF CHANGES IN PAYMENTS TO ESRD FACILITIES FOR THE CY 2013 ESRD FINAL RULE

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	A Number of facilities	B Number of treatments (in millions)	C Effect of 2013 changes in outlier policy [3] (percent)	D Effect of 2013 changes in wage indexes (percent)	E Effect of total 2013 changes [4] (percent)
All Facilities	5,726	41.4	0.4	0.0	3.0
Type					
Freestanding	5,176	38.0	0.5	0.0	2.9
Hospital based	550	3.4	0.3	0.1	3.6
Ownership Type					
Large dialysis organization	3,719	27.3	0.5	0.0	2.9
Regional chain	926	7.1	0.3	0.1	3.0
Independent	636	4.4	0.2	0.0	3.0
Hospital based [1]	434	2.6	0.3	0.2	3.6
Unknown	11	0.0	0.3	1.5	4.4
Geographic Location					
Rural	1,267	6.8	0.5	−0.2	2.9
Urban	4,459	34.6	0.4	0.0	3.0
Census Region					
East North Central	941	6.3	0.5	0.1	3.1
East South Central	472	3.1	0.6	−0.5	2.5
Middle Atlantic	641	5.1	0.4	0.0	3.1
Mountain	335	1.9	0.3	−0.3	2.6
New England	171	1.4	0.5	0.5	3.5
Pacific	667	5.6	0.2	0.6	3.4
Puerto Rico and Virgin Islands	41	0.3	0.2	−2.4	0.6
South Atlantic	1,259	9.5	0.6	−0.2	2.8
West North Central	416	2.2	0.4	0.1	3.2
West South Central	783	6.0	0.5	−0.2	2.8
Facility Size					
Less than 4,000 treatments [2]	1,105	2.5	0.4	0.0	3.0
4,000 to 9,999 treatments	2,225	11.6	0.5	0.0	3.0
10,000 or more treatments	2,370	27.2	0.4	0.0	3.0
Unknown	26	0.0	0.2	0.1	3.2
Percentage of Pediatric Patients					
Less than 2%	5,616	41.0	0.5	0.0	3.0
Between 2% and 19%	44	0.4	0.3	−0.1	3.0
Between 20% and 49%	8	0.0	0.1	−0.1	4.1
More than 50%	58	0.1	−0.2	0.0	2.2

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

[2] Of the 1,105 Facilities with less than 4,000 treatments, only 332 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 3.3% increase in payments.

[3] Includes the effects of the final payment policy on thrombolytics for those facilities that are paid under the blend.

[4] Includes the effect of Market Basket minus productivity increase of 2.3% 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 those facilities that choose to be paid under the transition.
Includes the effect of the Transition Budget-Neutrality Factor of 0.1 percent for all facilities.
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 final changes to the outlier payment policy described in section II.C.7 of this final 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 0.2 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 final 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 0.5 percent decrease to a 1.5 percent increase due to the update of the wage index.

Column E reflects the overall impact (that is, the effect of the final outlier policy changes, the effect of the final wage index, the effect of the ESRDB market basket increase minus productivity adjustment, 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, and the effect of the 0.1 percent transition budget-neutrality adjustment increase). We expect that overall, ESRD facilities will experience a 3.0 percent increase in estimated payments in 2013. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 0.6 percent increase in their estimated payments in CY 2013. This smaller 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 2.2 percent to 4.4 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 final 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 $8.4 billion. This estimate is based on various price update factors discussed in section VI.B in this final rule and takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 4.0 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 3.0 percent overall increase in the ESRD PPS payment amounts in CY 2013, we estimate that there will be an increase in beneficiary co-insurance payments of 3.0 percent in CY 2013, which translates to approximately $60 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. ESRD QIP

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 an 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 finalizing to determine a facility's Total Performance Score is described in section III.D.9 and III.D.10 of this final 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 final rule, we estimate that, of the total number of dialysis facilities (including those not receiving an ESRD QIP Total Performance Score), approximately 20 percent or 1,093 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 5,726 dialysis facilities paid through the ESRD PPS. Table 11 shows the overall estimated distribution of payment reductions resulting from the PY 2015 ESRD QIP.

TABLE 11—ESTIMATED DISTRIBUTION OF PY 2015 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (percent)	Number of facilities	Percent of facilities
0.0	4308	79.8
0.5	599	11.1
1.0	309	5.7
1.5	97	1.8
2.0	88	1.6

*Note: this table excludes 325 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 12.

TABLE 12—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–Dec 2011.
Vascular Access Type		
% Fistula	Oct 2010–Apr 2011	May 2011–Dec 2011.
% Catheter	Oct 2010–Apr 2011	May 2011–Dec 2011.
Kt/V		
Adult HD	Jul 2010–Mar 2011	Apr 2011–Dec 2011.
Adult PD	Jul 2010–Mar 2011	Apr 2011–Dec 2011.
Pediatric HD	Jul 2010–Mar 2011	Apr 2011–Dec 2011.

We used claims data for these calculations. 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.11.a of this final 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.D.12 of this final 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 final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2011 and December 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 January 2011 and December 2011 times the estimated payment reduction percentage). For PY 2015 the total payment reduction for all of the 1,093 facilities expected to receive a reduction is approximately $12 million ($12,087,940). Further, we estimate that the total costs associated with the collection of information requirements for PY 2015 described in section V.C. of this final 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 $24.5 million ($12,087,940 + 12,424,180 = $24,512,120) as a result of the PY 2015 ESRD QIP.

Table 13 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 will 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 13—IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2015

	Number of facilities	Number of Medicare treatments 2009 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	5,726	41.4	5,401	1,093	−0.17
Facility Type:					
Freestanding	5,176	38.0	4,989	931	−0.15
Hospital-based	550	3.4	412	162	−0.41
Ownership Type:					
Large Dialysis	3,719	27.3	3,612	662	−0.14
Regional Chain	926	7.1	882	151	−0.14

TABLE 13—IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2015—Continued

	Number of facilities	Number of Medicare treatments 2009 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Independent	636	4.4	584	150	−0.22
Hospital-based (non-chain)	434	2.6	318	128	−0.43
Unknown	11	0.0	5	2	−0.30
Facility Size:					
Large Entities	4,645	34.4	4,494	813	−0.14
Small Entities [1]	1,070	7.0	902	278	−0.30
Unknown	11	0.0	5	2	−0.30
Urban/Rural Status:					
1) Rural	1,267	6.8	1,188	263	−0.18
2) Urban	4,459	34.6	4,213	830	−0.16
Census Region:					
Northeast	810	6.5	752	166	−0.20
Midwest	1,352	8.5	1,238	310	−0.21
South	2,510	18.7	2,420	445	−0.15
West	1,001	7.5	952	154	−0.13
U.S. Territories [2]	53	0.3	39	18	−0.37
Census Division:					
East North Central	941	6.3	856	227	−0.23
East South Central	472	3.1	451	77	−0.15
Middle Atlantic	641	5.1	593	143	−0.22
Mountain	335	1.9	321	64	−0.15
New England	171	1.4	159	23	−0.13
Pacific	667	5.6	631	90	−0.11
South Atlantic	1,259	9.5	1,217	236	−0.16
West North Central	416	2.2	382	83	−0.17
West South Central	783	6.0	752	132	−0.13
U.S. Territories [2]	41	0.3	39	18	−0.37
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,105	2.5	864	214	−0.27
4,000–9,999 treatments	2,225	11.6	2,190	420	−0.15
Over 10,000 treatments	2,370	27.2	2,345	459	−0.14
Unknown	26	0.0	2	0	−0.00

[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.

The comments we received on this analysis are set forth below.

Comment: Several commenters requested that we provide, for both PY 2014 and PY 2015, the data, assumptions, and methodology used to calculate the rate of improvement, performance standards, achievement thresholds, and benchmarks for all measures to allow stakeholders to have the opportunity to assess the impact on facilities so that the community may provide meaningful comment. Commenters also argued that we have underestimated the PY 2014 average payment reduction (i.e., by 36 percent), and requested that we provide the model, data, and assumption we used for these estimates.

Response: As we noted above, the PY 2014 final rule was finalized on November 1, 2011 (76 FR 70228). We direct commenters to this rule for our analysis of the PY 2014 ESRD QIP. The methodology and assumptions that we used to calculate the estimated rate of improvement, performance standards, achievement thresholds, and standards are set forth in this section.

b. Alternatives Considered for the PY 2015 ESRD QIP In developing the 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, and III.D of this final rule. Poor management of anemia and inadequate dialysis, for example, can lead to otherwise-avoidable hospitalizations, decreased quality of life, and death. Infections are also a leading cause of hospitalization and death 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 via DFC to encourage facilities to improve their care. We believe the measures selected for the ESRD QIP will allow us to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis facilities.

In developing the 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 only on 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 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 that 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 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 score measure topics where each measure within the measure topic is scored individually and then weighted appropriately.

We considered requiring facilities to report data for 100 percent of their patients for the Mineral Metabolism and Anemia Management reporting measures in order to ensure complete, accurate data collection. We ultimately decided that, because there are some situations where a facility cannot control whether a patient's blood is drawn (for example, hospitalization), we should adopt a reporting threshold of less than 100 percent.

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 finalized 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 finalized 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 including an adjustment for measures with 11–25 cases. Finally, we discussed an adjustment applicable to measures with 26–50 cases. We believe that we should set the case minimum at 11 and adopt an adjustment for measures with 11–25 cases.

Finally, in deciding upon the calculation of the minimum Total Performance Score, we considered scoring the reporting measures at zero, consistent with PY 2014. We decided, however, to finalize a minimum Total Performance Score that includes half of the maximum score a facility could receive on these measures. We believe that this methodology appropriately places emphasis on complete reporting from all facilities.

We did not receive any comments related to this analysis of the alternatives that we considered for the PY 2015 ESRD QIP.

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 these provisions will result in savings in CY 2013 of $330 million. Removal of the cap on bad debt reimbursement to ESRD facilities up to a facility's unrecovered cost will have an impact on ESRD facilities by increasing their bad debt reimbursement amounts. It is estimated that the removal of this cap will result in $10 million in increased payments to ESRD facilities for CY 2013. Therefore, it is estimated that the combined overall savings in the CY 2013 would be $320 million.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 14 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 14—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.
Increased Beneficiary Co-insurance Payments	$60 million.
From Whom to Whom	Beneficiaries to ESRD providers.

ESRD QIP for PY 2015

Annualized Monetized Transfers	−$12.1 million.*
From Whom to Whom	Federal government to ESRD providers.
Category	**Costs**
Annualized Monetized ESRD Provider Costs	12.4 million.**

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS—Continued

Savings from Congressionally Mandated Reductions of Bad Debt Payments in CY 2013

Category	Transfers
Annualized Monetized Bad Debt Payments	$ −320 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.D.12 of this proposed rule.
** It is the cost associated with the collection of information requirements for all ESRD facilities.

VII. 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://www.sba.gov/sites/default/files/files/Size_Standards_Table.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 final rule that enabled us to identify the ESRD facilities that are part of an LDO or regional chain and therefore, were able to identify individual ESRD facilities that will 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 9. Using the definitions in this ownership category, we consider the 636 facilities that are independent and the 434 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 in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 3.6 percent increase in payments for CY 2013. An independent facility (as defined by ownership type) is estimated to receive a 3.0 percent increase in payments for 2013.

Based on the ESRD QIP payment reduction impacts to ESRD facilities for PY 2015, we estimate that of the 1,093 ESRD facilities expected to receive a payment reduction, 278 ESRD small entity facilities will experience a payment reduction (ranging from 0.5 percent up to 2.0 of total payments). We anticipate the payment reductions to average approximately $11,059 per facility among the 1,093 facilities receiving a payment reduction, with an average of $12,866 per small entity facilities receiving a payment reduction. The projected impacts for these small entities are estimates based on current data. The actual impacts may differ. 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 278 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 1,070 small entity facilities. For this entire group of 1,070 ESRD small entity facilities, a decrease of 0.30% percent in aggregate ESRD payments is observed.

The comment we received on this analysis is set forth below.

Comment: One commenter expressed concern that we have not provided additional funding for the ESRD QIP COI requirements to alleviate the aggregate associated cost; commenter is specifically concerned of the impact on small facilities.

Response: We recognize that a facility may have additional costs resulting from the ESRD QIP. We believe that these costs, however, are necessary in improving care and do not outweigh the utility of the program. We will continue to monitor these costs, paying specific attention to their effect upon small facilities.

Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 180 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 180 rural hospital-based dialysis facilities will experience an estimated 3.5 percent increase in payments. As a result, this final rule is estimated to not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

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. Additionally, we do not believe that the removal of the cap on bad debt reimbursements to ESRD facilities up to their unrecovered costs will have a significant impact on the operations of a substantial number of small entities and small rural hospitals. Thus, we are not providing a Regulatory Flexibility Act Analysis to codify the statutorily mandated reductions in bad debt payments, nor for the removal of the cap on bad debt reimbursement as it pertains to ESRD facilities.

VIII. 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 final rule does not include any mandates that will impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $139 million.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

X. Files Available to the Public via the Internet

This section lists the Addenda referred to in the preamble of this final 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 (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

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

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

■ 1. The authority citation for part 413 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 § 413.114(b), 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 a patient 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 a patient 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 a patient 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 on or after October 1, 2012 and before January 1, 2013, reduced by 12 percent with the resulting amount reimbursed up to the facility's costs.

(iii) For cost reporting periods beginning on or after January 1, 2013 and before October 1, 2013, reduced by 12 percent.

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

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

(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: October 26, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–26903 Filed 11–2–12; 4:15 pm]

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