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42 CFR Parts 413 and 414
Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS–1526–F]

RIN 0938–AR55

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

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

ACTION: Final rule.

SUMMARY: This rule updates and makes revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2014. This rule also sets forth requirements for the ESRD quality incentive program (QIP), including for payment year (PY) 2016 and beyond. In addition, this rule clarifies the grandfathering provision related to the 3-year minimum lifetime requirement (MLR) for Durable Medical Equipment (DME), and provides clarification of the definition of routinely purchased DME. This rule also implements budget-neutral fee schedules for splints and casts, and intraocular lenses (IOLs) inserted in a physician's office. Finally, this rule makes a few technical amendments and corrections to existing regulations related to payment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items and services.

DATES: *Effective Date:* These regulations are effective on January 1, 2014, except for amendments to §§ 414.100, 414.102, 414.106, 414.108, 414.200, and 414.226, which are effective on April 1, 2014.

FOR FURTHER INFORMATION CONTACT: Michelle Cruse, (410) 786–7540, for issues related to the ESRD PPS.

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Hafsa Vahora, (410) 786–7899, for issues related to the implementation of budget neutral fee schedules for splints and casts, and IOLs inserted in a physician's office.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

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

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

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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:

AHRQ Agency for Healthcare Research and Quality
ASP Average Sales Price
ATRA American Taxpayer Relief Act of 2012 BLS Bureau of Labor Statistics
CBSA Core Based Statistical Area
CCN CMS Certification Number
CDC Centers for Disease Control and Prevention
CKD Chronic Kidney Disease
CY Calendar Year
DFC Dialysis Facility Compare
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
ESA Erythropoiesis Stimulating Agent
ESRD End-Stage Renal Disease
ESRDB End-Stage Renal Disease bundled
ESRD PPS End-Stage Renal Disease Prospective Payment System
FDA Food and Drug Administration
GEM General Equivalence Mappings
HAIs Healthcare-Acquired Infections
HCPCS Healthcare Common Procedure Coding System
HHS Department of Health and Human Services
ICD International Classification of Diseases
ICD–9–CM International Classification of Disease, 9th Revision, Clinical Modification
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI IHS Global Insight
IOLs Intraocular Lenses
IPPS Inpatient Prospective Payment System
MAP Medicare Allowable Payment
MFP Multifactor Productivity
MLR Minimum Lifetime Requirement
NCD National Coverage Determination
NHSN National Health Safety Network
NQF National Quality Forum
OMB Office of Management and Budget
PFS Physician Fee Schedule
QIP Quality Incentive Program
SHR Standardized Hospitalization Ratio Admissions
SMR Standardized Mortality Ratio
TPS Total Performance Score
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) 2014. 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) (Public Law 110–275), and 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 (Public Law 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, section 1881(b)(14)(I) of the Act, as added by section 632(a) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), requires the Secretary, by comparing per patient utilization from 2007 with such data from 2012, to reduce the single payment amount to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals. Section 632(b) of ATRA prevents the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS before January 1, 2016.

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) 2016. 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. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

This final rule clarifies the definition of routinely purchased equipment covered under the DME benefit category and the scope of the 3-year minimum lifetime requirement (MLR) for DME. In addition, this final rule implements budget neutral fee schedules for splints and casts, and intraocular lenses (IOLs) inserted in a physician's office. Finally, this final rule makes a few technical amendments and corrections to existing regulations related to payment for DMEPOS items and services.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2014:* For CY 2014, the ESRD PPS base rate is $239.02. This reflects the CY 2013 ESRD PPS base rate of $240.36 adjusted by the ESRDB market basket (3.2 percent) minus productivity (0.4 percent) increase factor of 2.8 percent, the wage index budget neutrality factor of 1.000454, and the home dialysis training add-on budget neutrality adjustment factor of 0.999912 to get $247.18 ($240.36 * 1.028 * 1.000454 * 0.999912 = $247.18). We reduced this amount by the portion of the CY 2014 drug utilization adjustment that is being transitioned this year, or $8.16, to arrive at a final CY 2014 ESRD PPS base rate of $239.02 ($247.18 − $8.16 = $239.02).
- *The CY 2014 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. We did not propose any changes to the application of the wage index adjustment factor for CY 2014, and we will continue to apply the adjustment to the ESRD PPS base rate. For CY 2014 and CY 2015, we are continuing our policy for the gradual phase-out of the wage index floor and reducing the wage index floor values to 0.45 and 0.40, respectively.
- *The outlier policy:* We are updating the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult patients for CY 2014 using 2012 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries would increase from $47.32 to $54.01 and the adjusted average outlier services MAP amount would decrease from $41.39 to $40.49 as compared to CY 2013 values. For adult beneficiaries, the fixed-dollar loss amount would decrease from $110.22 to $98.67 and the adjusted average outlier services MAP amount would decrease from $59.42 to $50.25. The 1 percent target for outlier payments was not achieved in CY 2012. We believe using CY 2012 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2014 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier policy.
- *Application of ICD–10–CM Diagnosis Codes to the comorbidity payment adjustment codes:* Effective October 1, 2014, CMS will implement the 10th revision of the ICD coding scheme. We discuss and provide a crosswalk from ICD–9–CM to ICD–10–CM for codes that are subject to the comorbidity payment adjustment. We are finalizing our proposed policy that all ICD–10–CM codes to which ICD–9–CM codes that are eligible for the comorbidity payment adjustments crosswalk will be eligible for the comorbidity payment adjustments with two exceptions.
- *The self-dialysis and home dialysis training add-on adjustment:* In response to public comments, we are finalizing an increase in the amount of the self-dialysis and home dialysis training add-on adjustment of 50 percent for both peritoneal dialysis (PD) and home hemodialysis (HHD) training treatments furnished on or after January 1, 2014. In CY 2014, the nursing time accounted for in the training add-on adjustment will increase from one hour to 1.5 hours per training treatment, resulting in an increase of $16.72, for a total training add-on adjustment of $50.16 per training treatment. We note that the increase to the training add-on adjustment will be made in a budget neutral manner in that we have applied a training add-on budget-neutrality adjustment factor of 0.999912 to the base rate.

2. ESRD QIP

This final rule implements requirements for the ESRD QIP. With respect to the PY 2016 ESRD QIP, we are continuing some of the previous ESRD QIP measures, adding new measures, and expanding 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 Kt/V measure for adult hemodialysis patients, a clinical measure
  - A Kt/V measure for adult peritoneal dialysis patients, a clinical measure
  - A Kt/V measure for pediatric hemodialysis patients, a clinical measure
- To determine whether patients are treated using the most beneficial type of vascular access:
  - An arteriovenous fistula measure, a clinical measure
  - A catheter measure, a clinical measure
- To address effective bone mineral metabolism management:
  - Hypercalcemia, a clinical measure*
  - Mineral Metabolism, a reporting measure †
- To address safety:
  - National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Outpatients, a clinical measure *
- To assess patient experience:
  - ICH CAHPS survey reporting measure ‡

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

† Denotes that this measure is revised in the ESRD QIP.

‡ Denotes that this measure is expanded in the ESRD QIP.

We also establish CY 2014 as the performance period for the PY 2016

ESRD QIP, establish performance standards for each measure, and adopt scoring and payment reduction methodologies that are similar to those finalized for the PY 2015 ESRD QIP.

3. DMEPOS

- *Definition of routinely purchased DME:* This final rule clarifies the definition of routinely purchased DME set forth at section § 414.220(a), as well as addresses the classification of and payment for expensive items of DME and accessories (over $150) as a capped rental items in accordance with § 414.229, if the items were not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.
- *Clarification of to the 3-year MLR and Related Grandfathering Policy:* This final rule provides further clarification about how we will apply the 3-year MLR set forth at § 414.202, which must be satisfied for an item or device to be considered DME.
- *Implementation of budget neutral fee schedules for splints and casts, and IOLs inserted in a physician's office:* For CY 2014, we are implementing budget neutral fee schedule amounts for splints and casts, and IOLs inserted in a physician's office. Section 1842(s) of the Act authorizes CMS to implement fee schedule amounts for these items if they are established so that they are initially budget neutral. In 2011, total allowed charges for splints and casts were $5.6 million, while total allowed charges for IOLs inserted in a physician's office were $76 thousand.

C. Summary of Costs and Benefits

In section XI. 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 XI.B.1.a. of this final rule displays the estimated change in payments to ESRD facilities in CY 2014 compared to estimated payments in CY 2013. The overall impact of the CY 2014 changes is projected to result in an average increase in payments of 0.0 percent from CY 2013 to CY 2014. Hospital-based ESRD facilities have an estimated 0.8 percent increase in payments compared with freestanding facilities with an estimated 0.0 percent increase.

We estimate that there will be no change in aggregate ESRD PPS expenditures from CY 2013 to CY 2014. This reflects a $240 million increase from the payment rate update, a $30 million increase due to the updates to the outlier threshold amounts, and a $20 million increase due to the change in the blend of payments, and a $290 million decrease in expenditures specifically related to the drug utilization adjustment. The drug utilization adjustment for CY 2014 represents 27 percent of the total drug utilization adjustment amount of $29.93. The estimated 0.0 percent overall payment change will result in a small reduction in beneficiary coinsurance compared to CY 2013 beneficiary because the CY 2014 ESRD PPS base rate is slightly less than that CY 2013 base rate, discussed in section II.C.2.a.v.

2. Impacts for ESRD QIP

The overall economic impact of the proposed ESRD QIP is an estimated $15.2 million in PY 2016. In PY 2016, we expect the total payment reductions to be approximately $15.1 million, and the costs associated with the collection of information requirements for certain measures to be approximately $39.5 thousand. For PY 2017 and future payment years, we expect the costs associated with the collection of information requirements for the expanded ICH CAHPS measure in the proposed ESRD QIP to be approximately $9.7 million.

The ESRD QIP will continue to incentivize facilities to provide higher quality care to beneficiaries. The reporting measures associated with the collection of information requirements are critical to better understanding the quality of care beneficiaries receive, particularly patients' experience of care, and will be used to incentivize improvements in the quality of care provided.

3. Impacts for DMEPOS

The overall impact of implementing fee schedules for splints and casts, and IOLs inserted in a physician's office is insignificant. The reasonable charge amounts that we convert to fee schedule amounts will be budget neutral the first year and will be updated annually thereafter based on the consumer price index for all consumers (CPI–U) for the 12-month period ending June 30 of the previous year and, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. For the 3-year MLR, we believe that a vast majority of the categories of items that were classified as DME before January 1, 2012, did function for 3 or more years (76 FR 70289). The 3-year MLR is designed to represent a minimum threshold for determination of durability for equipment that is consistent with the statutory DME payment provisions and applies on a prospective basis, effective January 1, 2012. CMS recognizes that the healthcare industry and beneficiaries have come to rely on items that have qualified as DME on or prior to January 1, 2012, regardless of whether those items met the 3-year MLR set forth at § 414.202. We note that given that reliance and consistent with the regulation at § 414.202, CMS would not reopen those prior decisions and reclassify the equipment in light of the new 3-year standard. We believe that continuing the Medicare coverage for all the items that qualified as DME on or prior to January 1, 2012, would avoid disrupting the continuity of care for the beneficiaries that received these items for medical treatment prior to January 1, 2012, without creating a significant fiscal impact on the Medicare Program. We also do not expect any significant impact as a result of how this rule will be applied in terms of equipment that is modified. Based on our experience with the Medicare Program, items covered as DME prior to 2012 that have lifetimes of less than 3 years are well established and have been used in treating illnesses or injuries of patients for many years. The items are designed to provide treatment for the period of time generally needed for the patient and it is unlikely that devices will be modified to be less durable.

We expect that the overall impact of clarifying the definition of routinely purchased DME and finalizing our proposal to classify certain expensive items as cap rental will be a decrease in expenditures because payment on a 13-month capped rental basis rather than a lump sum purchase basis for certain, very expensive items will lower total payments for these items and because many beneficiaries would not rent the items for as long as 13 months.

II. Calendar Year (CY) 2014 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

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

On August 12, 2010, we published in the **Federal Register** a final rule (75 FR 49030 through 49214) titled, ''End-Stage Renal Disease Prospective Payment System,'' (hereinafter referred to as the CY 2011 ESRD PPS final rule). In the CY 2011 ESRD PPS final rule, we

implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

On November 10, 2011, we published in the **Federal Register**, a final rule (76 FR 70228 through 70316) titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies'' (hereinafter referred to as the CY 2012 ESRD PPS final rule). In that final rule, for the ESRD PPS, we made a number of routine updates for CY 2012, implemented the second year of the transition to the ESRD PPS, made several policy changes and clarifications, and made technical changes.

On November 9, 2012, we published in the **Federal Register**, a final rule (77 FR 67450 through 67531) titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers'' (hereinafter referred to as the CY 2013 ESRD PPS final rule). In that final rule, for the ESRD PPS, we made a number of routine updates for CY 2013, implemented the third year of the transition to the ESRD PPS, and made several policy changes and reiterations. For a summary of the provisions in that final rule, we refer readers to the CY 2014 ESRD PPS proposed rule at 78 FR 40836, 40840–40841 (July 8, 2013).

B. Summary of the Proposed Provisions and Responses to Comments on the CY 2014 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (78 FR 40836 through 40890), (hereinafter referred to as the CY 2014 ESRD PPS proposed rule), was published in the **Federal Register** on July 8, 2013, with a comment period that ended on August 30, 2013. In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of routine updates for CY 2014, (2) implement the fourth and last year of the transition where payments are based 100 percent on the ESRD PPS, and (3) make revisions to the ESRD PPS base rate as required by statute. We received approximately 1282 public comments on the ESRD PPS proposals, including comments from ESRD facilities; national renal groups, nephrologists 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 2014 ESRD PPS. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

C. Routine Updates and Policy Changes to the CY 2014 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 fourth 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 services furnished beginning in CY 2014, under 42 CFR 413.239(a)(4), 100 percent of the payment amount will be determined in accordance with section 1881(b)(14) of the Act. Accordingly, a blended rate will no longer be provided, all facilities will be paid 100 percent under the ESRD PPS, and there will no longer be a transition budget neutrality adjustment factor applied to these payments starting on January 1, 2014. Therefore, facilities that participate in the transition will no longer receive a portion of their payments based on the basic case-mix adjusted composite rate payment system. Because payments will no longer be based on the basic case-mix adjusted composite rate, we will not update the drug add-on or wage index values (which included a budget-neutrality adjustment factor) that comprised that rate. In this final rule, we only discuss updates and policy changes that affect the components of the ESRD PPS.

2. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the development of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment Medicare Allowable Payment (MAP) for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and codified in regulations at § 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 applicable outlier payments or training payments.

As discussed in section II.C.3. of this final rule, section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the rate of increase in the ESRD market basket, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). Accordingly, we applied the 2.8 percent increase factor, that is the ESRDB market basket (3.2 percent) minus productivity (0.4 percent) to the CY 2013 ESRD PPS base rate of $240.36, which results in a CY 2014 ESRD PPS base rate of $247.09 ($240.36 × 1.028 = $247.09).

In addition, as discussed in section II.C.4.d. of this final rule, we apply the wage index budget-neutrality adjustment factor of 1.000454 to the CY 2014 ESRD PPS base rate (that is, $247.09), yielding a CY 2014 ESRD PPS wage-index budget-neutrality adjusted base rate of $247.20 ($247.09 × 1.000454 = $247.20). Also, as discussed in section II.D.b. of this final rule, we finalized an increase in the home dialysis training add-on in a budget-neutral manner. Because this adjustment was applied in a budget-neutral manner, we needed to adjust the CY 2014 ESRD PPS base rate after the application of the wage index budget neutrality adjustment factor to account for the increase in training payments. This application yields a CY 2014 ESRD PPS base rate of $247.18 ($247.20 × 0.999912 = $247.18). This amount is then reduced by the portion of the drug utilization adjustment that is being implemented this year, which is $8.16, which yields a final CY 2014 base rate of $239.02. The drug utilization adjustment is addressed in the following section.

a. Adjustment to the ESRD PPS Base Rate To Reflect the Change in Utilization of ESRD-Related Drugs and Biologicals

Section 1881(b)(14)(I) of the Act, as added by section 632(a) of the ATRA, requires that, for services furnished on or after January 1, 2014, the Secretary shall make reductions to the single payment for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs) by comparing per patient utilization data from 2007 with such data from 2012. Section 1881(b)(14)(I) further requires that in making the reductions, the Secretary take into account the most recently available data on Average Sales Prices (ASP) and changes in prices for drugs and biologicals reflected in the ESRD market basket percentage increase factor under section 1881(b)(14)(F) of the Act. Consistent with these requirements, in the CY 2014 ESRD PPS proposed rule (78 FR 40843) we proposed to apply a payment adjustment to the CY 2014 ESRD PPS base rate that reflects the change in utilization of ESRD-related drugs and biologicals from CY 2007 to CY 2012.

i. Methodology for Reducing the CY 2014 ESRD PPS Base Rate

In the CY 2014 ESRD PPS proposed rule (78 FR 40841 through 40843), we discussed the methodology used for calculating the drug utilization adjustment that will reduce the ESRD PPS base rate. Because the ESRD PPS base rate is a per treatment base rate, the adjustment is calculated on a per treatment basis. We proposed to calculate the amount of the per treatment adjustment by applying CY 2014 prices for ESRD-related drugs and biologicals to the utilization data for CY 2007 and CY 2012. We noted that the CY 2014 ESRD PPS base rate is reflective of 2007 utilization because the base rate was derived from CY 2007 data. We explained that using prices for drugs and biologicals inflated to 2014 levels allows us to appropriately measure changes that are attributable to utilization patterns as opposed to differences in pricing for drugs and biologicals in 2007 and 2012. In addition, because we proposed to make the reduction in CY 2014, we priced the ESRD-related drugs and biologicals for the year in which the adjustment applies. We explained that for purposes of this analysis, we view utilization of drugs and biologicals as units of an ESRD-related drug or biological furnished to a patient on a per treatment basis. We took the estimated amount of the per treatment difference between the estimated spending on drugs and biologicals in CY 2007 and CY 2012 and reduced this amount by the same adjustment factors that were used to calculate the ESRD PPS base rate from the CY 2007 unadjusted rate per treatment, which are the standardization, outlier, and the 98 percent budget-neutrality adjustments. A detailed explanation of these adjustment factors is provided in the CY 2011 ESRD PPS final rule (75 FR 49081 through 49082). We proposed to reduce the CY 2014 ESRD PPS base rate by the resulting amount.

ii. Determining Utilization of ESRD-Related Drugs and Biologicals

In the CY 2014 ESRD PPS proposed rule (78 FR 40841 through 40842), we explained how we determined utilization of ESRD-related drugs and biologicals. Section 1881(b)(14)(I) of the Act requires the single payment amount to be reduced by an amount that ''reflects the Secretary's estimate of the change in utilization of drugs and biologicals described in clauses (ii), (iii), and (iv) of subparagraph (B) (other than oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary in the **Federal Register** on August 12, 2010 (75 FR 49030))''. As we mentioned above, for purposes of this analysis, we view utilization of drugs and biologicals as units of a drug or biological furnished to a patient per treatment. ESRD facilities report this information on claims. To calculate this adjustment, we analyzed the utilization of erythropoiesis stimulating agents (ESAs) and any oral forms of such agents furnished to individuals for the treatment of ESRD. We also analyzed the utilization of other injectable drugs and biologicals (such as iron sucrose and doxercalciferol) and any oral equivalent form of such drug or biological furnished to individuals for the treatment of ESRD that were included in the expanded bundle of services covered by the ESRD PPS. We did not include diagnostic laboratory tests or other items and services in the comparison analysis because section 1881(b)(14)(I) only refers to estimating the change in utilization of drugs and biologicals.

Section 1881(b)(14)(I) of the Act requires the Secretary to compare per patient utilization data from 2007 with per patient utilization data from 2012. For the CY 2007 utilization data for ESRD-related drugs and biologicals, we proposed to use the data analysis prepared for the CY 2011 ESRD PPS final rule. In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discuss in detail the development of the ESRD PPS base rate and, as we stated above, the base rate represents the average MAP for composite rate and separately billable services, which was derived from 2007 claims data. We also explained in the CY 2011 ESRD PPS final rule that in order to comply with section 1881(b)(14)(A)(ii) of the Act, we determined that 2007 was the year with the lowest per patient utilization of renal dialysis services by Medicare ESRD beneficiaries among the years 2007, 2008, and 2009. Therefore, utilization data for ESAs and other drugs and biologicals including the oral-equivalent forms of those drugs and biologicals furnished for the treatment of ESRD was readily available for purposes of analyzing 2007 utilization.

For the CY 2012 utilization data for ESRD-related drugs and biologicals, we proposed to use the latest available claims data based on the CY 2012 ESRD facility claims. For the proposed rule, we used CY 2012 ESRD facility claims updated through December 31, 2012 (that is, claims with dates of service from January 1 through December 31, 2012, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2012). We stated that we would use the CY 2012 claims file updated through June 30, 2013, (that is, claims with dates of service from January 1 through December 31, 2012, that were received, processed, paid, and passed to the National Claims History File as of June 30, 2013) to calculate 2012 utilization for the final rule. We solicited comments on the proposed use of 2007 and 2012 claims data to capture the utilization of ESRD-related drugs and biologicals in those years. The comments and our responses are set forth below.

Comment: Several commenters agreed with CMS that claims data from 2007 and 2012 are reliable sources for ESRD-related drugs and biologicals utilization.

Response: We thank the commenters for their support. For this final rule, we used the CY 2007 claims data that was used in preparation of the CY 2011 ESRD PPS final rule. In addition, we used the CY 2012 claims file updated through June 30, 2013, (that is, claims with dates of service from January 1 through December 31, 2012, that were received, processed, paid, and passed to the National Claims History File as of June 30, 2013) to calculate 2012 utilization.

In the CY 2014 ESRD PPS proposed rule (78 FR 40842), we explained that because section 1881(b)(14)(I) requires

that we compare per patient utilization of ESRD-related drugs and biologicals in 2007 with per patient utilization in 2012, we would also include utilization of drugs and biologicals furnished in ESRD facilities located in the United States Territories of Guam, American Samoa and the Northern Mariana Islands (the Pacific Rim), even though facilities in the Pacific Rim were not paid under the ESRD PPS during these years. Therefore, we proposed to use 2007 and 2012 utilization of ESRD-related drugs and biologicals (including oral equivalents) for ESRD facilities located in these territories in our analysis of the reduction required by section 1881(b)(14)(I). For the proposed rule, we did not readily have access to the 2007 utilization data for the ESRD facilities located in these areas; however, we planned to include these data in our calculation for the final rule. Because there are very few ESRD facilities in this region, we indicated that the inclusion of utilization of drugs and biologicals furnished in CY 2007 at these facilities would not have a significant impact on the amount of the adjustment.

We solicited comments on the proposal to include data on the utilization of drugs and biologicals furnished in ESRD facilities located in the Pacific Rim when comparing utilization of drugs and biologicals in CY 2007 with CY 2012. We did not receive any comments objecting to the use of data from ESRD facilities located in the Pacific Rim in the analysis. In the analysis for this final rule, we have included the drug utilization data from facilities located in the Pacific Rim.

iii. Pricing of ESRD-Related Drugs and Biologicals

In the CY 2014 ESRD PPS proposed rule (78 FR 40842 through 40843), we explained how we priced ESRD-related drugs and biologicals to CY 2014 to allow for an accurate comparison between utilization of those drugs and biologicals furnished in CY 2007 with utilization in CY 2012. In order to price ESRD-related drugs and biologicals based on CY 2014 prices, we started with CY 2011 prices as established and published in the CY 2011 ESRD PPS final rule.

In developing the CY 2011 ESRD PPS base rate, we included the MAP amounts for ESRD-related drugs and biologicals that were, prior to January 1, 2011, separately paid under Part B. We used the second quarter of 2010 ASP+6 prices (which was the most current data available at the time) and then used the Producer Price Index (PPI) to inflate the prices to CY 2011 (75 FR 49079). We also included the MAP amounts for the ESRD-related oral-equivalent drugs and biologicals that were, prior to January 1, 2011, separately paid under Part D (75 FR 49080). For setting the CY 2011 ESRD PPS base rate for these drugs, we used the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections (NHE) for updating prices for former Part D drugs to CY 2011 from CY 2007.

We proposed to inflate the prices established in the CY 2011 ESRD PPS final rule for ESRD-related drugs and biologicals and their oral equivalents to CY 2014 by applying the ESRD bundled (ESRDB) market basket, the productivity adjustment, and the wage index budget neutrality adjustment factors. Because the base rate and the ESRDB market basket account for ESRD-related drugs and biologicals and we have updated all components of the base rate annually using a market basket minus productivity with wage index budget neutrality adjustment factor, we believe that using these inflation factors is consistent with how these services are paid under the ESRD PPS. The drug component of the ESRDB market basket uses the PPI for prescription drugs as a proxy for the growth in drug prices. We believe using the ESRDB market basket to price drugs and biologicals for CY 2014 complies with the requirement in section 1881(b)(14)(I) that the Secretary take into account the changes in prices for drugs and biologicals reflected in the ESRDB market basket percentage increase factor. The ESRDB market basket minus productivity increase factors were 2.1 percent and 2.3 percent for CY 2012 and CY 2013, respectively. The proposed CY 2014 update was 2.5 percent. The wage index budget neutrality adjustment factors for the same years are 1.001520, 1.000613, and a CY 2014 proposed factor of 1.000411. Therefore, we proposed to use a total growth update factor of 7.3 percent (1.021 * 1.023 * 1.025 * 1.001520 * 1.000613 * 1.000411 = 1.073) to inflate prices for ESRD-related drugs and biologicals from CY 2011 levels to CY 2014 levels. We solicited comments on the use of the ESRDB market basket percentage increase factor to inflate prices for drugs and biologicals to CY 2014 levels. The comment and our response is set forth below.

Comment: A few commenters expressed concern that inflating the prices from 2007 levels does not capture the true cost of the drugs and biologicals for small and independent ESRD facilities and small dialysis organizations (SDOs). One commenter stated that if the price is an average number, then SDOs and mid-sized dialysis organizations (MDOs) would be at a disadvantage because their prices are far greater than the prices paid by large dialysis organizations. Therefore, the commenters did not believe that the costs incurred by SDOs and MDOs were accounted for by using 7.3 percent to inflate prices for ESRD-related drugs and biologicals from CY 2011 levels to CY 2014 levels and urged CMS to use actual drug costs reported on ESRD facility cost reports.

Response: The drug utilization adjustment is a per treatment reduction to the single ESRD PPS base rate, which is a payment amount that reflects the average cost for an ESRD facility to furnish a dialysis treatment. Because the drug utilization adjustment is a reduction to the average payment, the drug utilization analysis needs to be performed at an aggregate level, that is, across all facilities using the same sources of data regardless of ownership type. In addition, we do not believe that it would be beneficial to SDOs/MDOs to use drug costs that are reported in ESRD facility cost reports. Even if we were to use cost report drug data, the SDO/MDO costs for drugs would continue to be averaged out by that of the large dialysis organizations (LDOs), which furnish the majority of dialysis treatments. More importantly, we would only be able to consider the ESRD facility cost reports for cost reporting periods ending in 2011 and in 2012 for the drug utilization adjustment analysis, We would not have the information for cost reporting periods ending in 2013, which is when significant price increases have reportedly occurred.

For these reasons, we continue to believe using the ESRDB market basket to price drugs and biologicals for CY 2014 complies with the requirement in section 1881(b)(14)(I) that the Secretary take into account the changes in prices for drugs and biologicals reflected in the ESRDB market basket percentage increase factor and provides the most accurate way to price drugs at 2014 levels. Therefore, in this final rule we are finalizing the use of the ESRDB market basket percentage increase factor to inflate prices for drugs and biologicals to CY 2014 levels.

To determine the final growth update factor's value, we used the methodology discussed above with one modification (described below) and updated the calculation using the final CY 2014 ESRDB market basket minus the CY 2014 multifactor productivity adjustment and the final CY 2014 wage index budget neutrality adjustment factor, which are based on the most recently available data. The ESRDB

market basket minus productivity increase factors were 2.1 percent and 2.3 percent for CY 2012 and CY 2013, respectively. The final ESRDB market basket minus productivity increase factor for CY 2014 is 2.8 percent. The wage index budget neutrality adjustment factors for the same years are 1.001520, 1.000613, and a final CY 2014 factor of 1.000454.

In addition to the ESRDB market basket minus productivity increase factor and the wage index budget neutrality adjustment factor, to account for the home dialysis training add-on increase for CY 2014 we applied an additional factor of 0.999912. We made this modification so that the methodology for developing the growth update factor is consistent with the way we update the ESRD PPS base rate. For CY 2014, we are increasing the home dialysis training add-on in a budget-neutral manner, and therefore, we needed to include an adjustment that accounts for the increase. We are finalizing a total growth update factor of 7.64 percent (1.021 * 1.023 * 1.028 * 1.001520 * 1.000613 * 1.000454 * 0.999912 = 1.0764) to inflate prices for ESRD-related drugs and biologicals from CY 2011 levels to CY 2014 levels. For more information regarding the increase in the home dialysis training add-on payment, see section II.D.b. of this final rule.

In addition to proposing the use of the ESRDB market basket percentage increase factor to inflate prices for drugs and biologicals to CY 2014 levels, in the CY 2014 ESRD PPS proposed rule (78 FR 40843) we discussed an alternative method of using ASP instead of the PPI. Specifically, section 1881(b)(14)(I) requires the Secretary to ''take into account the most recently available data on average sales prices and changes in prices for drugs and biologicals reflected in the ESRDB market basket percentage increase factor'' in making the reduction to the ESRD PPS base rate to reflect the change in utilization of ESRD-related drugs and biologicals from CY 2007 to CY 2012. While we could have chosen to inflate prices for drugs and biologicals to 2014 levels with more recently available ASP data, we stated that we believed using a growth based on the ESRDB market basket is more appropriate because it reflects what Medicare is required to pay for drugs and biologicals through the ESRD PPS base rate.

In the CY 2014 ESRD PPS proposed rule (78 FR 40843), we discussed an alternative analysis using prices based on the first quarter 2013 ASP+6 percent prices and the National Drug Code (NDC) prices published on the CMS Web site located at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html* that are used for outlier calculations, and the PPI to project to CY 2014. The results were minimally different (a difference of $29.40 versus $29.52), and because we believed that the ESRDB market basket approach was a more appropriate measure of how Medicare pays for these drugs under the ESRD PPS, we proposed to use it to update drug prices. Nonetheless, we solicited comments on the potential use of ASP instead of the ESRDB market basket to inflate drug prices to 2014 levels for purposes of the drug utilization adjustment. The comments and our responses are set forth below.

Comment: An SDO expressed concern that the alternative analysis of comparing ASP to PPI is not accurate because there is an inherent problem with using ASP data. The commenter stated that ASP data does not accurately reflect the cost of epogen because the ASP data reports the combined price of epogen and procrit. The commenter further explained that procrit has a lower price than epogen but it is not a drug that ESRD facilities can purchase as an ESA to furnish to their patients because it is indicated for non-ESRD use. The commenter stated that while the average cost of procrit has diminished since 2007, the cost of epogen has risen significantly for SDOs and therefore the commenter believes that this results in a lower overall ASP amount because procrit dilutes the ASP price. A national organization for SDOs and an MDO expressed concern that due to the lag in the reporting and publishing of ASP data, the price increases that they have experienced were not fully reflected in the analysis.

Response: We thank the commenters for this information. The ASP+6 payment limits are based on actual marketplace prices submitted by manufacturers to CMS. Given that the ASP is an average price, some National Drug Codes (NDCs) in a given HCPCS code will be available at prices below the payment limit and others will be above the payment limit. The payment limits are evaluated and updated on a quarterly basis. We will initiate discussions with appropriate staff regarding the ASP for epogen to gain a better understanding of how including procrit impacts the ASP. We agree that the lag in reporting price increases in the ASP system as well as the combination of ASP data for Epoetin with that of procrit makes the use of ASP+6 prices to update the prices of drugs and biologicals to 2014 levels less desirable.

After consideration of the comments that we received on the use of ASP versus PPI, we continue to believe that using a growth based on the ESRDB market basket is more appropriate because it reflects what Medicare is required to pay for the drugs and biologicals through the ESRD PPS base rate and because, as commenters noted, ASP prices may not be accurate or up-to-date for drugs and biologicals used in the treatment of ESRD.

iv. Calculation of the Amount of the Per Treatment Reduction

In the CY 2014 ESRD PPS proposed rule (78 FR 40843), we provided detail on how the drug utilization reduction amount was calculated. We applied the 2014 prices to the CY 2007 and CY 2012 drug and biological utilization data to calculate aggregate amounts for each year. For drugs and biologicals for which we have utilization data for CY 2012, but that were not present on CY 2007 claims, we priced those drugs using the ASP+6 percent price for 2012, which is an average of the four quarter prices, and inflated it using the CY 2013 and the CY 2014 proposed ESRDB market basket, productivity, and wage index budget neutrality adjustment factors. We noted that while most of these drugs had minimal utilization, feraheme was the only significant exception. Specifically, feraheme was not available until January 2010 and once the drug was available, the use of the drug rose to the top 12th drug furnished to ESRD beneficiaries.

Next, we divided each year's estimated aggregate amount for drugs and biologicals by that year's count of treatments furnished to Medicare beneficiaries to get an average payment per treatment for the year. This resulted in a per treatment amount for drugs and biologicals of $83.76 in 2007 and a per treatment amount for drugs and biologicals of $51.42 in 2012. We then subtracted the average payment per treatment for CY 2012 from the average amount per treatment for CY 2007 to get a total of $32.34 ($83.76 − $51.42 = $32.34). We then reduced this amount by the standardization, the outlier, and the 98 percent budget neutrality adjustments to get a total of $29.52 ($32.34 × .9407 × .99 × .98 = $29.52). We applied these adjustments before reducing the base rate because the base rate was reduced by these adjustments when it was first established, and the reduction should be adjusted in the same way to make the two figures comparable. We then reduced the CY 2014 proposed base rate of $246.47 by $29.52, resulting in the CY 2014 proposed base rate of $216.95. A

reduction of $29.52 from the proposed CY 2014 ESRD PPS base rate would have amounted to a 12 percent reduction in Medicare payments. We solicited comments on the proposed methodology for the reduction to the ESRD PPS base rate to reflect the change in the utilization of ESRD-related drugs and biologicals from CY 2007 to CY 2012. The comments and our responses are set forth below.

Comment: We received comments from national organizations and a drug manufacturer that stated they were unable to determine if the methodology CMS used to calculate the reduction was proper because they did not have access to the same data that was used in the calculation.

Response: We disagree with commenters who contend that they were unable to determine whether CMS's methodology was proper because they did not have access to all of the data used to calculate the amount of the reduction. Our methodology for calculating the drug utilization adjustment required by section 1881(b)(14)(I) was described in substantial detail in the CY 2014 ESRD PPS proposed rule. As a result, we do not believe that it was necessary for commenters to have every data point used in our calculations in order to have commented meaningfully on the methodological approach to the adjustment. Nonetheless, between the information provided in the proposed rule and included in the CY 2011 ESRD PPS final rule, commenters did have data we used in calculating the drug utilization adjustment. Moreover, shortly after the CY 2014 ESRD PPS proposed rule was published we posted a table titled, ''Drug Utilization Adjustment'' onto the CMS Web site as a convenience to stakeholders following requests for the data points used in our calculation of the drug utilization adjustment amount. This table includes the data we used to perform the calculation of the reduction amount for the proposed rule and it is posted with the rule's addenda. Addendum C titled, ''Calculation of the Amount of the Per Treatment Reduction Using the End-Stage Renal Disease Bundled Market Basket'' contains updated data and the methodology used for this final rule. The Addendum can be found on the CMS Web site: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.*

Comment: We received a comment from the Medicare Payment Advisory Commission (MedPAC) stating that they compared their own analyses of the changes in drug utilization using CMS's methods and alternative methods to check for errors in the methodology. They concluded that CMS' methods are consistent with the ATRA mandate and appear to be reasonable.

Response: We thank the MedPAC for their support.

v. Final Amount of the Drug Utilization Adjustment

Using the methodology we proposed in the 2014 ESRD PPS proposed rule, we are updating the drug utilization adjustment based on the most current claims data available, that is, CY 2012 claims with dates of service from January 1 through December 31, 2012 that were received, processed, paid, and passed to the National Claims History File as of June 30, 2013. We applied the 2014 prices to the CY 2007 and CY 2012 drug and biological utilization data to calculate aggregate amounts for each year. For drugs and biologicals for which we have utilization data for CY 2012, but that were not present on CY 2007 claims, we priced those drugs using the ASP+6 percent price for 2012, which is an average of the four quarter prices, and inflated it using the CY 2013 and the CY 2014 ESRDB market basket, productivity, and wage index budget-neutrality adjustment factors.

Next, we divided each year's estimated aggregate amount for drugs and biologicals by that year's count of treatments furnished to Medicare beneficiaries to get an average payment per treatment for the year. This resulted in a per treatment amount for drugs and biologicals of $83.96 in 2007 and a per treatment amount for drugs and biologicals of $51.17 in 2012. We then subtracted the average payment per treatment for CY 2012 from the average amount per treatment for CY 2007 to get a total of $32.79 ($83.96 − $51.17 = $32.79). We then reduced this amount by the standardization, the outlier, and the 98 percent budget neutrality adjustments to get a total of $29.93 ($32.79 × .9407 × .99 × .98 = $29.93). As in the proposed rule, we applied these adjustments because the base rate was reduced by these adjustments when it was first established, and the reduction should be adjusted in the same way to make the two figures comparable. We are finalizing the drug utilization adjustment amount of $29.93. As discussed further below, this amount will be applied to the base rate over the course of a 3- to 4-year transition.

Comment: Several national organizations representing the dialysis industry and dialysis patients believe our CY 2011 ESRD PPS base rate is incorrect and recommended that we correct the base rate prior to application of the drug utilization adjustment to account for overstated estimates of payment adjustments, especially the comorbidity case-mix adjusters, the outlier policy, and the low-volume adjuster. Because these adjustments have been paid out at a rate less than anticipated, the commenters stated that we have not met our obligation under section 1881(b)(14)(A)(ii) of the Act, which requires the Secretary to ensure that the estimated total amount of payments for 2011 for renal dialysis services equals 98 percent of the estimated total amount of payments that would have been made for services furnished in 2011 if the ESRD PPS had not been implemented. Furthermore, these commenters indicated that they were unable to receive discharge information from hospitals to document the comorbid conditions, which is necessary to seek reimbursement for the comorbidity payment adjustments. In order to the make the comorbidity adjustments more accessible, the commenters urged us to revisit the documentation requirements or remove the comorbidity adjustments entirely and return the dollars to the base rate.

Dialysis organizations also encouraged CMS to substantially reduce the percentage of the outlier pool or eliminate it entirely. One commenter is concerned that SDO and non-profit providers are disproportionately impacted by this provision because they do not have the infrastructure of larger providers and therefore are less likely to capture all of the costs for a patient. The commenter went on to state the net effect of the outlier policy is that a provision that was originally put into place to protect small providers is actually penalizing them by decreasing the base rate. This same commenter recommended that CMS either suspend or, if that is not feasible, lower the outlier withhold from 1.0 percent to 0.5 percent.

Finally, several commenters referenced the GAO report 13–287, entitled, ''End-Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment'' and published March 1, 2013, that found discrepancies in the identification of low-volume facilities. One commenter suggested that CMS delay implementation of the drug utilization adjustment until the purported problems with the underlying PPS can be resolved.

Response: In developing the final ESRD PPS base rate for 2011, in accordance with section 1881(b)(14)(A)(ii) of the Act, we standardized the rate to account for the

payment adjustments and the outlier policy. As stated in the 2011 ESRD PPS final rule (75 FR 49081), to account for the overall effects of the proposed ESRD PPS case-mix patient and facility adjustment factors and wage indexes, we had to standardize payments in order to ensure that total projected PPS payments were equal to what would otherwise have been paid had the ESRD PPS not been implemented, prior to application of the 98 percent budget-neutrality adjustment. The standardization factor was calculated by dividing total estimated payments in 2011 under the basic case-mix adjusted composite rate payment system by estimated payments under the final ESRD PPS in 2011. We do not intend to revise the standardization factor that was applied to the 2011 ESRD PPS base rate to reflect actual payments made under each of the adjustments and therefore we did not propose to re-standardize the CY 2014 ESRD PPS base rate. Rather, we used the best data available and made a good faith effort to simulate payments under the ESRD PPS to determine the standardization factor that was applied to the CY 2011 ESRD PPS base rate. The final standardization adjustment was .9407 or a reduction of 5.93 percent from the unadjusted per treatment base rate.

Since the ESRD PPS began, organizations representing LDOs have expressed concern about the comorbidity adjustments and requested that we return the 5.93 percent standardization factor to the base rate. In response to this concern, in preparation for this final rule, we performed an analysis of the composition of the standardization factor and determined that the bulk of the 5.93 percent standardization reduction to the base rate arises from factors other than the comorbidities. Age adjustments account for approximately 3.0 percent, the onset of dialysis adjustment accounts for approximately 2.4 percent, the low volume adjustment accounts for approximately 0.3 percent, the body size adjustments account for approximately 0.2 percent, and the wage adjustment accounts for approximately −0.7 percent (this was negative and partially offset the effects of the other adjustments because the average wage adjustment was less than 1.00, unlike the other adjustments). The comorbidity adjustments jointly account for approximately 0.8 percent.

Section 632(c) of ATRA requires the Secretary, by not later than January 1, 2016, to conduct an analysis of the case mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments. Pursuant to this authority, CMS plans to conduct a regression analysis for the CY 2016 ESRD PPS rulemaking cycle to reassess the appropriateness of the patient and facility level payment adjustments. At that time, we plan to analyze the various payment adjustments under the PPS to determine whether they should continue to apply as well as whether the magnitude of the adjustments is appropriate.

In responses to the comments regarding the comorbidity adjustments, we will consider whether changes to documentation requirements are warranted with respect to qualifying for the comorbidity payment adjustment.

In regards to the outlier policy, as we explained in section II.C.6. of this final rule, 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 variations in the amount of erythropoiesis stimulating agents necessary for anemia management. Each year, we simulate payments under the ESRD PPS in order to set the outlier fixed dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1 percent outlier policy. We would not increase the base rate in years where outlier payments were less than 1 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments. Rather, we would simulate payments in the following year and adjust the fixed dollar loss and MAP amounts to try to achieve outlier payments that meet the 1 percent outlier percentage. This approach to updating the outlier policy is consistent with how we update outlier policies in other Medicare prospective payment systems, for example, the prospective payment system for inpatient psychiatric facilities. We believe that the outlier policy continues to be important for patient access to ESRD-related services because it offsets the cost of high-cost patients, particularly those who receive more drugs and biologicals than the average patient. We will reassess the outlier policy along with our review of the other payment adjustments for the CY 2016 ESRD PPS. With respect to the low-volume payment adjustment, we are reviewing the GAO's findings and are considering their recommendations.

Comment: A national organization representing large dialysis organizations (LDOs) and ESRD facilities recommended that prior to making any adjustment to reduce payments to reflect changes in utilization of drugs and biologicals, CMS should take into consideration what these commenters believe to be a cross subsidization of items and services that were previously paid for under the basic case-mix adjusted composite rate payment system with payments for formerly separately billable items. The commenters believe that because the composite rate, which historically did not have annual market basket increases, was underfunded, payments for separately billable drugs, laboratory tests, and supplies offset those losses. The organization provided a report that estimates that $15–20 of costs for items and services that were previously paid for under the basic case-mix adjusted composite rate payment system are subsidized by the incorporation into the base rate of formerly separately billable drugs and biologicals, laboratory tests, and supplies. The commenters stated that CMS has the authority to take into account that Congress intended that some previously separately billable drug dollars be used to compensate for items and services formerly paid for under the purportedly underfunded basic case-mix adjusted composite rate payment system. This comment was supported by other national providers and patient organizations.

Response: Section 1881(b)(14)(I) of the Act requires that the single payment amount be reduced by an amount that reflects the Secretary's estimate of the change in utilization of drugs and biologicals. It does not provide for the reduction to account for cross-subsidization of other components of the base rate. We do not believe we would be in compliance with section 1881(b)(14)(I) if we were to eliminate most of the drug utilization reduction to reflect the purported need for cross-subsidization of the composite rate with separately billable services.

Comment: In making the reduction to the ESRD PPS base rate, national organizations representing the dialysis industry and dialysis patients recommended that we factor in the 2 percent reduction already made to the original ESRD PPS base rate in 2011 as required by section 1881(b)(14)(A)(ii), which was implemented in the form of the 98 percent budget neutrality adjustment. The comments indicated that this reduction accounts for the anticipated reduction in drug utilization and has already been built into the payment rate. The commenters stated that CMS has the authority to temper the drug utilization adjustment because section 1881(b)(14)(I) does not require a dollar-for-dollar adjustment. Rather, the statute indicates that the adjustment

should ''reflect'' the Secretary's estimate of the change in utilization of drugs and biologicals. Therefore, the commenters contended, CMS has the authority to consider the 2 percent reduction implemented in 2011 as part of the drug utilization adjustment.

Response: In the CY 2014 ESRD PPS proposed rule (78 FR 40843), we explained that once we determined the per-treatment difference in utilization of drugs and biologicals ($32.34), we reduced this amount by the standardization, the outlier, and the 98 percent budget neutrality adjustment to yield the proposed drug utilization adjustment amount of $29.52. As noted previously, for this final rule, the difference in drug utilization per treatment was computed to be $32.79 and this amount was also reduced by the standardization, the outlier, and the 98 percent budget neutrality adjustment to yield the final drug utilization adjustment amount of $29.93. Therefore, the 98 percent budget neutrality adjustment was considered in computing the drug utilization adjustment. Moreover, because the 98 percent budget neutrality adjustment and the drug utilization adjustment both apply to the ''single'' payment rate required by section 1881(b)(14)(A), we do not believe it would be appropriate to reduce the drug utilization adjustment by the amount of the 98 percent budget neutrality adjustment, absent a clear statement of congressional intent that we should do so.

Comment: Several national dialysis organizations indicated that CMS has an obligation to ensure that the single payment amount is consistent with the factors set forth in section 1881(b)(2)(B) of the Act, which provides that payment amounts for renal dialysis services be determined on a ''cost-related basis or other economical and equitable basis.'' The commenters submitted data that displayed profit margins for ESRD facilities prior to the proposed one-time reduction and then what the profit margins would look like after the one-time reduction. The comments stated that if payment rates do not reflect the cost of providing care, then they are neither economical nor equitable. Also, since section 1881(b)(14)(I) did not repeal section 1881(b)(2)(B) and the sections do not conflict with one another, both must be considered. In addition, because Congress inserted an ''and'' between section 1881(b)(2)(B) requirements and section 1881(b)(7)—the reference to the payment system in effect at the time the provision was modified—this suggests the intent to have a two-step process for setting the payment rate. Commenters claim this conjunction suggests that the Secretary must not only apply the provisions that prescribe the payment model, but also evaluate the final payment amount against the factors outlined in subsection (b)(2)(B). Using these authorities, commenters claim CMS could temper any payment reduction so the final amount remains based either upon the cost of providing services or upon economic and equitable factors. The commenters indicated that a payment amount that does not cover the cost of providing care would not be cost-related or equitable. The commenters believe use of the word ''reflect'' in section 1881(b)(14)(I) provides CMS the authority to adjust the drug utilization adjustment consistent with other provisions of section 1881. The commenters contend that this interpretation is also supported by the fact that section 1881(b)(14)(I) notes that the drug utilization adjustment applies to ''this paragraph'' (which establishes the PPS bundle) and thus, does not override or repeal other provisions of this section, including section 1881(b)(2)(B).

Response: We disagree with the commenters that section 1881(b)(2)(B) of the Act applies to the ESRD PPS. The MIPPA revisions to section 1881 of the Act did not specify that we must take section 1881(b)(2) of the Act into account in implementing the ESRD PPS. Instead, it required that we base the ESRD PPS on the lowest per patient utilization year out of 2007, 2008, and 2009 and that the system should result in payments that are 98 percent of what would otherwise have been paid. Once we established that 2007 was the lowest per patient utilization year, we used cost report and claims data to compute the base rate. Section 1881(b)(14)(I) requires the Secretary to compare per patient utilization data for 2007 with such data for 2012 and then make reductions to the ESRD PPS single payment amount to reflect the Secretary's estimate of the change in utilization of drugs and biologicals. We do not believe this very specific statutory provision gives us discretion to mitigate the amount of the reduction based on the very general authority of section 1881(b)(2)(B), which, moreover, we believe no longer applies to payment for renal dialysis services.

Other commenters pointed out that the prospective payment systems should protect beneficiary access while conserving beneficiaries' and taxpayers' resources. Accordingly, in addition to proposing a full reduction of $29.52 in CY 2014, in the CY 2014 ESRD PPS proposed rule (78 FR 40843), we noted that a one-time reduction to the ESRD PPS base rate could be a significant reduction for ESRD facilities for the year and potentially impact beneficiary access to care. Therefore, we solicited comments on a potential transition or phase-in period of the proposed 12 percent reduction and the number of years for such transition or phase-in period. The comments related to a transition and our responses are set forth below.

Comment: We received a comment from MedPAC providing the details from their March 2013 report to Congress which is one of two reports that they issue each year to advise Congress on issues affecting the Medicare program (the March 2013 report is available at the following link: *http://www.medpac.gov/documents/Mar13_entirereport.pdf*). Specifically, MedPAC noted that there is historical evidence that implementation of PPSs in Medicare has been characterized by providers quickly reducing use of services included in the payment bundle, resulting in periods of ''overpayment'' where providers benefit from the change in practice patterns and the Medicare program does not realize savings until the payment is adjusted. The MedPAC recommended that the Medicare program move expeditiously toward correcting overpayments, while also adjusting payments so that providers have time to respond in a way that does not disrupt beneficiary access. The MedPAC further recommended that CMS consider their analyses of Medicare margins, that is, the extent to which facilities are reimbursed more than their cost of furnishing services to Medicare beneficiaries, in implementing the drug utilization reduction. Based upon the available 2011 cost reports at the time of their analysis, MedPAC estimated an aggregate 2011 Medicare margin of about 4 percent for free standing ESRD facilities.

Specifically, MedPAC recommended that the Secretary take action to freeze the payment rates for 2014 at 2013 levels, consistent with their recommendation to the Congress in their March 2013 report. MedPAC explained that this method would accomplish several goals. First, it would start to move the payment system toward greater accuracy and in doing so, protect scarce Medicare resources paid for by the beneficiary and the taxpayer. Second, it would protect beneficiary access and give MedPAC the ability to report back to Congress on any developing access issues should they occur. Third, it would give ESRD facilities time to respond to payment changes by identifying efficiencies in care. Lastly, it would give CMS,

MedPAC, and the Congress time to consider policies that should be changed concurrent with further refinements, such as targeting facilities critical to beneficiary access (rather than protecting industry-wide payment rates) and improving the case-mix adjustments.

Response: We agree with the MedPAC suggestion that freezing payments could ensure access to essential ESRD services while not further perpetuating overpayments. However, we believe that section 1881(b)(14)(I) of the Act requires that, effective January 1, 2014, we ''make reductions to the single payment that would otherwise apply. . . .'' and therefore, we believe the base rate must be reduced by some portion of the drug utilization adjustment amount to be consistent with this provision. We interpreted MedPAC's recommendation of freezing payment rates at the CY 2013 level, provided in both their public comment and in their March 2013 Report to Congress, to mean that payment is adequate in CY 2013. We believe that we can be in compliance with section 1881(b)(14)(I) and follow MedPAC's recommendation by applying a portion of the drug utilization reduction to the base rate to offset the payment update, that is, the ESRDB market basket minus productivity increase factor, and other impacts (such as, changes in the outlier thresholds) to create an overall impact of zero percent for ESRD facilities from the previous year's payments in CYs 2014 and 2015. We relied on the impact chart provided in the impact analysis section of our annual rules to determine the impact of various policy changes on aggregate ESRD facility payments and took those values into consideration to determine the drug utilization adjustment for this year, and we will do the same next year.

To implement a portion of the drug utilization adjustment in CY 2014, we adjusted the CY 2013 ESRD PPS base rate by the CY 2014 ESRDB market basket minus productivity increase factor, the wage index budget-neutrality factor, and the home dialysis training add-on budget-neutrality factor. As we mentioned above, we took into consideration other impacts (provided in Table 12 presented in section XI.B.1.a. of this final rule) of the CY 2014 ESRD PPS that will cause a change in average payments to ESRD facilities in order to create and overall impact of zero percent. Specifically, for CY 2014, we are accounting for the changes to outlier payments and the movement from a 75/25 blend of PPS and pre-PPS payments to 100 percent ESRD PPS payments (for those ESRD facilities transitioning to the ESRD PPS) to create a zero percent average impact for facilities from the CY 2013 estimated payments. As indicated in Table 12, the average increase resulting from changes to the fixed dollar loss threshold and Medicare allowable payment (MAP) amounts under the ESRD PPS outlier policy is estimated to be a 0.4 percent increase over 2013 payments. For the ESRD PPS transition change to 100 percent ESRD PPS payments, the estimated average increase is 0.2 percent. These percentage increases, in addition to the ESRDB market basket minus productivity adjustment increase of 2.8 percent as discussed in section II.C.3. of this final rule, yield a drug utilization reduction for CY 2014 of 3.3 percent or $8.16 per treatment. Specifically, in Table 12, the overall impact of all of the changes for CY 2014 ESRD PPS totals 3.4 percent, however, in a multiplicative system to achieve a zero percent overall impact we had to divide 1 by 1.034 to derive a 0.967 or 3.3 percent decrease. Therefore, we are finalizing a transition of the drug utilization adjustment amount as an annual offset to payment rate updates and other impacts that would otherwise cause a change in average payments to ESRD facilities, thereby creating an overall impact of zero percent for ESRD facilities from the previous year's payments. We are finalizing this methodology for CY 2014 and CY 2015.

For CY 2016, we will evaluate how to apply the balance of the adjustment when we conduct an analysis of the case-mix adjustments required by section 632(c) of ATRA and implement the inclusion of oral-only ESRD-related drugs and biologicals consistent with section 632(b) of ATRA. At that time, this evaluation will allow us to determine if we should apply the balance of the reduction in CY 2016 or provide one additional transition year so that the entire amount of the drug utilization adjustment will have been applied to the base rate no later than CY 2017. This transition approach will make it easier for ESRD facilities to plan and budget, allow time for providers to respond to payment changes by identifying efficiencies, and allow time for CMS to consider further refinements to the ESRD PPS.

Comment: We received several comments from national organizations representing ESRD facilities stating that they were unable to provide useful or constructive comments on the nature, extent and operation of a transition until they understand how CMS intends to correct the base rate to reflect cross-subsidization of the composite rate services with separately billable services, standardization, comorbidity case-mix adjusters, the low-volume adjuster, and the outlier policy. However, the commenters stated that the transition should not be viewed as a substitute for making necessary corrections to the current payment system.

The commenters suggested that if CMS does utilize a transition to implement the drug utilization adjustment, then it should do so over a period of 2 to 4 years to minimize system disruption for beneficiaries, assess the impact on access, and correct course, as needed. The commenters further explained that a transition would allow providers to adjust to the payment reduction and engage in a more thoughtful process to evaluate and close facilities that cannot be made viable, reduce service, and change staffing. The commenters also explained that the transition would allow CMS to evaluate the impact of the payment reduction.

Response: As stated previously, we do not intend to offset the drug utilization adjustment amount to reflect purported cross-subsidization of items and services paid for under the composite rate with formerly separately billable services, nor do we intend to update the standardization and outlier reductions made to the 2011 ESRD PPS base rate to reflect actual payments of the adjustments. However, the transition approach we are adopting will spread the reduction over a 3- to 4-year period to minimize system disruption.

Comment: One national organization that represents small dialysis organizations and several independent ESRD facilities suggested that we treat small dialysis organizations differently from large dialysis organizations when implementing a transition of the reduction to the base rate because we determined in the CY 2014 ESRD PPS proposed rule (78 FR 40888) that a one-time reduction to the base rate would have a significant economic impact on a substantial number of small entities. The commenter explained that ESRD facilities that are owned by small dialysis organizations have less flexibility and working capital to withstand a substantial decrease in revenue. The commenter urged CMS to hold off on implementing the reduction for the first 6 months of CY 2014 because the rule is not likely to be finalized until November 2013 and without a 6-month delay, ESRD facilities would not have sufficient time to plan for and make adjustments in their operations. The commenter further suggested that the amount of the reduction should be transitioned over a period of 6 years after the 6-month

deferral and should not exceed 2 percent of the base rate in any given year.

Another national organization that represents not-for-profit ESRD facilities with support from several ESRD facilities recommended a transition under which the base rate is not reduced by more than $5.00 in a given year. One commenter recommended that CMS continue to provide a market basket update each year and apply the drug utilization adjustment to the base rate after the market basket update is applied. The commenter stated that CMS does not have an obligation to meet a certain overall reduction in expense over time and that it has discretion to implement a transition that does not effectively end with a lower rate than would have been in place if there were no transition. One commenter suggested that CMS implement the transition as optional, just as how the original ESRD PPS implementation allowed the option of accepting the full bundle or a 4-year transition.

Another commenter suggested that CMS create a differential payment for non-profit and SDOs. The commenter pointed out that the Regulatory Flexibility Act allows CMS to assess the impact of the regulation on small entities. A medium dialysis organization that was created as a result of a divestiture requirement imposed by the Federal Trade Commission (FTC) pointed out that the proposed drug utilization adjustment will undermine specific FTC action to preserve competition in the dialysis facility's marketplace. The commenter stated that overall the diminished competition in the marketplace will result in lower capacity, lower quality of care, and higher private payer prices in those markets.

Response: We agree with the commenters that implementing the full amount of the drug utilization adjustment in CY 2014 would have a significant impact on access to ESRD services. We believe that the transition approach we are taking, which will apply the drug utilization adjustment amount to the base rate over several years, will allow ESRD facilities an opportunity to plan for and adjust their future operations accordingly. Because facilities are currently operating efficiently under the CY 2013 payment rates and we are largely offsetting future increases to achieve an average impact of zero percent for ESRD facilities in CYs 2014 and 2015, we do not believe a 6-month grace period is necessary. We note that the dollar value of the 3.3 percent drug utilization reduction for CY 2014 is $8.16 per treatment. Although this amount is higher than the $5.00 reduction suggested by the commenters, we believe that ESRD facilities will be able to maintain their current programs and services because payments will remain close to CY 2013 levels for the next 2 years. With regard to the comment that we should provide a market basket increase prior to application of the reduction, we note that under our approach to the drug utilization adjustment we apply the ESRDB market basket minus productivity increase prior to making the drug utilization reduction.

In regards to the commenters that suggested that CMS create a different payment amount or transition scheme for non-profit ESRD facilities and SDOs, as well as for those ESRD facilities that were created due to FTC-ordered divestiture, we believe that we must provide for a single payment rate in accordance with section 1881(b)(14)(A)(i) of the Act, but that the transition will mitigate the potential negative effects of the adjustment that commenters pointed out. In addition, any other adjustments to the payment rate, such as an adjustment for non-profit facilities and SDOs would be established through regression analysis.

Comment: One patient advocacy group supported the drug utilization reduction but pointed out that the industry got the benefit of a base rate that included higher utilization of ESRD-related drugs and biologicals since CY 2011, but CMS did not make an adjustment to the payment until CY 2014 and continued to increase the base rate using the ESRDB market basket. The commenter further pointed out that prior to implementation of the ESRD PPS, annual increases to the composite rate were sporadic.

Response: We share the commenter's view that small, medium, and large dialysis facilities have benefited from an inflated base rate since CY 2011. As noted previously, there is historical evidence that implementation of PPSs has resulted in providers quickly reducing use of services included in the bundle, thereby creating periods of overpayment in which providers benefit from the change in practice patterns and the Medicare program does not realize savings until the payment is adjusted. Section 1881(b)(14)(I) of the Act provided the specific authority to reduce the base rate to reflect only the change in utilization of ESRD-related drugs and biologicals and not all renal dialysis services. We note that annual market basket increases to the ESRD PPS base rate are required by section 1881(b)(14)(F)(i)(I) of the Act, although these increases are reduced by the multifactor productivity adjustments required by section 1881(b)(14)(F)(i)(II) of the Act.

Comment: Several commenters expressed concern that with the implementation of the ESRD PPS and QIP have come a significant number of unfunded mandates that the Agency has not acknowledged in any specific way and the market basket does not address. The commenters recommended that a thorough analysis of costs should include those that have increased since the initiation of the bundle when calculating the drug utilization reduction. Notable among these are the costs of new IT requirements for participation in CROWNWeb, administration of Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, participation in the National Healthcare Safety Network (NHSN), and transitioning to ICD–10–CM coding. One small dialysis organization indicated that the costs of these initiatives are as much as $5 per treatment. In addition to the costs discussed, commenters urged us to consider the reductions caused by sequestration and QIP penalties. The commenters urged us to take these costs into consideration when computing the drug utilization adjustment.

Response: We understand the commenter's concerns. Nonetheless, section 1881(b)(14)(I) of the Act requires us to make reductions to the single payment amount to reflect the Secretary's estimate of the change in utilization of drugs and biologicals from 2007 to 2012. Section 1881(b)(14)(I) does not give us authority to take into account any additional factors that may impact the cost of care, such as the sequestration, and the QIP requirements. We note that entering data in CROWNWeb is a Condition for Coverage for dialysis facilities (42 CFR § 494.180(h)), and that CROWNWeb was implemented in accordance with the 1995 Paperwork Reduction Act. In regards to the transition to ICD–10–CM coding scheme, this is a requirement that is shared by all Health Insurance Portability and Accountability Act of 1996 covered entities and is not unique to ESRD facilities.

Comment: Hundreds of comments from ESRD patients, their family members, friends and caregivers, to national organizations representing dialysis patients and facilities, to ESRD facility staff expressed grave concerns about steps facilities would take if we were to adopt the proposed drug utilization adjustment. They were concerned about facility closures, staffing cuts, cuts to hours of operation,

loss of transportation services, and their continued access to life-saving ESRD treatment. Some commenters indicated that facilities have already begun to shift costs to patients and cut back staffing and programs even though the reduction will not be applied until January 1, 2014. Patients who attend nocturnal dialysis programs stated that without these programs they would be unable to continue working. ESRD facility staff also expressed concern about the magnitude of the proposed reduction and the likelihood of facility closures and resulting job losses. One commenter pointed out that pediatric patients often require more intensive staffing; it is not uncommon for younger pediatric patients to need a staffing ratio of two nurses to one patient. The commenter stated that the drastic payment reduction proposed by CMS will challenge pediatric facilities to provide safe care for these vulnerable patients.

Commenters expressed concern about facility closures and their continued access to quality ESRD services, especially in rural and inner city areas. Many commenters noted the burden and expense of traveling long distances should their facilities close. Another commenter stated that the drug utilization adjustment threatens the networks of dialysis facilities where profitable facilities allow organizations to subsidize those facilities that operate at a loss in underserved areas. Conversely, a few comments indicated support for the proposed drug utilization adjustment, stating that facilities are primarily interested in higher profits and high corporate salaries at the expense of patient care.

One patient advocacy group expressed concern about the corporate practice by ESRD facilities of shifting the responsibility of prescribing therapy and medication from the nephrologist to the dialysis organization. Another commenter representing nephrology nurses expressed concern that the proposed reduction will cause ESRD facilities to curtail the number of nursing positions and no longer maintain staff education and competencies. Other commenters pointed out that many commercial payers use Medicare reimbursement rates as a basis for their reimbursement, limiting ESRD facilities' ability to make up the lost revenue from other sources. Several commenters expressed concern that the 12 percent payment reduction in CY 2014 may hinder the ESRD facilities' ability to participate in the Center for Medicare and Medicaid Innovation's (CMMI) Comprehensive ESRD Care model which is testing innovative models of care.

Response: We believe that the approach we have taken to transition the drug utilization reduction over a 3 to 4-year timeframe will minimize disruption in the delivery of ESRD services and will hopefully lead facilities to reverse cuts they may have already implemented in anticipation that the full amount of the drug utilization adjustment would be applied to the base rate in CY 2014. In addition, part of our rationale for the transition was to enable facilities to maintain their current programs and services. We developed a comprehensive claims-based monitoring system when we implemented the ESRD PPS in 2011 and will use that system to identify changes in practice patterns, prescribing patterns, health outcomes, and ownership that may impact the furnishing of ESRD services. We have provided sufficient information in this final rule about how we plan to transition the drug utilization adjustment so that ESRD facilities can assess whether to participate in the CMMI Comprehensive ESRD Care model.

Comment: One commenter recommended that CMS specify how it plans to ensure that access to and quality of care is not compromised by the drug utilization adjustment. They provided a list of monitoring elements including ESA and other drug utilization rates, hospital admission/readmission rates, transfusion rates, availability to patients of dietitian and social worker services, changes in numbers of shifts per facility, changes in staffing ratios or staffing composition (that is, fewer nurses), consolidation/sales of dialysis facilities in markets with limited numbers of providers, and facility closures. The commenter recommended that CMS post quarterly updates on monitored aspects of care that are feasible to report publically.

Response: We intend to monitor access through the comprehensive claims monitoring program we implemented when the ESRD PPS began in 2011. We believe that the transition approach we are adopting for implementing the drug utilization reduction will mitigate many of the unintended consequences identified by the commenters. We note that many of the suggested monitoring elements are already part of the comprehensive claims monitoring program (for example, ESA and other drug utilization rates, use of inpatient hospital services, and transfusion rates). Other elements suggested by the commenters warrant additional review by CMS to assess the burden associated with collecting the information. We currently provide a workbook that displays several key trends from CY 2011 through CY 2013 on the CMS Web site: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html*. This workbook is updated on a quarterly basis.

Comment: Comments from ESRD patients indicated that they believe Medicare will no longer pay for dialysis or that the cost of the reduction would be shifted to patients.

Response: We want to reassure ESRD patients, their families, and caregivers that Medicare will continue to cover dialysis services, but at a lower rate. As a result of the small reduction to the ESRD PPS base rate (that is, from the CY 2013 ESRD PPS base rate of $240.36 to CY 2014 ESRD PPS base rate of $239.02), beneficiary co-insurance will also decrease slightly. We believe the transition approach we are finalizing makes cost shifting to beneficiaries less likely.

In summary, to comply with section 1881(b)(14)(I) of the Act we have computed the drug utilization adjustment to be $29.93 as detailed in section II.C.2.a.v. above. Specifically, we used the CY 2007 claims data that was used in the preparation of the CY 2011 ESRD PPS final rule for CY 2007 utilization and included the drug utilization data from facilities located in the Pacific Rim. For CY 2012 utilization we used the CY 2012 claims file updated through June 30, 2013, (that is, claims with dates of service from January 1 through December 31, 2012, that were received, processed, paid, and passed to the National Claims History File as of June 30, 2013) to calculate 2012 utilization.

To determine the final growth update factor's value, we used the methodology discussed above resulting in a 7.64 percent growth update factor to inflate prices for ESRD-related drugs and biologicals from CY 2011 levels to CY 2014 levels. The 7.64 percent growth update factor represents the ESRDB market basket minus the multifactor productivity adjustments finalized in CYs 2012, 2013, and 2014, the wage index budget-neutrality adjustment factors finalized in CYs 2012, 2013, and 2014, and the home dialysis training add-on budget neutrality adjustment factor finalized for CY 2014. We applied the CY 2014 prices to the CY 2007 and CY 2012 drug utilization data to calculate aggregate amounts for each year. Next, we divided each year's estimated aggregate amount for drugs and biologicals by that year's count of treatments furnished to Medicare beneficiaries to get an average payment per treatment for the year. This resulted

in a per treatment amount for drugs and biologicals of $83.96 in 2007 and a per treatment amount for drugs and biologicals of $51.17 in 2012. We then subtracted the average payment per treatment for CY 2012 from the average amount per treatment for CY 2007 to get a total of $32.79 ($83.96 − $51.17 = $32.79). We then reduced this amount by the standardization, the outlier, and the 98 percent budget neutrality adjustments to get a total of $29.93 ($32.79 × .9407 × .99 × .98 = $29.93). We are finalizing $29.93 as the total drug utilization reduction.

In response to comments we are finalizing the following approach for implementing the amount of the drug utilization adjustment over a 3- to 4-year transition period. For CYs 2014 and 2015, we are implementing a transition of the drug utilization adjustment by offsetting the payment update, that is the ESRDB market basket minus productivity increase factor and other impacts (such as, changes to the outlier thresholds), by a portion of the reduction amount necessary to create an overall impact of zero percent for ESRD facilities from the previous year's payments. We relied on the impact chart provided in the impact analysis section of our annual rules to determine the impact of various policy changes on aggregate ESRD facility payments and took those values into consideration to determine the drug utilization adjustment for this year, and we will do the same for next year.

For CY 2014, this approach results in a base rate reduction of $8.16, which yields a CY 2014 ESRD PPS base rate of $239.02. This reflects the CY 2013 ESRD PPS base rate of $240.36 adjusted by the ESRDB market basket minus productivity increase factor of 2.8 percent, the wage index budget neutrality factor of 1.000454, and the home dialysis training add-on budget neutrality adjustment factor of 0.999912 to get $247.18 ($240.36*1.028*1.000454*0.999912 = $247.18). Then we reduced this amount by the portion of the drug utilization reduction that is being implemented this year—$8.16—to arrive at a final CY 2014 ESRD PPS base rate of $239.02 ($247.18 − $8.16=$239.02).

For CY 2016, we will evaluate how to apply the balance of the reduction when we conduct an analysis of the case-mix adjustments as required by section 632(c) of ATRA and implement the inclusion of oral-only ESRD-related drugs and biologicals as permitted by section 632(b) of ATRA. Following this evaluation, we will determine whether we should apply the balance of the reduction in CY 2016 or provide one additional transition year so that the full amount of the drug utilization adjustment will have been applied to the base rate over a 4-year transition period ending in CY 2017.

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 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 also 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.

b. Market Basket Update Increase Factor and Labor-related Share for ESRD Facilities for CY 2014

As required under section 1881(b)(14)(F)(i) 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 for ESRD treatment, 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 a 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 CY 2008-based ESRDB market basket described in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162) to compute the CY 2014 ESRDB market basket increase factor and labor-related share based on the best available data. Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Insight (IGI), Inc.'s forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Using this methodology and the IGI forecast for the first quarter of 2013 of the CY 2008-based ESRDB market basket (with historical data through the fourth quarter of 2012), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2014 ESRDB market basket increase factor was 2.9 percent.

For the CY 2014 ESRD payment update, we proposed to continue using a labor-related share of 41.737 percent for the ESRD PPS payment, which was finalized in the CY 2011 ESRD final rule (75 FR 49161).

Comment: Several commenters supported the ESRDB proposed market basket update.

Response: We appreciate the commenters support and are finalizing our update to the ESRDB market basket for CY 2014 based on the most recent forecast of the ESRDB market basket.

c. Productivity Adjustment for CY2014

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

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

The projection of MFP is currently produced by IGI. The details regarding the methodology for forecasting MFP and how it is applied to the market basket were finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70234). Using this method and the IGI forecast for the first quarter of 2013 of the 10-year moving average of MFP, the proposed CY 2014 MFP factor was 0.4 percent. We did not receive any comments on this proposal.

Accordingly, are finalizing the CY 2014 MFP adjustment to the ESRDB market basket for CY 2014 based on the most recent forecast available.

d. Calculation of the Final ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2014

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. We proposed to use 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) and based on the most recent forecast of the data.

It is our policy that if more recent data are available after publication of the proposed rule (for example, a more recent estimate of the market basket or MFP adjustment), we will use such data, if appropriate, to determine the CY 2014 market basket update and MFP adjustment in the CY 2014 ESRD PPS final rule. Thus, in accordance with section 1881(b)(14)(F)(i) of the Act, the final ESRDB market basket percentage increase factor for CY 2014 is based on the 3rd quarter 2013 forecast of the CY 2008-based ESRDB market basket, which is estimated to be 3.2 percent. This market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2014) of 0.4 percent, which is based on IGI's 3rd quarter 2013 forecast. The resulting final MFP-adjusted ESRDB market basket update for CY 2014 is equal to 2.8 percent, or 3.2 percent less 0.4 percentage point.

4. The CY 2014 Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a payment adjustment by geographic wage index payment adjustment, 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 Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-based geographic area designations to define urban and rural areas and their corresponding wage index values. In the CY 2012 ESRD PPS final rule (76 FR 70239–70241), we finalized that, under the ESRD PPS, we will continue to utilize the ESRD PPS wage index methodology, first established under the basic case-mix adjusted composite rate 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. The CBSA-based geographic area designations were originally described in OMB bulletin 03–04, issued June 6, 2003. This bulletin, as well as subsequent bulletins, are available online at *http://www.whitehouse.gov/omb/bulletins_default*.

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that correspond with the IPPS hospital wage index. For CY 2014, we use the FY 2014 pre-floor, pre-reclassified hospital wage index to adjust the ESRD PPS payments. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which establishes revised delineations of statistical areas based on OMB standards published in the **Federal Register** on June 28, 2010 and 2010 Census Bureau data. Because the FY 2013 pre-floor, pre-reclassified hospital wage index was finalized prior to the issuance of this Bulletin, the FY 2013 pre-floor, pre-reclassified hospital wage index does not reflect OMB's new area delineations based on the 2010 Census. Further, as stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications must be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the FY 2014 IPPS/LTCH PPS proposed rule; therefore, the FY 2014 pre-floor, pre-reclassified hospital wage index does not reflect OMB's new area delineations based on the 2010 Census. CMS intends to propose changes to the hospital wage index based on this OMB Bulletin in the FY 2015 IPPS/LTCH PPS proposed rule. Therefore, we anticipate that the OMB Bulletin changes will be reflected in the FY 2015 hospital wage index. Because we base the ESRD PPS wage index on the hospital wage index, we anticipate that the OMB Bulletin changes would be reflected in the FY 2015 hospital wage index and, thus, in the CY 2015 ESRD PPS wage index.

For CY 2014, we will continue to use the same methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117), for determining the wage indices for ESRD facilities in CY 2014. Specifically, we proposed to adjust wage indices for CY 2014 to account for annually updated wage levels in areas in which ESRD facilities are located. We proposed to use the most recent, FY 2014 IPPS pre-floor, pre-reclassified hospital wage index, which, as discussed above, does not reflect OMB's new area delineations based on the 2010 Census. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The CY 2014 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the CY 2014 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html*.

In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized a policy to use the labor-related share of 41.737 for the ESRD PPS portion of the payment. For the CY 2014 ESRD PPS, we did not propose any changes to the labor-related share of 41.737. However, because all providers that elected to participate in the transition are entering the fourth year of the transition and will begin being paid 100 percent under the ESRD PPS, the 53.711 labor-related share that was applied to the composite rate portion of the blended payment is no longer applicable. We discuss the methodology for the ESRD PPS labor-related share in our CY 2011 ESRD PPS final rule (75 FR 49161), where we noted that the labor-related share is typically the sum of Wages and Salaries, Benefits, Housekeeping and Operations, Professional Fees, Labor-related Services, and a portion of the Capital-related Building and Equipment expenses. For additional discussions on the labor-related share please refer to section II.C.3.b. of this final rule.

Comment: We received several comments expressing concern about applying the same labor-related share in CY 2014, as was finalized in CY 2011. Many commenters suggested that CMS review the labor-related share and update the factor to reflect 2012 cost report data. Other commenters noted that smaller providers cannot ''offset negative impacts across a national market base'' and therefore are disadvantaged by rising salary costs in labor markets that compete regionally. A few commenters suggested that CMS has erred in not updating the labor-related share for CY 2014 to appropriately reflect the decrease in pharmaceutical spending identified in ESRD facility cost reports for 2011 and 2012. One commenter noted that the current labor-related share calculation is based upon

2008 cost report data, and the decrease in pharmaceutical spending since that time has resulted in an ''understated labor-related share'' used to adjust wages when making ESRD PPS payments.

Response: The ESRD bundled labor-related share is based on the cost weights for wages and salaries, benefits, housekeeping and operation, professional fees, labor-related services and a portion of the capital-related building and equipment expenses. Because we did not propose to rebase or revise the ESRDB market basket for CY 2014, the labor-related share will remain 41.737 percent. At the time of preparing the CY 2014 ESRD PPS proposed rule we had access to cost report data through 2010. The 2011 cost report data was captured on the revised ESRD cost report form and complete data files were not available in time to estimate cost shares on the 2011 data in time for the proposed rule. In order to estimate if any major changes had occurred since 2008 (the current base years of the ESRDB market basket) we did produce ESRD market basket cost shares based on the Medicare Cost Report data for 2009 and 2010 (which were the latest, complete year of data we had available at the time) and we did not have access to the files in order to estimate the cost weights based on data from 2011 or later. We did run the cost report data for 2009 and 2010 and found that the cost share weights for the market basket and the estimated labor-related share as described in the CY 2011 ESRD PPS final rule (75 FR 49161) did not change significantly. We understand that under the bundled payment system the relative shares of wages and salaries and pharmaceuticals may change. We will be rebasing and revising the ESRD market basket for CY 2015 based on the most up-to-date and complete year of cost report data available, which will be based on data from a year after 2011. This will reflect the costs for ESRD services that were reported in a payment year under the bundled system.

a. Payment Under the ESRD PPS for Facilities Located in Guam, American Samoa, and the Northern Mariana Islands

It came to our attention after the ESRD PPS was implemented that ESRD facilities located in the United States Territories of Guam, American Samoa and the Northern Mariana Islands (collectively, the Pacific Rim) have been paid on the basis of reasonable costs and charges, rather than under the ESRD PPS. Because section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a renal dialysis facility for renal dialysis services in lieu of any other payment for services furnished on or after January 1, 2011, and section 1881(b)(14)(E)(i) requires that the payment amounts under the ESRD PPS by fully implemented for services furnished on or after January 1, 2014, ESRD facilities located in the Pacific Rim must be paid under the ESRD PPS beginning for services furnished on or after January 1, 2014. In order to pay these facilities under the ESRD PPS, we would need to identify a wage index value for these areas to make payment adjustments for geographic wages according to § 413.231 of the regulations. We proposed to use the current value calculated under the existing methodology, that is, the pre-floor, pre-reclassified, hospital wage data that is unadjusted for occupational mix for the island of Guam of 0.9611, which is displayed in Addendum B (Wage Indices for Rural Areas), because the FY 2014 IPPS pre-floor, pre-reclassified hospital wage data does not include wage data for American Samoa and the Northern Mariana Islands. Accordingly, we proposed to apply the wage index value for Guam to facilities located in American Samoa and the Northern Mariana Islands as discussed below in section II.C.4.b. of this final rule.

Comment: We received two comments suggesting that the ESRD PPS does not sufficiently account for the unique economic circumstances faced by dialysis facilities located in the Territory of Guam. One commenter noted higher costs for shipping and warehousing of supplies, as well as significant training costs, which results from high employee turnover when military personnel and their families relocate to the mainland. Another commenter requested that Medicare continue to make payments to ESRD facilities located in Guam under reasonable costs and charges payment methodologies.

Response: We appreciate the concern expressed by commenters' regarding the payment change. However, section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a renal dialysis facility for renal dialysis services in lieu of any other payment. In order to comply with the statute, ESRD facilities located in the Pacific Rim must be paid under the ESRD PPS and will be paid under this system for renal dialysis services furnished on or after January 1, 2014. We understand that ESRD facilities located in Guam, as well as many other geographic areas where Medicare services are furnished, have unique geographic, labor, or regulatory circumstances that have an impact on their provision of dialysis services. For example, the states of Hawaii and Alaska have similar shipping and storage considerations as Guam and these areas are paid under the ESRD PPS. Likewise, the island of Puerto Rico, (which shares the status of a United States Territory), must comply with unique staffing requirements, in that only registered nurses may furnish dialysis services to dialysis patients and these facilities are paid under the ESRD PPS. Further, many ESRD facilities are located near military bases where there is high turnover of staff and these facilities are also paid under the ESRD PPS. Nonetheless, CMS has no authority to continue to pay ESRD facilities located in the Territory of Guam or elsewhere in the Pacific Rim based on reasonable costs or any other payment methodology. Therefore, beginning January 1, 2014, in accordance with section 1881(b)(14)(A)(i) of the Act, all ESRD facilities furnishing renal dialysis services to Medicare beneficiaries will be paid 100 percent under the ESRD PPS, including ESRD facilities located in the Pacific Rim.

b. Policies for Areas With No Wage Data

In the CY 2011 ESRD PPS final (75 FR 49116 through 49117), 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 is no hospital data. We further explained our approach for areas with no hospital data in the CY 2012 ESRD PPS final rule (76 FR 70241). 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. Therefore, we use our established methodology to compute an appropriate wage index using the average wage index values from contiguous CBSAs, to represent a reasonable proxy.

As stated previously, the FY 2014 IPPS pre-floor, pre-reclassified hospital wage data does not include wage data for American Samoa and the Northern Mariana Islands, which are rural areas with no hospital data. While we appreciate that the islands of the Pacific Rim are not actually contiguous, we believe the same principle applies here, and that Guam is a reasonable proxy for American Samoa and the Northern

Mariana Islands. We believe that Guam represents a reasonable proxy because the islands are located within the Pacific Rim and share a common status as United States Territories. We noted that if hospital data becomes available for American Samoa or the Northern Mariana Islands, we will use that data for the CBSA instead of the proxy. As discussed previously, the current wage index value for Guam using the existing methodology is 0.9611. Therefore, for CY 2014, we proposed to apply this wage index value of 0.9611 to ESRD facilities located in America Samoa and the Northern Mariana Islands and included this value in Addendum B.

For CY 2014, the only urban area without wage index data is Hinesville-Fort Stewart, GA. As we discussed in our CY 2013 ESRD PPS final rule (77 FR 67459), 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. Accordingly, we proposed to apply the statewide urban average wage index value for Georgia of 0.7582 to Hinesville-Fort Stewart, GA and included this value in Addendum A.

We received no public comments regarding our proposal to use the wage index value for Guam of 0.9611 as an appropriate proxy for American Samoa and the Northern Mariana Islands. Therefore, we are finalizing our proposal. For renal dialysis services furnished in American Samoa or the Northern Mariana Islands and paid under the ESRD PPS on or after January 1, 2014, a wage index value of 0.9611, as calculated for the Territory of Guam, will be applied to the ESRD PPS base rate when making Medicare payments. The wage index values for Guam, America Samoa and the Northern Mariana Islands are included in Addendum B.

We received no comments on our proposal to apply the computed statewide urban average wage index value for Georgia to the CBSA for Hinesville-Fort Stewart, GA. Therefore, we are finalizing the proposal with the following clarification. In the CY 2014 ESRD PPS proposed rule (78 FR 40845), we incorrectly stated the computed value for the statewide urban average wage index value for Georgia of 0.7582. The correct value computed for the urban average wage index value for Georgia and applied to Hinesville-Fort Stewart, GA was correctly identified in Addendum A of the CY 2014 ESRD PPS proposed rule as 0.8602. We apologize for this error. In addition, the urban wage index values have been updated with more recent data for this final rule, and therefore for CY 2014 we are finalizing a statewide urban average wage index value for Georgia of 0.8700 and will apply this value to the CBSA for Hinesville-Fort Stewart, GA and include this value in Addendum A.

c. Reduction to the ESRD Wage Index Floor

A wage index floor value has been used in lieu of the calculated wage index values below the floor in making payment for renal dialysis services under the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized that we would continue to reduce the wage index floor by 0.05 for each of the remaining years of the transition. In the CY 2012 ESRD PPS final rule (76 FR 70241), 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. Most recently, in the CY 2013 ESRD PPS final rule (77 FR 67459 through 67461), we discussed the elimination of the wage index floor beginning in CY 2014, noting that we would propose a new methodology in CY 2014 to address wages in rural Puerto Rico because we would no longer be applying a wage index floor.

As described above, our intention has been to provide a wage index floor only through the transition to 100 percent implementation of the ESRD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241). However, the CY 2014 wage index values for both urban and rural Puerto Rico remain below the finalized CY 2013 ESRD PPS wage index floor of 0.500 (77 FR 67459), and we believe that both rural and urban facilities in Puerto Rico would benefit from continuing the gradual reduction of the floor. We believe that continuing the wage index floor for CY 2014 and CY 2015 will allow renal dialysis facilities located in Puerto Rico the benefit afforded to other geographical areas in the fifty states, that is, a gradual and systematic elimination of the wage index floor. Therefore, for CY 2014 and for CY 2015, we proposed to continue to apply the wage index floor to areas with wage indexes below the floor. For CY 2014, Puerto Rico is the only area with a wage index value below the proposed floor; however, to the extent that other geographical areas fall below the floor in CY 2015, we believe they should have the benefit of a gradual reduction in the floor as well. Thus, for CY 2014 and CY 2015, we proposed to continue our policy of gradually reducing the wage index floor by 0.05 per year. Specifically, we proposed a wage index floor value of 0.450 for CY 2014 and a wage index floor value of 0.400 for CY 2015. We believe that continuing our policy of applying a wage index floor for an additional two years would allow Puerto Rico to benefit from the anticipated and predictable phase out of the wage index floor. While we would not expect to continue this policy past CY 2015, we will review the appropriateness of a wage index floor for CY 2016 at that time.

Comment: We received a few comments requesting that CMS review hospital wage data and consider the appropriateness of a wage index floor. For example, a commenter from Wheeling, WV, suggested that CMS consider increasing the wage index floor value, so that rural facilities with low wage index values will be able to compete with urban facilities in attracting qualified staff members. Another commenter requested that CMS modify the current wage index methodology to capture ''true'' ESRD facility wages in Puerto Rico. The current methodology relies upon hospital wage data and the commenter contended that the hospital occupational wage mix does not adequately reflect wages in ESRD facilities in Puerto Rico, where registered nurses are required to furnish dialysis care. In addition, the commenter requested that the wage index floor be frozen at 2011 levels.

Response: We thank the commenters for their comments and we appreciate their concerns regarding the impact of a wage index floor on dialysis facilities. We have committed to reviewing the appropriateness of applying a wage index floor for CY 2016. However, for CY 2014 and CY 2015, we are finalizing our proposal. We will continue our policy of gradually reducing the wage index floor by 0.05 per year. Accordingly, we are finalizing in this rule a wage index floor value of 0.450 for CY 2014, and a wage index floor value of 0.400 for CY 2015. This policy will benefit ESRD facilities located in Puerto Rico, where wage index values remain below the wage index floor values finalized in this rule. We note that if another geographic CBSA area wage index value falls below the floor in CY 2015, the facilities in that CBSA will also have the benefit of the wage index floor.

In summary, for CY 2014, we will continue to use the same wage index methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117). That is, we will use the most recent IPPS pre-floor, pre-reclassified hospital wage index to calculate the ESRD PPS wage index values. Thus, for CY 2014, we will use the FY 2014 IPPS pre-floor, pre-reclassified hospital wage index to

calculate the CY 2014 ESRD PPS waged index. The 2014 wage index values for urban areas, Addendum A (Wage Indices for Urban Areas) and the CY 2014 wage index values for rural areas, Addendum B (Wage Indices for Rural Areas) may be viewed at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html*.

Lastly, for CY 2014 and CY 2015, we are continuing our policy of gradually reducing the wage index floor by 0.05 per year. That is, we are finalizing a wage index floor value of 0.450 for CY 2014, and a wage index floor value of 0.400 for CY 2015.

d. Wage Index Budget-Neutrality Adjustment

Section 1881(b)(14)(D)(iv)(II) of the Act gives us broad discretion to implement payment adjustments to the ESRD PPS, including an adjustment of the ESRD PPS by a geographic index. Section 1881(b)(14)(D)(iv)(II) specifically refers to section 1881(b)(12)(D) as an example of such a geographic index, and in the CY 2011 ESRD PPS final rule, we finalized the use of the same wage index methodology that we utilized under the basic case-mix adjusted composite rate payment system (75 FR 49116). We had applied a wage index budget-neutrality adjustment factor under the basic case-mix adjusted composite payment system, and accordingly, in the CY 2012 ESRD PPS final rule, we finalized a policy for CY 2012 and future years to apply wage index budget-neutrality adjustment factors to the composite rate portion of the ESRD PPS blended payments for facilities participating in the transition as well as to the base rate for the ESRD PPS portion of the blended payment and the full ESRD PPS for those facilities that elected to receive 100 percent of their payment under that system (76 FR 70241 and 70242). We also finalized the methodology for computing the wage index budget-neutrality adjustment factors for CY 2012 and subsequent years (76 FR 70242).

For CY 2014, we did not propose any changes to the methodology, but we noted that we will no longer compute a wage index budget-neutrality adjustment factor for the composite rate portion of the ESRD PPS blended payment because all facilities will be paid 100 percent under the ESRD PPS in CY 2014. For ease of reference, we explain the methodology for computing the budget-neutrality adjustment factor here. For the CY 2014 wage index budget-neutrality adjustment factor, we use the fiscal year (FY) 2014 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2012 outpatient claims (paid and processed as of June 30, 2013), and geographic location information for each facility, which may be found through Dialysis Facility Compare. Dialysis Facility Compare (DFC) can be found at the DFC Web page on the CMS Web site at *http://www.medicare.gov/dialysisfacilitycompare/*. The FY 2014 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.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/*. The wage index data are located in the section entitled, ''FY 2014 Final Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA''.

We computed the proposed CY 2014 wage index budget-neutrality adjustment factor using treatment counts from the 2012 claims and facility-specific CY 2013 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2013. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2014. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2014. The total of these payments becomes the new CY 2014 amount of wage-adjusted expenditures for all ESRD facilities.

The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2014 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2014 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. Therefore, we proposed a wage index budget-neutrality adjustment factor of 1.000411, which would be computed in ESRD PPS base rate payment methodology when making payment for renal dialysis services in CY 2014.

We received no public comments on this proposal, and therefore, we are finalizing the proposed CY 2014 wage index budget-neutrality adjustment factor as updated with the most recently available data. In the proposed rule, the CY 2014 wage index budget-neutrality adjustment factor was computed at 1.000411. This calculation was based upon the use of the FY 2014 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data computed for wage index values and the CY 2012 Medicare outpatient claims data file as of December 31, 2012. For CY 2014, we are finalizing a wage index budget-neutrality adjustment factor of 1.000454. This final calculation reflects the most recent Medicare claims data available, which is the FY 2014 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data computed for wage index values and the CY 2012 Medicare outpatient claims data file (that is, claims with dates of service from January 1, through December 31, 2012, that were received, processed, paid, and passed to the National Claims History file as of June 30, 2013).

5. Application of the International Classification of Diseases (ICD), Tenth Revision, to the Comorbidity Payment Adjustment Codes

In the CY 2011 ESRD PPS final rule (75 FR 49094), we explained that section 1881(b)(14)(D)(i) of the Act, as added by section 153(b) of MIPPA, requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account, among other things, patient comorbidities. Comorbidities are specific patient conditions that coexist with the patient's principal diagnosis that necessitates dialysis. The comorbidity payment adjustments recognize the increased costs associated with comorbidities and provide additional payment for certain conditions that occur concurrently with the need for dialysis.

To develop the comorbidity payment adjustments, we used a stepwise regression model to analyze comorbidity data and found that certain comorbidities are predictors of variation in payments for ESRD patients. Details on the development of the comorbidity categories eligible for a comorbidity payment adjustment, including an explanation of the stepwise regression model that we used to analyze comorbidity data, is discussed in the CY 2011 ESRD PPS final rule (75 FR 49094 through 49108). We analyzed the comorbidity categories and excluded those categories from the comorbidity payment adjustments that met any of three exclusion criteria (75 FR 49095 through 49100): (1) Inability to create accurate clinical definitions; (2) potential for adverse incentives regarding care; and (3) potential for

ESRD facilities to directly influence the prevalence of the comorbidity either by altering dialysis care, changing diagnostic testing patterns, or liberalizing the diagnostic criteria.

We finalized six comorbidity categories that are eligible for a comorbidity payment adjustment, each with associated International Classification of Disease, 9th Revision, Clinical Modification (ICD–9–CM) diagnosis codes (75 FR 49100). Among these categories are three acute, short-term diagnostic categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) and three chronic diagnostic categories (hereditary hemolytic anemia with sickle cell anemia, myelodysplastic syndrome, and monoclonal gammopathy). The comorbidity categories eligible for an adjustment and their associated ICD–9–CM codes were published in the Appendix of the CY 2011 ESRD PPS final rule as Table E: ICD–9–CM Codes Recognized for a Comorbidity Payment Adjustment (75 FR 49211).

In the CY 2012 ESRD PPS final rule (76 FR 70252), we clarified that the ICD–9–CM codes eligible for a comorbidity payment adjustment are subject to the annual ICD–9–CM coding updates that occur in the hospital IPPS final rule and are effective October 1st of every year. We explained that any updates to the ICD–9–CM codes that affect the categories of comorbidities and the diagnoses within the comorbidity categories that are eligible for a comorbidity payment adjustment would be communicated to ESRD facilities through sub-regulatory guidance. Accordingly, Change Request (CR) 7476, Transmittal 2255, entitled, ''Quarterly Update to the End-Stage Renal Disease Prospective Payment System,'' was issued on July 15, 2011 to update the ICD–9–CM codes eligible for a comorbidity payment adjustment in accordance with the annual ICD–9–CM update effective October 1, 2011. This CR can be found on the CMS Web site at the following link: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2255CP.pdf*. There have not been updates to the ICD–9–CM codes eligible for a comorbidity payment adjustment since October 1, 2011.

Effective October 1, 2014, CMS will implement the 10th revision of the ICD coding scheme—ICD–10–CM. Because the transition to ICD–10–CM coding will occur during CY 2014, we discuss here the crosswalk from ICD–9–CM to ICD–10–CM codes for the purpose of determining eligibility for a comorbidity payment adjustment.

We crosswalked the ICD–9–CM codes that are eligible for a comorbidity payment adjustment to ICD–10–CM codes using the General Equivalence Mappings (GEM) tool, which is the authoritative source for crosswalking developed by the National Center for Health Statistics and CMS. The crosswalk from ICD–9–CM to ICD–10–CM diagnosis codes resulted in three scenarios: one ICD–9–CM code crosswalked to one ICD–10–CM code; one ICD–9–CM code crosswalked to multiple ICD–10–CM codes; or multiple ICD–9–CM codes crosswalked to one ICD–10–CM code. We applied the three exclusion criteria listed above to each of the ICD–10–CM codes to which the ICD–9–CM codes crosswalked.

In our clinical evaluation, we found the ICD–9–CM codes generally crosswalked to one ICD–10–CM code that codes for the same diagnosis, has the same code descriptor, and does not meet any of our exclusion criteria. Accordingly, with the exceptions noted below, we proposed that ICD–10–CM codes will be eligible for a comorbidity payment adjustment where they crosswalk from ICD–9–CM codes that are eligible for a comorbidity payment adjustment. There are, however, two instances where ICD–9–CM codes crosswalk to ICD–10–CM codes that we believe meet one or more of the exclusion criteria described above, and we proposed to exclude these codes from eligibility for a comorbidity payment adjustment.

a. One ICD–9–CM Code Crosswalks to One ICD–10–CM Code

Table 1 lists all the instances in which one ICD–9–CM code crosswalks to one ICD–10–CM code. We proposed that all of those ICD–10–CM codes would receive a comorbidity payment adjustment with the exception of K52.81 Eosinophilic gastritis or gastroenteritis. Currently, 535.71 Eosinophilic gastritis with hemorrhage is one of 40 ICD–9–CM diagnosis codes under the acute comorbidity category of Gastrointestinal (GI) Bleeding. The descriptor of K52.81, the ICD–10–CM code to which this ICD–9–CM code crosswalks, does not include the word ''hemorrhage.'' In the CY 2011 ESRD PPS final rule (75 FR 49097), we specifically limited the GI bleeding category for the comorbidity payment adjustment to GI bleed with hemorrhage because we believed that the gastrointestinal tract bleeding category met our first exclusion criterion—inability to create accurate clinical definitions—because it was overly broad. We also believed that use of this diagnosis category could lead to gaming consistent with the second and third exclusion criteria listed above. For these reasons, we limited the gastrointestinal tract bleeding diagnosis category to gastrointestinal tract bleeding with hemorrhage, which we believe creates accurate clinical definitions and mitigates the potential for adverse incentives in ESRD care. Accordingly, we proposed to exclude ICD–10–CM code K52.81 Eosinophilic gastritis or gastroenteritis from eligibility for the comorbidity payment adjustment because the code descriptor does not indicate the diagnosis of a hemorrhage. We proposed that all of the other ICD–10–CM codes listed in the Table 1 below would be eligible for a comorbidity payment adjustment.

TABLE 1—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE

GASTROINTESTINAL BLEEDING			
ICD–9	Descriptor	ICD–10	Descriptor
530.21	Ulcer of esophagus with bleeding	K22.11	Ulcer of esophagus with bleeding
535.71	Eosinophilic gastritis, with hemorrhage	K52.81	Eosinophilic gastritis or gastroenteritis
537.83	Angiodysplasia of stomach and duodenum with hemorrhage	K31.811	Angiodysplasia of stomach and duodenum with bleeding
569.85	Angiodysplasia of intestine with hemorrhage	K55.21	Angiodysplasia of colon with hemorrhage
BACTERIAL PNEUMONIA			
ICD–9	Descriptor	ICD–10	Descriptor
003.22	Salmonella pneumonia	A02.22	Salmonella pneumonia

TABLE 1—ONE ICD–9–CM CODE CROSSWALKS TO ONE ICD–10–CM CODE—Continued

482.0	Pneumonia due to Klebsiella pneumonia	J15.0	Pneumonia due to Klebsiella pneumoniae
482.1	Pneumonia due to Pseudomonas	J15.1	Pneumonia due to Pseudomonas
482.2	Pneumonia due to Hemophilus influenzae [H. influenzae]	J14	Pneumonia due to Hemophilus influenzae
482.32	Pneumonia due to Streptococcus, group B	J15.3	Pneumonia due to streptococcus, group B
482.40	Pneumonia due to Staphylococcus, unspecified	J15.20	Pneumonia due to staphylococcus, unspecified
482.41	Methicillin susceptible pneumonia due to Staphylococcus aureus	J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
482.42	Methicillin resistant pneumonia due to Staphylococcus aureus	J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
482.49	Other Staphylococcus pneumonia	J15.29	Pneumonia due to other staphylococcus
482.82	Pneumonia due to escherichia coli [E. coli]	J15.5	Pneumonia due to Escherichia coli
482.83	Pneumonia due to other gram-negative bacteria	J15.6	Pneumonia due to other aerobic Gram-negative bacteria
482.84	Pneumonia due to Legionnaires' disease	A48.1	Legionnaires' disease
507.0	Pneumonitis due to inhalation of food or vomitus	J69.0	Pneumonitis due to inhalation of food and vomit
507.8	Pneumonitis due to other solids and liquids	J69.8	Pneumonitis due to inhalation of other solids and liquids
510.0	Empyema with fistula	J86.0	Pyothorax with fistula
510.9	Empyema without mention of fistula	J86.9	Pyothorax without fistula
PERICARDITIS			
ICD–9	Descriptor	ICD–10	Descriptor
420.91	Acute idiopathic pericarditis	I30.0	Acute nonspecific idiopathic pericarditis
HEREDITARY HEMOLYTIC AND SICKLE CELL ANEMIA			
ICD–9	Descriptor	ICD–10	Descriptor
282.0	Hereditary spherocytosis	D58.0	Hereditary spherocytosis
282.1	Hereditary elliptocytosis	D58.1	Hereditary elliptocytosis
282.41	Sickle-cell thalassemia without crisis	D57.40	Sickle-cell thalassemia without crisis
282.43	Alpha thalassemia	D56.0	Alpha thalassemia
282.44	Beta thalassemia	D56.1	Beta thalassemia
282.45	Delta-beta thalassemia	D56.2	Delta-beta thalassemia
282.46	Thalassemia minor	D56.3	Thalassemia minor
282.47	Hemoglobin E-beta thalassemia	D56.5	Hemoglobin E-beta thalassemia
282.49	Other thalassemia	D56.8	Other thalassemias
282.61	Hb-SS disease without crisis	D57.1	Sickle-cell disease without crisis
282.63	Sickle-cell/Hb-C disease without crisis	D57.20	Sickle-cell/Hb-C disease without crisis
282.68	Other sickle-cell disease without crisis	D57.80	Other sickle-cell disorders without crisis
MYELODYSPLASTIC SYNDROME			
ICD–9	Descriptor	ICD–10	Descriptor
238.7	Essential thrombocythemia	D47.3	Essential (hemorrhagic) thrombocythemia
238.73	High grade myelodysplastic syndrome lesions	D46.22	Refractory anemia with excess of blasts 2
238.74	Myelodysplastic syndrome with 5q deletion	D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
238.76	Myelofibrosis with myeloid metaplasia	D47.1	Chronic myeloproliferative disease

b. One ICD–9–CM Code Crosswalks to Multiple ICD–10–CM Codes

Table 2 lists all of the instances in which one ICD–9–CM code crosswalks to multiple ICD–10–CM codes. In those instances, we proposed that all the crosswalked ICD–10–CM codes would receive a comorbidity payment adjustment, with the exception of D89.2 Hypergammaglobulinemia, unspecified. ICD–9–CM code 273.1 Monoclonal paraproteinemia is the only ICD–9–CM code eligible for the comorbidity payment adjustment under the chronic comorbidity category of Monoclonal gammopathy. ICD–9–CM code 273.1 Monoclonal paraproteinemia crosswalks to two ICD–10–CM codes: D47.2 Monoclonal gammopathy and D89.2 Hypergammaglobulinemia, unspecified. We analyzed both of these ICD–10–CM codes and determined that D47.2 Monoclonal gammopathy should be eligible for the comorbidity payment adjustment because, like ICD–9–CM code 273.1 Monoclonal paraproteinemia, it indicates that there is an excessive amount of a single monoclonal gammaglobulin. When we analyzed the comorbidity category for the CY 2011 ESRD PPS final rule, single monoclonal gammaglobulin was shown to have an association with higher ESA usage, thereby resulting in higher costs to dialysis facilities. After clinical evaluation of D89.2 Hypergammaglobulinemia, unspecified, however, we determined that this ICD–10–CM code should not be eligible for the comorbidity payment adjustment because D89.2 Hypergammaglobulinemia, unspecified indicates only that 1 or more immunoglobulins are elevated, but does not identify which immunoglobulin(s) are elevated. We believe that the lack of specificity of this particular code results in an inability to create an accurate clinical definition, which is the first of the three exclusion criteria. Accordingly, we proposed that D89.2 Hypergammaglobulinemia, unspecified would not be eligible for the comorbidity payment adjustment. We proposed that all of the other ICD–10–CM codes listed in Table 2 below would be eligible for the comorbidity payment adjustment.

TABLE 2—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES

GASTROINTESTINAL BLEEDING			
ICD–9	Descriptor	ICD–10	Descriptor
562	Diverticulosis of small intestine with hemorrhage	K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding
		K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
562.03	Diverticulitis of small intestine with hemorrhage	K57.01	Diverticulitis of small intestine with perforation and abscess with bleeding
		K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding
		K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding
		K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
562.12	Diverticulosis of colon with hemorrhage	K57.31	Diverticulosis of large intestine without perforation or abscess with bleeding
		K57.91	Diverticulosis of intestine, part unspecified, without perforation or abscess with bleeding
		K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
562.13	Diverticulitis of colon with hemorrhage	K57.21	Diverticulitis of large intestine with perforation and abscess with bleeding
		K57.33	Diverticulitis of large intestine without perforation or abscess with bleeding
		K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding
		K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
BACTERIAL PNEUMONIA			
ICD–9	Descriptor	ICD–10	Descriptor
513.0	Abscess of lung	J85.0	Gangrene and necrosis of lung
		J85.1	Abscess of lung with pneumonia
		J85.2	Abscess of lung without pneumonia
PERICARDITIS			
ICD–9	Descriptor	ICD–10	Descriptor
420.0	Acute pericarditis in diseases classified elsewhere	A18.84	Tuberculosis of heart
		I32	Pericarditis in diseases classified elsewhere
		M32.12	Pericarditis in systemic lupus erythematosus
420.90	Acute pericarditis, unspecified	130.1	Infective pericarditis
		I30.9	Acute pericarditis, unspecified
420.99	Other acute pericarditis	I30.8	Other forms of acute pericarditis
		I30.9	Acute pericarditis, unspecified
HEREDITARY HEMOLYTIC AND SICKLE CELL ANEMIA			
ICD–9	Descriptor	ICD–10	Descriptor
282.2	Anemias due to disorders of glutathione metabolism	D55.0	Anemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency
		D55.1	Anemia due to other disorders of glutathione metabolism
282.3	Other hemolytic anemias due to enzyme deficiency	D55.2	Anemia due to disorders of glycolytic enzymes
		D55.3	Anemia due to disorders of nucleotide metabolism
		D55.8	Other anemias due to enzyme disorders
		D55.9	Anemia due to enzyme disorder, unspecified
282.42	Sickle-cell thalassemia with crisis	D57.411	Sickle-cell thalassemia with acute chest syndrome
		D57.412	Sickle-cell thalassemia with splenic sequestration
		D57.419	Sickle-cell thalassemia with crisis, unspecified
282.62	Hb-SS disease with crisis	D57.00	Hb-SS disease with crisis, unspecified
		D57.01	Hb-SS disease with acute chest syndrome
		D57.02	Hb-SS disease with splenic sequestration
282.64	Sickle-cell/Hb-C disease with crisis	D57.211	Sickle-cell/Hb-C disease with acute chest syndrome
		D57.212	Sickle-cell/Hb-C disease with splenic sequestration
		D57.219	Sickle-cell/Hb-C disease with crisis, unspecified
282.69	Other sickle-cell disease with crisis	D57.811	Other sickle-cell disorders with acute chest syndrome
		D57.812	Other sickle-cell disorders with splenic sequestration
		D57.819	Other sickle-cell disorders with crisis, unspecified

TABLE 2—ONE ICD–9–CM CODE CROSSWALKS TO MULTIPLE ICD–10–CM CODES—Continued

MONOCLONAL GAMMOPATHY			
ICD–9	Descriptor	ICD–10	Descriptor
273.1	Monoclonal paraproteinemia	D47.2	Monoclonal gammopathy
		D89.2	Hypergammaglobulinemia, unspecified
MYELODYSPLASTIC SYNDROME			
ICD–9	Descriptor	ICD–10	Descriptor
238.72	Low grade myelodysplastic syndrome lesions	D46.0	Refractory anemia without ring sideroblasts, so stated
		D46.1	Refractory anemia with ring sideroblasts
		D46.20	Refractory anemia with excess of blasts, unspecified
		D46.21	Refractory anemia with excess of blasts 1
		D46.4	Refractory anemia, unspecified
		D46.A	Refractory cytopenia with multilineage dysplasia
		D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
238.75	Myelodysplastic syndrome, unspecified	D46.9	Myelodysplastic syndrome, unspecified
		D46.Z	Other myelodysplastic syndromes

c. Multiple ICD–9–CM Codes Crosswalk to One ICD–10–CM Code

Table 3 displays the crosswalk where multiple ICD–9–CM codes crosswalk to one ICD–10–CM code. For the reasons explained above, we propose that all of the crosswalked ICD–10–CM codes listed below would be eligible for a comorbidity payment adjustment.

TABLE 3—MULTIPLE ICD–9–CM CODES CROSSWALK TO ONE ICD–10–CM CODE

GASTROINTESTINAL BLEEDING			
ICD–9	Descriptor	ICD–10	Descriptor
533.20	Acute peptic ulcer of unspecified site with hemorrhage and perforation, without mention of obstruction	K27.2	Acute peptic ulcer, site unspecified, with both hemorrhage and perforation
533.21	Acute peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction		
533.40	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage, without mention of obstruction	K27.4	Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage
533.41	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage, with obstruction		
533.60	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, without mention of obstruction	K27.6	Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage and perforation
533.61	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation, with obstruction		
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	K28.0	Acute gastrojejunal ulcer with hemorrhage
534.01	Acute gastrojejunal ulcer, with hemorrhage, with obstruction		
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	K28.2	Acute gastrojejunal ulcer with both hemorrhage and perforation
534.21	Acute gastrojejunal ulcer with hemorrhage and perforation, with obstruction		
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	K28.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage, with obstruction		
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	K28.6	Chronic or unspecified gastrojejunal ulcer with both hemorrhage and perforation
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, with obstruction		
BACTERIAL PNEUMONIA			
ICD–9	Descriptor	ICD–10	Descriptor
482.30	Pneumonia due to Streptococcus, unspecified	J15.4	Pneumonia due to other streptococci
482.31	Pneumonia due to Streptococcus, group A		
482.39	Pneumonia due to other Streptococcus		
482.81	Pneumonia due to anaerobes	J15.8	Pneumonia due to other specified bacteria
482.89	Pneumonia due to other specified bacteria		

In summary, based on our clinical evaluation of the ICD–10–CM codes to which the eligible ICD–9–CM codes crosswalk, we proposed that both D89.2 Hypergammaglobulinemia, unspecified and K52.81 Eosinophilic gastritis or gastroenteritis would not be eligible for the comorbidity payment adjustment. We proposed that all other ICD–10–CM codes to which eligible ICD–9–CM codes crosswalk that are listed in the Tables above would be eligible for a comorbidity payment adjustment effective October 1, 2014. We solicited comment on the ICD–10–CM codes that we proposed to exclude and those that we proposed would be eligible for a comorbidity adjustment. The comments that we received and our responses are set forth below.

Comment: We received a few comments that acknowledged the implementation of the ICD–10–CM coding scheme. Two commenters supported our proposal to exclude D89.2 Hypergammaglobulinemia, unspecified and K52.81 Eosinophilic gastritis or gastroenteritis from eligibility for a comorbidity payment adjustment.

Response: We thank commenters for their support. We are finalizing our proposal that the ICD–10–CM codes listed in the Tables above are eligible for a comorbidity payment adjustment, and that ICD–10–CM codes D89.2 Hypergammaglobulinemia, unspecified and K52.81 Eosinophilic gastritis or gastroenteritis are excluded from eligibility for a comorbidity payment adjustment.

Comment: One commenter questioned why CMS includes monoclonal gammopathy but excludes multiple myeloma and plasma cell leukemia. The commenter encouraged CMS to determine methods for proper disease identification as myeloma is the most common malignancy leading to ESRD.

Response: In the CY 2011 ESRD PPS final rule (75 FR 49099), we discuss the exclusion of the cancer comorbidity diagnostic category from eligibility for a comorbidity payment adjustment. We explained that providing a payment adjustment for the cancer comorbidity category could overstate costs for some patients whose dialysis treatment is no longer affected by their history of cancer and could understate the costs of patients whose current cancer diagnosis and treatment affect their dialysis treatments. Until we are able to differentiate the cost between the two groups, we are unable to accurately reflect the ESRD resources being used to determine a comorbidity payment adjustment for patients with multiple myeloma and leukemia.

Comment: We received two comments stating that implementing ICD–10–CM in 2014 will be another unfunded mandate and small dialysis organizations will suffer the most.

Response: We understand that the transition from ICD–9–CM to ICD–10–CM may present a challenge for some ESRD facilities; however, the compliance date for implementation of ICD–10–CM is October 1, 2014 for all Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities, regardless of their size.

6. 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 are the following items and services that are included in the ESRD PPS bundle: (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 (75 FR 49142), 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. The ESRD-related drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services were specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. With respect to the outlier policy, Transmittal 2094 identified additional drugs and laboratory tests that may be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

In the CY 2012 ESRD PPS final rule (76 FR 70246), we eliminated the issuance of a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011. However, we use separate guidance to continue to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes in order to provide unit prices for calculating imputed outlier services. We also can identify, through our monitoring efforts, items and services that are incorrectly being identified as eligible outlier services in the claims data. Any updates to the list of renal dialysis items and services that qualify as outlier services are made through administrative issuances.

Our regulations at 42 CFR § 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. In accordance with § 413.237(c) of the regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

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

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 and 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the applicable patient-specific case-mix

adjusters 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). Thus, for CYs 2011 and 2012, the MAP and fixed dollar loss amounts were computed based on pre-ESRD PPS claims data and utilization. For CY 2013, the outlier services MAP amounts and fixed dollar loss amounts were based on 2011 data (77 FR 67464). Therefore, the outlier thresholds for CY 2013 were based on utilization of ESRD-related items and services furnished under the ESRD PPS. Because of the lower utilization of erythropoietin stimulating agents (ESA) and other outlier services in CY 2011, we lowered the MAP amounts and fixed dollar loss amounts for both adult and pediatric patients for CY 2013 to allow for an increase in payments for ESRD beneficiaries requiring higher resources.

a. Impact of Changes to the Outlier Policy

In the CY 2014 ESRD PPS proposed rule (78 FR 40850 through 40852), we did not propose any changes to the methodology used to compute the MAP or fixed dollar loss amounts. Rather, we proposed to update the outlier services MAP amounts and fixed dollar loss amounts to reflect the utilization of outlier services reported on the 2012 claims using the December 2012 claims file (that is, claims with dates of service January 1 through December 31, 2012, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2012). In this final rule, for CY 2014, we used the June 2013 update of the CY 2012 National Claims History File to update the outlier services MAP amounts and fixed dollar loss amounts. The impact of this update is shown in Table 4 below, which compares the outlier services MAP amounts and fixed dollar loss amounts used for the outlier policy in CY 2013 with the updated estimates for CY 2014. The estimates for the CY 2014 outlier policy, which are included in Column II of Table 4, were inflation adjusted to reflect projected 2014 prices for outlier services.

TABLE 4—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Final outlier policy for CY2013 (based on 2011 data price inflated to 2013)*		Column II Final outlier policy for CY2014 (based on 2012 data price inflated to 2014)*	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment [1]	$38.65	$61.38	$37.29	$51.97
Adjustments:				
Standardization for outlier services [2]	1.0927	0.9878	1.1079	0.9866
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount [3]	$41.39	$59.42	$40.49	$50.25
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$47.32	$110.22	$54.01	$98.67
Patient months qualifying for outlier payment	7.6%	5.1%	6.7%	5.3%

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect updated prices for outlier services (that is, 2013 prices in Column I and projected 2014 prices in Column II).

[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 2012 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 2012 data to yield total outlier payments that represent 1 percent of total projected payments for the ESRD PPS.

As shown in Table 4, the estimated fixed dollar loss amount that determines the 2014 outlier threshold amount for adults (Column II) is lower than that used for the 2013 outlier policy (Column I). The estimated fixed dollar loss amount that determines the 2014 outlier threshold amount for pediatric patients (Column II) is higher than that used for the 2013 outlier policy (Column I). The main reason for the reduction for adult patients is that the lower utilization of ESA and other outlier services continued to decline during the second year of the PPS. This can be seen by comparing the outlier service MAP amount per treatment for adult patients in Column I ($61.38, which is based on 2011 data) with that amount in Column II ($51.97, which is based on 2012 data).

For pediatric patients, the overall average outlier service MAP amount per treatment decreased from $38.65 in 2011 to $37.29 in 2012. In addition, there was a greater tendency in 2012 for a relatively small percentage of pediatric patients to account for a disproportionate share of the total outlier service MAP amounts. The one percent target for outlier payments is therefore expected to be achieved based on a smaller percentage of pediatric outlier cases using 2012 data compared to 2011 data (6.7 percent of pediatric patient months are expected to qualify for outlier payments rather than 7.6 percent). These patterns led to the estimated fixed dollar loss amount for pediatric patients being higher for the outlier policy for CY 2014 compared to the outlier policy for CY 2013. Generally, there is a relatively higher likelihood for pediatric patients that the outlier threshold may be adjusted to reflect changes in the distribution of outlier service MAP amounts. This is due to the much smaller overall number of pediatric patients compared to adult patients, and to the fact that the outlier threshold for pediatric patients is calculated based on data for a much smaller number of pediatric patients compared to adult patients.

For this final rule, based on the use of the most recently available data, we are updating the fixed dollar loss amounts that are added to the predicted MAP amounts per treatment to

determine the outlier thresholds for CY 2014 from $110.22 to $98.67 for adult patients and from $47.32 to $54.01 for pediatric patients compared with CY 2013 amounts. We are also updating the adjusted average outlier services MAP amounts for CY 2014 from $59.42 to $50.25 for adult patients and from $41.39 to $40.49 for pediatric patients compared with CY 2013 amounts.

We estimate that the percentage of patient months qualifying for outlier payments under the current policy will be 5.3 percent and 6.7 percent for adult and pediatric patients, respectively, based on the 2012 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 ESAs and other injectable drugs).

b. Outlier Policy Percentage

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. For this final rule, based on analysis of the June 2013 update of the CY 2012 National Claims History File, outlier payments represented approximately 0.2 percent of total payments, again falling short of the 1 percent target due to the continuing decline in use of ESAs and other outlier services. Use of 2012 data to recalibrate the thresholds, which reflect lower utilization of ESAs and other outlier services, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2014 and result in increased payments for ESRD beneficiaries requiring higher resource utilization.

We note that recalibration of the fixed dollar loss amounts for CY 2014 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 increases payments to providers for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations increase for renal dialysis services eligible for outlier payments.

We received the following comments on this proposal:

Comment: Commenters generally supported CMS's proposal to use CY 2012 claims data to update and recalibrate the outlier policy with the most recent data available for adult and pediatric patients for CY 2014.

Response: We thank the commenters for their support of our CY 2014 proposal to update the ESRD PPS outlier payment policy for adult and pediatric patients with the most recent data available. As stated previously, for this final rule, we used the June 2013 update of the 2012 National Claims History File. This data file represents the most recent available data of CY 2012 paid Medicare claims.

Comment: A few commenters urged CMS to ensure with a ''high level of probability'' that the full one percent outlier holdback will be expended in CY 2014. One commenter contended that updating the outlier policy with recent data does not address the ongoing problem of ''overstating the outlier'' and ''artificially'' reducing the base rate. Some commenters suggested that the ''chronic underpayment of the outlier pool'' suggests that an outlier policy is unnecessary. Other commenters urged CMS to avoid future ''underpayment'' of the outlier policy by lowering or eliminating the threshold for CY 2014. A few commenters requested that CMS ''consider giving back'' the amounts not paid in CY 2012 by increasing the CY 2014 base rate to include outlier monies held back but not paid out in CY 2012.

Response: We are unable to assure the commenters that the one percent outlier holdback will fully be expended in CY 2014. The total amount of outlier payments are dependent upon patient utilization of high cost outlier-eligible services (most significantly ESAs), that are furnished to Medicare beneficiaries in a given payment year. Using the most recent claims and utilization data, we simulated 2014 Medicare payments and established the MAP and fixed dollar loss amounts to achieve one percent of the total ESRD PPS payments for CY 2014. Given the continued decline in utilization of ESAs and other outlier services from CY 2011 to CY 2013, it is possible that the one percent outlier may not be fully paid out in CY 2014. At the same time, since the MAP and fixed dollar loss amounts have been reduced, it is also possible that the outlier payments could exceed the 1 percent of payments that are held back. Either outcome is possible because we cannot predict with certainty the utilization of outlier services in a future year. However, we make a good faith effort to estimate future use of outlier services by simulating payment using the most current data available. To the extent that actual 2014 outlier payment do not reach that level, we will update the MAP and fixed dollar loss amounts for CY 2015.

We disagree with the commenter who contended that CMS is overstating the outlier and artificially reducing the base. We remind the commenter that updating the outlier payment policy for CY 2014 does not change payments for dialysis items and services that are not eligible for outlier payments. Rather, the outlier payment is a per treatment payment increase, available to ESRD facilities when they furnish Medicare beneficiaries with high cost dialysis items and services that are eligible for outlier payments. If the ESRD facilities are not furnishing high cost, outlier-eligible, dialysis items and services to the patient then we believe that the base rate, and applicable adjustments, is an appropriate payment. Nonetheless, we continue to believe that use of the most recent data available to update the outlier payment policy should result in appropriate outlier payments. We disagree with the commenters who contended that CMS outlier payment policy has resulted in ''chronic underpayment of the outlier,'' and we continue to believe that the one percent outlier policy has not been fully realized under the ESRD PPS because of the continued decline in ESA utilization, rather than an inherent flaw in the outlier payment methodology. We also disagree with commenters who suggest that CMS has the authority to eliminate the outlier policy for CY 2014 or at some point in the future, as the statute at section 1881(b)(14)(D)(ii) clearly states that the ESRD PPS ''shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management.''

We also disagree that with commenters that we should ''give back'' outlier monies to account for not achieving the 1 percent outlier threshold. As we explained in the CY 2013 ESRD PPS final rule (77 FR 67450, 67465), ''[t]he 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 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 or

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.'' Finally, we plan to review the outlier policy as a whole when we refine the system in the future.

D. The Self-Dialysis and Home Dialysis Training Add-On Payment

a. Medicare Policy for Self-Dialysis Training, Home Dialysis Training, and Retraining

The existing Medicare policy for furnishing self-dialysis training, home dialysis training, and retraining was finalized in our CY 2011 ESRD PPS final rule (75 FR 49062 through 49064) and further discussed in the Medicare Benefits Policy Manual, (Publication 100–02, Chapter 11, Section 30). Self-dialysis or home dialysis can only be performed after an ESRD patient has completed an appropriate course of training. The scope of training services that a certified ESRD home dialysis training facility must furnish to ESRD patients as a condition of coverage are described at 42 CFR 494.100(a). For instance, 42 CFR 494.100(a)(2) states that the training must be conducted by a registered nurse who meets the requirements of 42 CFR 494.140(b)(2). For additional information on the requirements for ESRD facilities in furnishing dialysis training, see 42 CFR Part 494, and for additional information regarding home dialysis training certification, see the State Operations Manual, which may be viewed on the Medicare Web site at the following link: *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html.*

Our regulation at 42 CFR 494.70 (Condition: Patients' rights) requires that facilities inform patients (or their representatives) of their rights and responsibilities when they begin their treatment and protect and provide for the exercise of those rights. Our regulation at 42 CFR 494.70(a)(7) requires a facility to inform patients about all treatment modalities and settings, including but not limited to transplantation, home dialysis modalities, and in-facility hemodialysis. This includes the patient's right to receive resource materials for dialysis modalities not offered by the facility. We expect that all ESRD facilities comply with this regulation and furnish resource information on home dialysis, even if the home modality is not offered by the facility. When ESRD facilities are certified for home dialysis training, we expect the facility to provide training throughout the self-dialysis or home dialysis experience (42 CFR 494.100). Self-dialysis or home dialysis training services and supplies may include but are not limited to personnel services, dialysis supplies, written training manuals and materials, and ESRD-related items and services.

We discuss Medicare's training policies in Table 5 (Medicare's Self or Home Training by Modality) for the following dialysis modalities:

- Home Hemodialysis Training
- Intermittent Peritoneal Dialysis Training
- Continuous Ambulatory Peritoneal Dialysis Training
- Continuous Cycling Peritoneal Dialysis Training

We would expect that patients who elect self-dialysis or home dialysis training will be good candidates for these modalities and that they will be successful in completing the training. We also expect facilities to comply with the patient assessment Condition of Participation including the requirement in 42 CFR 494.80(a)(9) to include in the assessment: ''Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting (for example, home dialysis), and the patient's expectations of care outcomes.''

TABLE 5—MEDICARE'S SELF OR HOME TRAINING BY MODALITY

Home Hemodialysis (HHD) Training.	HHD training is generally furnished in 4 weeks. Medicare will pay the ESRD facility for up to 25 HHD training sessions. In some HHD programs, the dialysis caregiver is trained to perform the dialysis treatment in its entirety and the patient plays a secondary role. In other programs, the patient performs most of the treatment and is only aided by a helper.
Intermittent Peritoneal Dialysis (IPD) Training.	IPD training is generally furnished in 4 weeks. Medicare will pay the ESRD facility for up to 15 PD training sessions. In the IPD program, the patient's caregiver is usually trained to carry out the dialysis care. The patient plays a minimal role, as most are unable to perform self-care dialysis because of other debilitating conditions.
Continuous Ambulatory Peritoneal Dialysis (CAPD) Training.	CAPD training is generally furnished in 2 weeks. Medicare will pay the ESRD facility for up to 15 PD training sessions. In CAPD programs both the patient and the caregiver are trained.
Continuous Cycling Peritoneal Dialysis (CCPD) Training.	CCPD training is generally furnished in 2 weeks. Medicare will pay the ESRD facility for up to 15 PD training sessions. In CCPD programs both the patient and the caregiver are trained.

b. Payment Methodology

In our CY 2011 ESRD PPS final rule (75 FR 49062 through 49064), we included training costs in computing the ESRD PPS base rate, but stated that the ESRD PPS base rate alone does not account for the staffing costs associated with training treatments furnished by a registered nurse. Thus, we finalized the training add-on payment, to be an additional payment made under the ESRD PPS, when one-on-one self or home dialysis training is furnished by a nurse working for a Medicare-certified training facility to a Medicare beneficiary for either hemodialysis or the peritoneal dialysis training modalities listed in Table 5. Likewise, we noted in our CY 2012 ESRD PPS final rule (76 FR 70252), that ''ESRD facilities receive a per-treatment payment that accounts for case-mix, geographic location, low-volume, and outlier payment regardless [of whether] the patient receives dialysis at home or in the facility, plus the training add-on[,]'' if applicable.

We discuss our policies for retraining sessions in the Medicare Benefit Policy Manual, Publication 100–02, Chapter 11, Section 30.2.E. The add-on payment is also applied for retraining sessions after a patient or caregiver has completed the initial training program and if the patient continues to be an appropriate candidate for self or home dialysis modalities. We would expect that most Medicare beneficiaries receive

retraining sessions when they receive new equipment, have a change in caregiver, or a change in modality. The ESRD facility may not bill Medicare for retraining services when they install home dialysis equipment or furnish monitoring services. For example, an ESRD facility nurse may not bill for retraining sessions when they update a home dialysis patient's treatment record, order monthly supplies, or instruct the patient on the use of a new medication for the treatment of infection. When retraining sessions are furnished to a patient or caregiver, there is an expectation that the patient or caregiver is already knowledgeable of the elements of home dialysis, and if additional training is being done for a change of equipment or a change in modality, fewer sessions would be necessary because of the transferability of certain basic skills for home dialysis.

If a Medicare beneficiary exceeds the maximum amount of training sessions based upon their modality, and, if they continue to be a good candidate for home modalities, additional training sessions or retraining sessions may be paid by Medicare with medical justification. In such cases, the ESRD facility must indicate the medical justification with the claim for the training or retraining session submitted for payment. Because the requirement of medical justification is specific to the patient's training needs, circumstances (such as a change in caregiver), or condition (change in modality), we would not expect that an ESRD facility would routinely bill Medicare for training or retraining sessions on any patient.

In CY 2011, we finalized the amount for the training add-on adjustment at $33.44 per treatment, and noted that this amount would be added to the ESRD PPS payment when a training treatment is furnished by the ESRD facility to a Medicare beneficiary. In addition, we noted that because the training add-on payment is directly related to nursing salaries, and that nursing salaries differ greatly based on geographic location, we would adjust the training add-on payment by the geographic area wage index applicable to the ESRD facility. (For further discussions on wage indices, please see section II.C.4. of this final rule.) To summarize, when home dialysis training sessions are furnished to a Medicare beneficiary by a Medicare-certified home dialysis training facility, Medicare will make the ESRD PPS computed base rate payment with all applicable adjustments, and then the separate add-on payment for self or home dialysis training.

In the CY 2013 ESRD PPS final rule (77 FR 67468 through 67469), we addressed comments on Medicare's self and home dialysis training policies under the ESRD PPS. In that final rule, we stated that commenters were concerned that the payment for home dialysis training is insufficient and does not reflect the true costs of training and that they indicated various ranges of time required for home training in terms of time per day and number of training sessions. At that time, we responded to those comments by confirming that CMS will continue to monitor and analyze trends in home dialysis training, but that we believe our payment methodology is adequate for ESRD facilities furnishing training services.

In the CY 2014 ESRD PPS proposed rule, we sought public comments on the costs associated with furnishing self or home dialysis training (78 FR 40854). We requested comments on the elements of PD vs. HHD training sessions, specifically the costs of furnishing such training, the appropriate number of training sessions, and the duration of the training sessions. Lastly, we sought comments on a ''holdback'' payment methodology, which we discussed in the CY 2011 ESRD PPS final rule (75 FR 49063). Under this methodology, a portion of the training payments would be withheld from the ESRD facility until the ESRD patient demonstrates that they have successfully transitioned to a home modality. Specifically, in the CY 2014 proposed rule (78 FR 40854), we sought comments on the costs associated with furnishing self or home dialysis training, the training elements of PD and HHD training, and the number of training sessions.

Although we did not specifically propose to increase the training add-on payment amount in the CY 2014 ESRD PPS proposed rule (78 FR 40852 through 40854), we received several hundred comments from Medicare beneficiaries, dialysis patients, caregivers, friends and family members, industry stakeholders and other interested parties in response to our request for comments that overwhelmingly encouraged us to evaluate the training add-on adjustment and to increase the training add-on payment amount in this final rule. Commenters generally noted the substantial patient benefits of utilizing home dialysis modalities, including improved quality of life; continued employment; and the ability to travel and live a ''normal life.'' In addition, commenters identified many significant training elements that were not contemplated in the original training add-on adjustment payment methodology, such as self cannualation and certain aspects of operating a HHD machine.

After a review of the considerable number of compelling public comments and MedPAC's ''Report to Congress'' of March 2013, ''Considering alternative dialysis treatment options: Use of more frequent hemodialysis and home dialysis'' that advocates for greater use of home dialysis modalities among Medicare beneficiaries, we are finalizing a 50 percent increase to the home dialysis training add-on adjustment payment amount beginning in CY 2014. We are persuaded to finalize this increase because we agree with commenters that access to home modalities is limited, and that the current home dialysis training add-on payment amount per treatment, which represents 1 hour of nursing time, does not adequately represent the staff time required to ensure that a patient is able to perform home dialysis safely.

Therefore, beginning January 1, 2014, the payment add-on will be computed based upon 1.5 hours of nursing time per training treatment, which amounts to a payment increase of $16.72 per training treatment. The training add-on adjustment payment amount for CY 2014 and future years will be $50.16 and will continue to be adjusted by the facility's wage index. We believe increasing the training time is an appropriate change because commenters largely contended that the number of allowable training sessions is adequate, but that the payment amount is insufficient.

We also note that the finalized per training treatment add-on payment amount of $50.16 is in line with the costs reported on the 2010 ESRD facility cost reports, which indicates an average facility training cost of $53.00 per training treatment. In addition to the home dialysis training add-on payment, the base rate also compensates facilities for the cost of providing home dialysis training.

We received the following comments:

Comment: The majority of commenters recognized the importance of dialysis training services and modality choice for a beneficiary's well-being. Many patient comments included personal stories about their ability to lead fulfilling lives after they transferred to HHD, including being able to return to work, travel, and participate in family activities. The commenters confirmed that the training elements for HHD are significant and require additional face-to-face nursing time. Commenters identified such elements as setting up

and orienting the patient to the HHD unit; explaining safety alarms; troubleshooting alarms; and teaching the patient self cannualation as training elements that they do not believe were adequately paid for by the base rate and the training add-on payment.

Some commenters noted that a single training add-on payment amount for both PD and HHD training services disincentives HHD training. The commenters contend that the training add-on payment amount is sufficient for PD training services, but that higher training costs are incurred by the facility when they furnish HHD training services. A few commenters urged CMS to ''fix'' this bias in the training payment so that more patients have access to the modality of HHD services. One commenter pointed out that Medicare's existing regulations require that dialysis patients be informed of all dialysis options, however, the modality of HHD is not available to many patients because facilities will not invest in home dialysis training programs under the current payment methodology.

Response: Again, we thank the patients for their willingness to share their home dialysis training experiences with CMS, and in particular, to patients for commenting on the importance of modality choice in returning to work and participating fully in their lives. While we did not propose to increase the home dialysis training add-on payment amount, we found the comments very compelling. In particular, we agree with commenters that the current home dialysis training add-on payment amount, together with the base rate, does not sufficiently cover the costs of providing the critical HHD training elements that commenters identified. We also agree with commenters that the single home dialysis training add-on payment could disincentivize training in HHD, as opposed to PD, as the cost of HHD training is higher than the cost of PD training. As we noted in the CY 2013 ESRD PPS final rule (77 FR 67468), we do not intend to encourage the use of one type of home dialysis modality over another; rather we believe that decisions regarding the appropriate home dialysis modality should be made by beneficiaries in consultation with their physicians. Where a beneficiary and his or her physician decide that HHD is the appropriate home dialysis modality, we do not want the amount of the home dialysis training add-on payment to discourage the use of that modality.

We appreciate the comments detailing face-to-face nursing time and the training provided during that time. These comments noted significant face-to-face training time for the training elements of self cannualation, effective machine set-up, explaining warning alarms, troubleshooting alarms, and what the patient and caregiver should do in case of an emergency. We agree with the commenters that these training elements are significant to a patient's ability to safely and effectively dialyze in the home, and that these training elements are unique to HHD training services. HHD training elements were not included in the original training add-on payment adjustment because prior to the PPS, home training services furnished to Medicare beneficiaries were largely based upon training elements for the modality of PD, with few patients receiving HHD services at home. We agree with commenters that self cannualation and troubleshooting alarms are critical training elements for HHD, and that they require additional training time. For all of these reasons, we are increasing the per-treatment home dialysis training treatment payment to account for 1.5 hours of nursing time per training session furnished on or after January 1, 2014, instead of 1 hour per training session.

We expect all ESRD facilities to comply with our regulation at 42 CFR 494.70(a)(7) and inform beneficiaries of the availability of HHD, even if this modality is not offered by the facility. Although we believe increasing the amount of the home dialysis training add-on payment adjustment in this final rule will further enable patients to dialyze at home, we also believe that the ESRD PPS, along with Medicare Conditions for Coverage requirements set forth in 42 CFR § 494.100(a), contributed to the increase in utilization rates for home modalities. In the CY 2011 ESRD PPS final rule, we stated that the ESRD PPS monitoring program would assess the effect of the expanded bundled payment on home dialysis utilization rates (75 FR 49058). We continue to monitor Medicare submitted and paid claims to assess home modality utilization rates. This data is available on the ESRD PPS Spotlight and may be viewed at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html*.

Comment: Commenters applauded CMS for seeking industry feedback for refinements to self and home dialysis training policies. In general, commenters requested that CMS increase the payment amount for dialysis training services to more accurately reflect the actual costs incurred by facilities when they furnish self or home dialysis training services to a Medicare beneficiary. Many commenters noted that the training add-on payment, equal to 1 hour of registered nursing time, $33.44, is ''inadequate'' to cover the training costs incurred by the facility when they furnish a home dialysis training treatment. Numerous commenters urged CMS to increase the training add-on payment amount to ''appropriately recognize'' a facility's costs when furnishing home dialysis training services and specifically noted the higher cost incurred by the facility when they furnish HHD training services.

Response: We thank the facility commenters who shared detailed analysis regarding their training costs. A few commenters furnished CMS with an ''Updated Home Hemodialysis Cost Study: 2010 Medicare Cost Report Analysis.'' The analysis shows that current Medicare policies to reimburse for home dialysis training fall short of the average costs facilities incur when they furnish training treatments. As stated above, we noted in our CY 2011 ESRD PPS final rule (75 FR 49062 through 49064), that the ESRD PPS base rate alone does not account for the staffing costs associated with training treatments furnished by a registered nurse and that the training add-on payment is an additional payment made under the ESRD PPS to acknowledge the one-on-one self or home dialysis training furnished by a nurse. We clarified this policy again in the CY 2013 ESRD PPS final rule (77 FR 67468) where we stated, ''Training costs are included in the ESRD PPS base rate, however, we also provide an add-on adjustment for each training treatment furnished by a Medicare-certified home dialysis training facility.'' As such, it is not the intent of the add-on treatment to reimburse a facility for all of the training costs furnished during training treatments. Rather, the single ESRD PPS base rate, all applicable case-mix and facility level adjustments, as well as the add-on payment should be considered the Medicare payment for each training treatment and not the training add-on payment alone. Nonetheless, we agree with commenters that the home dialysis add-on payment, together with the base rate, does not account for all of the training elements commenters identified.

We note that patient and caregiver commenters indicated a training time for home dialysis training of 2 to 6 weeks in length, with face-to-face nursing time of 2 to 6 hours per training day. Commenters also acknowledged that many of the training days took place in the training facility, in a group setting, and not in the patient's home.

In addition, some commenters reported that nursing staff were not present for the final week of training, as the patient had achieved total independent self-care. While we understand that training for home dialysis is specific to the patients' needs and that several factors, including a patient's health status and emotional and mental state, are considerations for the length and number of training services furnished, we are concerned about the wide-ranging variance in training times and the duration of training sessions indicated in the comments. While believe that an increase in the amount of the home dialysis training add-on payment is appropriate, we note that, based on the comments we received, training services furnished to Medicare beneficiaries appear inconsistent across training facilities. We will continue to monitor training services furnished to Medicare beneficiaries in the future.

Comment: A few commenters urged CMS to increase the training add-on payment amount without making a reduction to the base rate to maintain budget neutrality. One commenter noted that, ''we believe that CMS has the discretion to independently make this change without adjustments for budget neutrality.'' A few commenters urged CMS to make no change to the training add-on payment amount that would further reduce the base rate for CY 2014.

Response: We appreciate commenters concern for protecting the ESRD PPS base rate. However, we are not changing the payment methodology used to compute the training add-on adjustment and the training add-on payment will continue to be budget neutral, which means the base rate will be affected. We believe that an additional half hour per training session better reflects the costs facilities incurred when furnishing training services to Medicare beneficiaries. The training add-on payment increase will be budget neutral for CY 2014 in that we will reduce the base rate by $0.02 to account for the cost of the increase.

We computed the final CY 2014 home dialysis training add-on budget-neutrality adjustment factor using treatment counts from the 2012 claims and facility-specific CY 2014 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2014 with no adjustment to the training add-on factor. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2014. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the final adjusted home dialysis training add-on of $50.16 for CY 2014. The total of these payments becomes the new CY 2014 amount of expenditures for all ESRD facilities.

The training add-on budget-neutrality factor is calculated as the target amount divided by the new CY 2014 amount. When we multiplied the training add-on budget-neutrality factor by the applicable CY 2014 estimated payments, aggregate payments to ESRD facilities would remain budget-neutral when compared to the target amount of expenditures. The training add-on budget-neutrality factor ensures that training add-on adjustments do not affect aggregate Medicare payments. Therefore, we are finalizing a training add-on budget-neutrality adjustment factor of .999912, which will be applied directly to the CY 2014 ESRD PPS base rate.

Comment: A few commenters noted that the training add-on payment is a ''fixed'' payment and does not adjust from year to year for inflation or wages. One commenter noted that the training add-on payment is not included in the annual market basket used to update the ESRD PPS and that CMS should address this inconsistency.

Response: We agree with comments that the training add-on payment adjustment is a fixed payment amount and is not updated by the annual wage data from the Bureau of Labor and Statistics. However, we also note that although the training add-on payments are not adjusted by the ESRD PPS market basket, the payment is adjusted by the geographic wage index values. This geographic adjustment allows Medicare payments to appropriately reflect the local wage of a registered nurse in the geographic areas where the training services are furnished. We appreciate commenters' suggestions for updating the training add-on payment amount with a market basket or other inflation indicator such as the most recent wage data. We will take these comments into account in considering future refinements to the home dialysis training add-on payment adjustment.

Comment: Several commenters discouraged CMS from considering a holdback payment methodology for making training add-on payments. One commenter expressed serious concerns regarding a holdback policy for home dialysis training, stating that the policy would ''penalize facilities'' for unsuccessful training. Another commenter contended that providers should not be held responsible for patients who decide that they are not able to adequately perform home dialysis.

Response: We thank the commenters for their comments and note that CMS did not receive a single comment that endorsed the holdback payment methodology. We agree with commenters that a holdback payment methodology penalizes the facilities for patients who decide that they are not able to perform self or home dialysis and that this decision may not be a reflection of the quality of the training the patient received.

In summary, in response to comments, CMS will finalize a payment increase of 50 percent for both PD and HD training treatments. Beginning January 1, 2014, the payment add-on will be computed based upon 1.5 hours of nursing time per training treatment, which amounts to a payment increase of $16.72 per training treatment. The training add-on adjustment payment amount for CY 2014 and future years will be $50.16 and will continue to be adjusted by the facility's wage index. ESRD facilities may continue to bill a maximum of 25 training sessions per patient for HHD training and 15 sessions for CCPD and CAPD. For all home modalities, we will pay for additional training sessions when medical necessity is documented. We believe increasing the training time is an appropriate policy refinement, as CMS evaluated the training elements reported to be furnished during training treatments and determined that self-cannualation, equipment preparation and alarm management were significant training elements that require additional time per training treatment and that payment of an additional half hour per treatment would appropriately recognize the costs incurred by facilities when they furnish training treatments. We will reduce the base rate by $0.02 to account for the increase in the amount of the home dialysis training add-on payment adjustment.

E. Delay of Payment for Oral-Only Drugs Under the ESRD PPS

Section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for ''renal dialysis services'' in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of that section states that these services include ''other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or

biological[.]'' We interpreted this provision as including not only injectable drugs and biologicals used for the treatment of ESRD (other than ESAs, which are included under clause (ii)), but also all non-injectable drugs used for the treatment of ESRD furnished under Title XVIII. We also concluded that, to the extent ESRD-related oral-only drugs do not fall within clause (iii) of the statutory definition of renal dialysis services, such drugs would fall under clause (iv), and constitute other items and services used for the treatment of ESRD that are not described in clause (i). Accordingly, we defined ''renal dialysis services'' at 42 CFR 413.174 as including, among other things, ''[o]ther items and services that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under title XVIII of the Act (including drugs and biologicals with only an oral form).'' Although oral-only drugs are included in the definition of renal dialysis services, in the CY 2011 ESRD PPS final rule we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014 (75 FR 49044). We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only ESRD-related drugs and biologicals to their patients. Accordingly, 42 CFR 413.174(f)(6) provides that payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form is incorporated into the PPS payment rates effective January 1, 2014.

On January 3, 2013, the Congress enacted ATRA. Section 632(b) of ATRA states that the Secretary ''may not implement the policy under section 413.176(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2016.'' Accordingly, payment for oral-only drugs will not be made under the ESRD PPS before January 1, 2016, instead of on January 1, 2014, which is the date originally finalized for payment of ESRD-related oral-only drugs under the ESRD PPS (75 FR 49044). We proposed to pay for oral-only drugs consistent with section 632(b) of ATRA and implement this delay by revising the effective date for providing payment for oral-only ESRD-related drugs under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2014 to January 1, 2016.

Because we proposed that oral-only drugs will be included in the ESRD PPS starting in CY 2016, we also proposed to change the reference to January 1, 2014 for the outlier policy described in 42 CFR 413.237(a)(1)(iv) to January 1, 2016. In the CY 2011 ESRD PPS final rule (75 FR 49138), we defined outlier services as including oral-only drugs effective January 1, 2014. In addition to modifying the date on which oral-only drugs will be eligible for outlier payments, we also proposed to clarify our regulation at 42 CFR 413.237(a)(1)(iv) by changing the word ''excluding'' to ''including'' to make clear that oral-only drugs are ESRD outlier services for purposes of the outlier policy effective January 1, 2016, consistent with the policy we established in the CY 2011 final rule (75 FR 49138).

We received the following comments on this proposal:

Comment: A few comments supported our amended regulations codifying the delay of oral-only drugs paid under the ESRD PPS payment bundle until January 1, 2016. One commenter suggested that CMS use this 2-year delay to ''gather stakeholder input and conduct careful assessment'' of the costs facilities will incur when furnishing oral-only drugs to dialysis patients. Another commenter cautioned CMS not to ''negatively impact'' Medicare beneficiaries by taking away patient protections, such as comprehensive drug utilization reviews, currently enjoyed under Medicare Part D plans. The commenter contends that phosphate binders and calcimimetics have significant drug interactions with commonly prescribed ESRD medications and could result in significant drug safety issues for patients if effective mechanisms for identifying drug-drug interactions are not available.

Response: We thank the commenters for their support in implementing section 632(b) of ATRA. We appreciate the commenters' suggestion on how CMS should best use the 2-year delay. In addition, we appreciate the commenters' concern for patient safety and beneficiary protections that are available under Medicare Part D. In anticipation of the inclusion of oral-only ESRD-related drugs in the payment bundle beginning in CY 2016, we intend to consider appropriate patient protections.

After consideration of the public comments we received, we are finalizing the proposed revisions to 42 CFR 413.174 and 413.237 without modification. We will delay the effective date for providing payment for oral-only ESRD-related drugs under the ESRD PPS at 42 CFR 413.174(f)(6) until January 1, 2016. Likewise, 42 CFR 413.237(a)(1)(iv) is revised to make clear that oral-only drugs are ESRD outlier services for purposes of the outlier policy effective January 1, 2016.

F. Miscellaneous Comments

We received many 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 2014 ESRD PPS proposed rule. Some of these comments are discussed below.

Comment: A few commenters requested that CMS amend the ESRD facility cost report and eliminate the cap on medical director fees. One commenter noted that the limitation for reporting medical director fees on Medicare cost reports is $165,000 annually, and that this amount reflects the wage of a physician of internal medicine and not a board-certified nephrologist. The commenter requested that CMS evaluate wages for nephrologists and adjust the reasonable compensation equivalent (RCE) on ESRD facility cost reports. Other commenters requested that CMS recognize the cost of supporting the ESRD networks. One commenter suggested that CMS include the $0.50 per treatment network fee as a cost, or an offset to revenue, on ESRD cost reports.

Response: We thank commenters for their suggestions. We will consider these comments for future refinements. We note that CMS has already implemented several updates and enhancements to the ESRD facility Medicare cost report. For example, the addition of cost report ''Worksheet C'' allows facilities to report a computation of the average cost per treatment by modality furnished under the ESRD PPS payment bundle.

Comment: Several commenters expressed confusion regarding eligibility requirements for the Low Volume Payment Adjustment (LVPA) available under the ESRD PPS. A few commenters requested clarification on the identification of free-standing and hospital-based low-volume facilities, while other commenters noted the Government Accountability Office (GAO) report 13–287 (End-Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment) and urged CMS to expeditiously refine this significant payment adjustment for deserving facilities as outlined in the report.

Response: We agree with commenters that the LVPA is an important and

significant payment adjustment for eligible facilities under the ESRD PPS. CMS discussed the eligibility requirements for the LVPA payment adjustment in the CY 2011 ESRD PPS final rule (75 FR 49117 through 49125), and codified the adjustment in our regulations at 42 CFR § 413.232. For specific inquiries regarding LVPA eligibility, we suggest that facilities contact their Medicare Administrative Contractor (MAC) directly. As part of potential future refinements, we plan to evaluate our current policies for the LVPA to ensure that we are effectively targeting low-volume facilities, in order to support access to dialysis services.

Comment: Some commenters requested that CMS consider payment implications outside of the ESRD PPS payment methodology for dialysis services. For example, a few commenters cautioned CMS that a static payment policy may ''dampen'' incentives to develop innovations and new technologies in the treatment of ESRD and urged CMS to establish a new technology adjustment.

Response: We thank the commenters and appreciate the suggestion that we consider different payment mechanisms that would encourage innovation for ESRD treatments and ensure quality patient care.

Comment: A few commenters requested that CMS consider a ''case-mix adjustor to address racial and ethnic disparities in ESRD treatment,'' and noted that some patient sub-groups require higher utilization of ESAs and other pharmaceuticals in furnishing quality patient care.

Response: We thank the commenters for expressing their concern regarding possible racial and ethnic disparities in the treatment of ESRD, and note that we discuss our analysis of a potential race case-mix adjustor in our CY 2011 ESRD PPS final rule (75 FR 49108 through 49115). In that rule, we noted that while section 1881(b)(14)(D)(i) of the Act allows CMS to consider the implementation of race/ethnicity payment adjustments, we believed that other patient characteristics such as ''body-size and co-morbidities,'' and not a patient's race contribute to higher treatment costs. We stated that ''[i]n particular, we are not convinced that race or ethnicity adjustments are necessary to ensure beneficiary access to ESRD services. That is, we believe that there may be race-neutral biological factors that have not yet been identified in the ESRD PPS modeling that could explain the increased cost associated with providing renal dialysis services to members of certain racial or ethnic groups.'' (75 FR 49109.) We will continue to monitor the health outcomes for all Medicare ESRD beneficiaries, and assess the underlying clinical conditions that incur higher treatment costs for future analysis.

Comment: A few facility commenters noted a geographic effect on ''payer mix trends'' for facilities located in inner city areas with nearly exclusive Medicare and Medicaid patients. Other commenters encouraged CMS to consider a payment mechanism that appropriately recognize the ''higher costs'' incurred by facilities when furnishing ESRD treatments to inner city patients, as these demographics have more minority patients, ''a large number of whom are African American, who have shown to require a higher volume of pharmaceutical products.''

Response: We thank the commenters for sharing the economic perspective of inner city ESRD facilities and we agree that inner city communities may have unique economic or demographic factors to manage in furnishing ESRD services. However, we disagree that the ESRD PPS payment methodology does not appropriately recognize these unique circumstances when making payments for dialysis services. For example, the outlier policy is a payment mechanism specifically designed to recognize higher cost patients in terms of drug, laboratory services, and supply utilization. In addition, we provide a wage index adjustment to reflect geographic differences in wages. Likewise, patient case-mix (that is, body size and comorbidities) and the LVPA facility adjustments recognize patient and facility characteristics that contribute to higher costs of care. And lastly, ESRD facilities are allowed to recover a portion of uncollected beneficiary coinsurance as outlined in 42 CFR § 413.89. While we continue to believe that the ESRD PPS payment methodology appropriately recognizes high cost patients and high cost geographic areas, we will continue to monitor patient utilization for all Medicare beneficiaries and will consider these comments in future refinements.

Comment: One commenter noted that historical and future Medicare bad debt policies do not allow for the full recovery of a facility's bad debt and estimates a payment shortfall of approximately $4 to $5 per treatment in uncompensated care. Other commenters pointed out that inner city facilities provide services in a ''fragile economic environment'' where they are unable to collect beneficiary co-payments.

Response: We thank the commenter for sharing their concerns regarding Medicare bad debt policies. CMS finalized the self-implementing statutory provision for the reduction in bad debt in the CY 2013 ESRD PPS final rule (77 FR 67518).

Comment: An organization that represents kidney health professionals urged CMS to publicize ways for ESRD patients, their families, and care providers to alert CMS to changes in care delivery that raise concern about negative effects on the quality of care provided as a result of the drug utilization reduction. They suggested such mechanisms could include, but are not limited to; the Medicare 1–800 number system; the ESRD Network complaint and quality of care reporting system; and a dedicated CMS email address.

Response: We appreciate the commenters' concern regarding ensuring quality care; however, because the implementation strategy for the drug utilization reduction will be transitioned over time, we believe that ESRD facilities should be able to maintain their current programs and services. We do not expect that the drug utilization reduction will negatively impact the quality of service a facility provides; therefore, we believe that our current methods (the 1–800 number system and the ESRD Network complaint and quality of care reporting system, as opposed to a dedicated email address) for beneficiaries, their families, and providers to communicate with CMS are adequate at this time.

Comment: Several commenters expressed concern regarding data transparency in rate setting, and requested that CMS release a CY 2014 data rate setting file.

Response: We agree with the commenters that a rate setting file would enhance transparency, and therefore, we are working to make such a file available in the future.

Comment: A few national organizations representing dialysis facilities expressed concern that a change to the census process in the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) has resulted in a delay in the date of first dialysis reconciliation and verification. The commenters noted that, as a result, facilities are unable to obtain, or there is a delay in receiving, the onset of dialysis payment adjustment.

Response: We appreciate the commenters bringing the on-set payment adjustment issues to our attention. We will consider these comments and work with agency staff to ensure that the on-set payment adjustment is applied appropriately in the future.

Comment: One commenter pointed out the significant payment difference in dialysis treatments furnished and paid through the hospital outpatient prospective payment system (OPPS) versus those paid under the ESRD PPS.

Response: We agree with the commenter that the payment difference for emergency or unscheduled dialysis services and maintenance renal dialysis services is significant, and note that the OPPS payment amount is based upon hospital claims data and reflects a significantly higher level of effort and resources to treat the patient in the hospital.

Comment: A commenter representing teaching hospitals expressed concern that the proposed drug utilization reduction would have a serious impact on teaching hospitals and the patients they treat. The commenter recommended that the regulatory impact analysis display the impact for hospital-based facilities according to teaching status for CY 2014.

Response: We appreciate the commenter's recommendation. While we are unable to include this information for the CY 2014 impact analysis, we will consider modifying the impact table to identify hospital-based ESRD facilities that are part of teaching hospitals in the future.

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

A. Background

For more than 30 years, monitoring the quality of care provided to patients with end-stage renal disease (ESRD) by dialysis 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 1881(h) of the Social Security Act (the Act), which was added by section 153(c) of Medicare Improvements for Patients and Providers Act (MIPPA). CMS established the ESRD QIP for payment year (PY) 2012, the initial year of the program in which payment reductions were applied, in two rules published in the **Federal Register** on August 12, 2010, and January 5, 2011 (75 FR 49030 and 76 FR 628, respectively). Subsequently, on November 10, 2011, CMS published a rule in the **Federal Register** outlining the PY 2013 and PY 2014 ESRD QIP requirements (76 FR 70228). On November 9, 2012, CMS published a rule in the **Federal Register** outlining the ESRD QIP requirements for PY 2015 and future payment years (77 FR 67450).

Section 1881(h) of the Act requires the Secretary to establish an ESRD QIP by (i) selecting measures; (ii) establishing the performance standards that apply to the individual measures; (iii) specifying a performance period with respect to a year; (iv) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (v) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS). This final rule discusses each of these elements and the policies we are finalizing for their application to PY 2016 and future payment years of the ESRD QIP. As of January 1, 2014, ESRD facilities located in Guam, American Samoa, and the Northern Marina Islands will be paid under the ESRD PPS. Under section 1881(h)(1)(A) of the Act, these facilities will receive a reduction to their ESRD PPS payments, beginning with January 1, 2014 dates of service, if they do not meet the requirements of the ESRD QIP.

B. Summary of the Proposed Provisions and Responses to Comments on the ESRD QIP for PY 2016

The proposed rule, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (78 FR 40836), hereinafter referred to as the CY 2014 ESRD PPS proposed rule, appeared in the **Federal Register** on July 8, 2013, with a comment period that ended on August 30, 2013. In that proposed rule, we made proposals for the ESRD QIP, including introducing, expanding, and revising measures; refining the scoring methodology; modifying the program's public reporting requirements; and continuing the 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, patient advocacy groups, and the Medicare Payment Advisory Commission (MedPAC).

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 ESRD QIP. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule.

C. Considerations in Updating and Expanding Quality Measures Under the ESRD QIP for PY 2016 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 on particular services furnished to a beneficiary to a program that ties payments to providers and suppliers based on the quality of services they deliver. By paying for the quality of care rather than quantity of care, we believe we are strengthening the healthcare system by focusing on better care and lower costs through improvement, prevention and population health, expanded healthcare coverage, and enterprise excellence—while also advancing the National Strategy for Quality Improvement in Health Care (National Quality Strategy). CMS is currently working to update a set of domains and specific measures of quality for our VBP programs, and to link the aims of the National Quality Strategy with our payment policies on a national scale. We are working in partnership with beneficiaries, providers, advocacy groups, the National Quality Forum (NQF), the Measures Application Partnership, operating divisions within 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 collaborating with stakeholders to ensure that the ESRD QIP serves the needs of our beneficiaries and also advances the goals of the National Quality Strategy to coordinate healthcare delivery, reduce healthcare costs, enhance patient satisfaction, promote healthy communities, and increase patient safety.[1]

We believe that the development of an ESRD QIP that is successful in supporting the delivery of high-quality healthcare services in dialysis facilities is paramount. We seek to adopt measures for the ESRD QIP that promote better, safer, and more-efficient care. Our measure development and selection activities for the ESRD QIP take into account national priorities such as those

[1] 2012 Annual Progress Report to Congress: National Strategy for Quality Improvement in Health Care, *http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf.*

established by the National Priorities Partnership (*http://www.nationalprioritiespartnership.org/*), HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), the National Strategy for Quality Improvement in Healthcare (*http://www.healthcare.gov/center/reports/quality03212011a.html*), and the HHS National Action Plan to Prevent Healthcare Associated Infections (HAIs) (*http://www.hhs.gov/ash/initiatives/hai/esrd.html*). To the extent feasible and practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, are recommended by multi-stakeholder organizations, and developed with the input of providers, beneficiaries, and other stakeholders.

2. Brief Overview of Proposed PY 2016 Measures

For the PY 2016 ESRD QIP and future payment years, we proposed a total of 14 measures. We believe that the PY 2016 ESRD QIP proposed measures promote high-quality care for patients with ESRD, and also strengthen the goals of the National Quality Strategy. We proposed to adopt the following measures to evaluate facilities on the clinical quality of care:

- To evaluate anemia management:
  - Hemoglobin Greater Than 12 g/dL, a clinical measure
  - Patient Informed Consent for Anemia Treatment, a clinical measure*
  - Pediatric Iron Therapy, a reporting measure*
  - Anemia Management, a reporting measure (revised)
- To evaluate dialysis adequacy:
  - A Kt/V measure for adult hemodialysis patients, a clinical measure
  - A Kt/V measure for adult peritoneal dialysis patients, a clinical measure
  - A Kt/V measure for pediatric hemodialysis patients, a clinical measure
- To determine whether patients are treated using the most beneficial type of vascular access:
  - An arterial venous (AV) fistula measure, a clinical measure
  - A catheter measure, a clinical measure
- To address effective bone mineral metabolism management:
  - Hypercalcemia, a clinical measure*
  - Mineral Metabolism, a reporting measure (revised)
- To address patient safety:
  - National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Outpatients, a clinical measure*
- To address patient-centered experience:
  - In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS), a reporting measure**
- To gather data regarding comorbidities:
  - Comorbidity, a reporting measure*

* Indicates that the proposed measure would be new to the ESRD QIP.

** Indicates that the proposed measure is newly expanded in the ESRD QIP.

At that time, we did not propose to adopt measures that address care coordination, efficiency, population and community health, or cost of care. However, we solicited comments on potential measures that would cover these areas. Our responses to these comments are discussed in section III.C.4 below.

3. Measures Application Partnership Review

Section 1890A(a)(1) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the entity with a contract (currently the NQF) under section 1890(a) of the Act 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 to make available to the public (not later than December 1 of each year) 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 2013 was transmitted to the Secretary on February 1, 2013, and is available at (*http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*). As required by section 1890A(a)(4) of the Act, we considered these recommendations in selecting quality and efficiency measures for the ESRD QIP.

We publicly made available a number of measures in accordance with section 1890A(a)(2) of the Act, and these measures were reviewed by the Measures Application Partnership. Of these measures, a subset is related to a number of proposed new measures for the PY 2016 ESRD QIP (one each for anemia management, hypercalcemia, infection monitoring, comorbidity reporting, and ESA usage). The Measures Application Partnership supported the following:

- NQF-endorsed measure NQF #1454: Proportion of patients with hypercalcemia
- NQF-endorsed measure NQF #1433: Use of Iron Therapy for Pediatric Patients (which forms the basis for the proposed Pediatric Iron Therapy reporting measure)
- NQF-endorsed measure NQF #1460: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure (which forms the basis for the proposed Bloodstream Infection in Hemodialysis Outpatients clinical measure)
- NQF-endorsed measure NQF #0369: Dialysis Facility Risk-adjusted Standardized Mortality Ratio (the proposed Comorbidity reporting measure may assist in calculating performance on this measure, should we propose to adopt it in the future)

The Measures Application Partnership supported the direction of the following measures:

- NQF-endorsed measure NQF #1463: Standardized Hospitalization Ratio for Admissions (the proposed Comorbidity reporting measure may assist in calculating performance on this measure, should we propose to adopt it in the future)
- M2774: Blood Transfusion Appropriateness (which forms the basis for the Patient Informed Consent for Anemia Treatment clinical measure)

We have taken comments from the Measures Application Partnership and the NQF into consideration for the PY 2016 ESRD QIP. In addition, we received several other comments on the Measures Application Partnership, and the measures development process in general. These comments and our responses are set forth below.

Comment: Several commenters noted that four of the five new measures proposed for the PY 2016 ESRD QIP are not endorsed by the NQF. These commenters were also concerned that there are NQF-endorsed versions of some of these measures, and that the

MAP reviewed the NQF-endorsed versions during its pre-rulemaking activities. The commenters believe that by proposing to adopt measures that the MAP did not actually review, CMS has not acted in accordance with the pre-rulemaking process set forth at section 1890A(a) of the Act. Commenters also believe that measures ''based on'' NQF-endorsed measures lack credibility. Some commenters recommended adopting the NQF-endorsed versions of the measures instead of the versions that we proposed to adopt in the proposed rule. Other commenters recommended that if CMS makes modifications to NQF-endorsed measures, CMS should resubmit the modified measures to the NQF for endorsement before proposing to adopt them for the ESRD QIP.

Response: We agree that consensus-building is an essential part of measure development and implementation, but we disagree that the new measures proposed for the PY 2016 program circumvented the MAP pre-rulemaking review process. We note that one of the five newly proposed clinical measures, Hypercalcemia, has been NQF-endorsed (NQF #1454). Another one of the newly proposed clinical measures, NHSN Bloodstream Infection in Hemodialysis Outpatients, is not substantively different than NQF-endorsed measure #1460. As described in more detail below, the only differences between the NQF-endorsed NHSN measure and the proposed NHSN measure involve programmatic implementation (i.e., the requirement to complete the NHSN Dialysis Event Protocol and the requirement to submit 12 months of data to NHSN).

As explained more fully below, we have decided not to finalize the Comorbidity reporting measure due to concerns raised in public comments submitted in response to the PY 2016 ESRD QIP proposed rule. However, we note that the measure would have required facilities to report data that could be incorporated into two NQF-endorsed measures that were reviewed by the MAP.

A fourth measure, the Patient Informed Consent for Anemia Treatment clinical measure, is not being finalized due to concerns raised in public comments submitted in response to the proposed rule (explained in more detail below). Nevertheless, this measure did receive feedback from the MAP in February 2013, which voted to support the direction of the measure, pending further measure development.

The proposed Pediatric Iron Therapy reporting measure is also not being finalized in this final rule in response to comments received on the proposed rule (explained in more detail below). This measure, however, would have been based on NQF #1433, which received a time-limited endorsement from NQF and was supported by the MAP.

Comment: Several commenters disapproved of the current processes used for measure development because (1) the current process is neither transparent nor consensus based; and (2) it was impossible to provide meaningful comment on the future measures described in the proposed rule because the preamble did not provide sufficient information to understand what CMS was proposing to do in the future. These commenters urged CMS to establish a systematic, phased-in process for incorporating new measures into the ESRD QIP, and to work with the community to identify a few domains that can be appropriately and explicitly prioritized.

Response: We currently develop measures using the Measures Management System Blueprint (Blueprint), which is described in detail at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html.* This process was used to develop some of the quality measures for use in the ESRD QIP. The development process we use is designed to be transparent and result in consensus-based measures that are appropriate for inclusion in our quality reporting and pay-for-performance programs. For example, we conduct extensive environmental scans and research other relevant evidence as part of measure development. We also seek advice from Technical Expert Panels (TEPs), which provide independent guidance on measures under development, and from the public through a comment solicitation process. We also ask the NQF to endorse many of the measures we develop, which gives the public another opportunity to provide input into the measures we are considering for our programs. When we consider adopting measures that we did not develop, we routinely consider measures that are NQF-endorsed because the NQF endorsement process ensures that measure specifications and testing remain transparent to the public. The NQF also provides the public with an opportunity to provide input and feedback prior to measure endorsement.

We recognize that our list of potential future measures does not typically contain detailed information about measures that we are considering for future use. However, we nonetheless believe that the list further makes transparent our future policy goals. We also note that before we can adopt any measure on that list, we must complete the measure development process outlined above. We are always interested in hearing from the community regarding what measures should be prioritized for development and implementation and encourage a continued dialog.

Comment: Several commenters recommended that nephrology nurses should be part of every TEP because, compared with physicians, they have a better understanding of the practical aspects of collecting and entering data.

Response: We make an effort to include in our measure development process input from a variety of stakeholders, including nephrology nurses, who provide care to the ESRD population. We plan to continue this approach as we continue our measure development activities.

D. Measures for the PY 2016 ESRD QIP and Subsequent PYs of the ESRD QIP

We previously finalized ten measures in the CY 2013 ESRD PPS final rule for the PY 2015 ESRD QIP and future PYs (77 FR 67471), and these measures are summarized in Table 6 below. We proposed to continue to use nine of the ten measures for the PY 2016 ESRD QIP and future payment years, modifying three of the measures as follows:

- ICH CAHPS (reporting measure): Expand
- Mineral Metabolism (reporting measure): Revise
- Anemia Management (reporting measure): Revise

For the PY 2016 ESRD QIP and future payment years, we proposed to add three new clinical measures (Patient Informed Consent for Anemia Treatment, Hypercalcemia, and NHSN Bloodstream Infection in Hemodialysis Outpatients) and two new reporting measures (Pediatric Iron Therapy, and Comorbidity). (See Table 7.) We believe that, collectively, these measures will continue to promote improvement in dialysis care in the PY 2016 ESRD QIP and in future payment years.

TABLE 6—MEASURES ADOPTED FOR THE PY 2015 ESRD QIP AND FUTURE PAYMENT YEARS

NQF #	Measure title and description
N/A	Anemia Management: Hgb >12. Percentage of Medicare patients with a mean hemoglobin value greater than 12 g/dL.
0249	Hemodialysis Adequacy: Minimum delivered hemodialysis dose. Percent of hemodialysis patient-months with spKt/V greater than or equal to 1.2.
0318	Peritoneal Dialysis Adequacy: Delivered dose above minimum. Percent of peritoneal dialysis patient-months with spKt/V greater than or equal to 1.7 (dialytic + residual) during the four month study period.
1423	Pediatric Hemodialysis Adequacy: Minimum spKt/V. Percent of pediatric in-center hemodialysis patient-months with spKt/V greater than or equal to 1.2.
0257	Vascular Access Type: Arterial Venous (AV) Fistula. Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter >= 90 days. Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A [1]	National Healthcare Safety Network (NHSN) Dialysis Event Reporting. Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A [2]	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration [+]. Attestation that facility administered survey in accordance with specifications.
N/A [3]	Mineral Metabolism Reporting [+]. Number of months for which facility reports uncorrected serum calcium and phosphorus for each Medicare patient.
N/A	Anemia Management Reporting [+]. Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.

[1] We note that an NQF-endorsed bloodstream infection measure (NQF#1460) exists.
[2] We note that a related measure utilizing the results of this survey has been NQF-endorsed (#0258). 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 implement NQF#0258.
[3] We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (#0255), and a calcium monitoring measure that NQF had previously endorsed (#0261).
[+] Indicates a measure we are proposing to revise for PY 2016 and future years of the ESRD QIP.

TABLE 7—NEW MEASURES PROPOSED FOR THE PY 2016 ESRD QIP AND FUTURE PAYMENT YEARS

NQF #	Measure title
N/A	Anemia of chronic kidney disease: Patient Informed Consent for Anemia Treatment.
N/A [1]	Use of Iron Therapy for Pediatric Patients Reporting.
1454	Proportion of Patients with Hypercalcemia.
N/A [2]	NHSN Bloodstream Infection in Hemodialysis Outpatients.
N/A [3]	Comorbidity Reporting.

[1] We note that the NQF has previously endorsed a pediatric iron therapy measure (#1433) upon which this measure is based.
[2] We note that the NQF has previously endorsed a National Healthcare Safety Network (NHSN) bloodstream infection measure (#1460) upon which this measure is based.
[3] We note that the NQF has previously endorsed risk-adjusted hospitalization and mortality measures (#1463 and #0369). The proposed Comorbidity reporting measure may assist in calculating performance on these measures, should we propose to adopt them in the future.

We received several comments on proposed measures for the PY 2016 ESRD QIP and future payment years. The comments and our responses are set forth below.

Comment: One commenter urged CMS to find a way to incentivize quality attainment and improvement rather than solely focusing on penalizing facilities.

Response: We do not have the statutory authority to award bonus payments to facilities for high performance under the ESRD QIP. Furthermore, we continue to believe that the structure of the ESRD QIP appropriately incentivizes improvements in the quality of care for patients with ESRD.

Comment: Several commenters stated that the ESRD QIP should have consistent exclusions for all measures unless there is a specific clinical or operational reason to do otherwise. These commenters recommended the following exclusions for PY 2014, PY 2015, and subsequent years: (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) in-center hemodialysis patients who receive fewer than 7 treatments in a month (or home peritoneal dialysis patients with fewer than 14 days of treatment) because it is difficult to affect outcomes with fewer treatments or less treatment time, as patients may miss draws, and it is difficult to predict a hospitalization, 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 because it may be difficult for facilities to procure adherence, but the good-faith exception ensures that facilities will attempt to ensure proper patient education and compliance; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. These commenters stated that their recommended exclusions are ''consistent with CMS' own measures that were NQF-endorsed in 2007, CROWNWeb, and the URR reporting specifications.'' Additionally, these commenters believe that their recommended exclusions would hold facilities accountable only for those patients to whom they regularly furnish care.

Response: We thank the commenters for their recommendations regarding the uniform application of exclusion criteria to the ESRD QIP. We interpret the commenter's statement about CMS measures that were NQF-endorsed in 2007 to mean the Hemodialysis Adequacy (NQF #0249), Peritoneal Adequacy (NQF #0318), Vascular Access Type: Fistula (NQF #0257) and Vascular Access Type: Catheter (NQF #0256) measures. While we generally agree that exclusion criteria should be consistent where feasible, we also believe that exclusions should take into account the population to which a given measure applies. In addition, we believe that exclusions should take into account the settings (for example, in-center hemodialysis as opposed to home hemodialysis) for which the measures were developed. We will continue to look for ways to align exclusion criteria for measures in the ESRD QIP in future payment years as long as there is evidence to support such consistency.

Comment: Several commenters expressed concerns that the ESRD QIP is adopting too many measures. These commenters noted that as more measures are adopted, the importance of any single measure to a facility's payment is reduced. The commenters also noted that CMS established criteria for retiring an ESRD QIP measure in the PY 2015 ESRD QIP, and the commenter is concerned that CMS has yet to propose the removal or retirement of any ESRD QIP measure while simultaneously continuing to propose the inclusion of new measures with little relative impact on patient outcomes (that is, patient informed consent of anemia treatment and reporting of comorbidities).

Response: We recognize that as more measures are added to the ESRD QIP, the significance of a facility's score on any single measure in relation to the overall TPS is reduced. In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a list of criteria we will use to make determinations about whether to remove or replace a measure: ''(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.'' We are currently in the process of evaluating all of our ESRD QIP measures against these criteria, and based on our findings, we will consider removing or replacing one or more measures next year.

Comment: One commenter expressed concerns that laboratory measures continue to be proposed for the ESRD QIP without reference to the sources, magnitude, and implications of unavoidable analytical variation. This commenter believes that between-laboratory variation renders laboratory-based clinical performance measures poor candidates for inclusion in a quality incentive program. The commenter recommended that the results of the same-sample, between-laboratory analysis should be shared with any TEP considering a laboratory-based performance measure.

Response: In April 2013, CMS convened a mineral bone disease TEP that reached conclusions similar to those pointed out by this commenter, and recommended that CMS convene an additional TEP for the purpose of addressing the issue of variability in all laboratory-based measures. We are continuing to consider how this issue might best be addressed through future measure development.

1. PY 2015 Measures Continuing in PY 2016 and Future Payment Years

We are continuing using six measures adopted in the CY 2013 ESRD PPS final rule for the PY 2016 ESRD QIP and future payment years of the program. We are also continuing to use two measure topics adopted. Our policies regarding the scoring of these measures are discussed in sections III.C.5 through III.C.11 and III.C.13. For the reasons stated in the CY 2012 ESRD PPS final rule (76 FR 70262, 70264 through 70265, 70269) and in the CY 2013 ESRD PPS final rule (77 FR 67478 through 67480, 67487 through 67490), we will continue using:

- The Hemoglobin Greater than 12 g/dL measure.

The Dialysis Adequacy measure topic, which is comprised of

- Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose (NQF # 0249),
- Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum (NQF #0318);
- Minimum spKt/V for Pediatric Hemodialysis Patients (NQF #423); and

The Vascular Access Type measure topic, which is comprised of

- Vascular Access Type: Arterial Venous (AV) Fistula (NQF #0257); and
- Vascular Access Type: Catheter >= 90 days (NQF #0256).

The technical specifications for these measures can be found at: *http://www.dialysisreports.org/ESRDMeasures.aspx.*

We received the following comments on measures continuing in the PY 2016 ESRD QIP:

Comment: One commenter noted that measures appropriate for in-center hemodialysis are not necessarily appropriate for peritoneal dialysis or home hemodialysis. The commenter recommended accounting more fully for these distinctions in existing measure specifications, as well as the adoption of quality measures that focus on home hemodialysis.

Response: We agree that the needs of patients receiving dialysis through different modalities must be considered while implementing quality measures, and we seek to take these issues into account through TEP feedback during measure development and maintenance, as well as via public feedback. We continue to pursue additional quality measures that will support quality assessment and improvement for all modalities.

Comment: Many commenters expressed concerns that the ESRD QIP includes catheter and fistula measures without including a graft measure. These commenters stated that this creates a disincentive for using a clinically appropriate access (that is, a graft) even when it is in the best interest of a patient.

Response: We are aware of the concern relating to the lack of a graft measure in the ESRD QIP measure set. We are in the process of determining whether to propose to revise the current Vascular Access Type measures, and/or whether it is feasible to develop and propose to adopt an independent graft measure.

Comment: One commenter expressed concerns that the low performance standard and benchmark for the hemoglobin greater than 12 g/dL measure places facilities with large numbers of home peritoneal dialysis patients at a disadvantage. The commenter stated that home peritoneal dialysis patients are more likely than in-center hemodialysis patients to have hemoglobin levels greater than 12 g/dL, so facilities with large numbers of home

peritoneal dialysis patients are disproportionately likely to have more than 1.2 percent of their patients with a hemoglobin level greater than 12 g/dL.

Response: We disagree that the apparent difference in average hemoglobin levels for in-center hemodialysis and home peritoneal dialysis patients warrants a revision to the measure specifications for the Hemoglobin Greater Than 12 g/dL measure. First, the FDA-approved labeling for ESAs does not differentiate appropriate hemoglobin levels based on dialysis modality. In addition, we are not aware of evidence-based support for the assertion that it is acceptable for a greater proportion of ESA-treated peritoneal dialysis patients to achieve hemoglobin levels greater than 12 g/dL. For these reasons, we continue to believe that the Hemoglobin Greater Than 12 g/dL measure does not place certain types of facilities at a disadvantage.

Comment: One commenter supported the continuation of the hemoglobin greater than 12 g/dL measure because of the potential problems stemming from the over-prescription of ESAs. However, the commenter stated that fewer ESRD QIP measures may be more effective in accurately and efficiently monitoring the quality of care delivered by dialysis facilities, and that CMS should focus more on a Hemoglobin Less Than 10g/dL measure as a means to monitor anemia management.

Response: We agree that quality measurement and assessment should contribute to the ESRD QIP as parsimoniously as is feasible while capturing quality for the complex treatment of dialysis patients. We will continue to take this into consideration in future rulemaking. Our rationale for removing the Hemoglobin Less Than 10 g/dL measure was published in the CY 2012 ESRD PPS proposed rule (76 FR 40519), and we believe those concerns remain sufficiently valid to merit not reintroducing the measure to the ESRD QIP at this time.

Comment: Several commenters recommended retiring the Hemoglobin Greater Than 12 g/dL measure. These commenters noted that the benchmark for the measure is 0 percent and the performance standard is 1.2 percent. The commenters believe that such a condensed performance range means the measure is incapable of distinguishing performance between facilities. The commenters also stated that the measure is no longer needed because facilities no longer have an incentive to overuse ESAs under the PPS.

Response: We recognize that facility performance for the Hemoglobin Greater Than 12 g/dL measure is very high overall, and that this is likely a consequence of including ESAs in the ESRD PPS bundled payment. We decided to continue using the measure in the PY 2016 program because we continue to believe that over-prescription of ESA constitutes a significant risk for patients with ESRD, and we continue to believe that the Hemoglobin Greater than 12 g/dL measure helps ensure that patients are not over-prescribed ESAs.

2. Expansion of One PY 2015 Measure and Revision of Two PY 2015 Measures for PY 2016 and Subsequent Payment Years

As stated earlier, we believe it is important to continue using measures from one payment year to the next payment year of the program to encourage continued improvements in patient care. Therefore, we proposed to expand and revise the measures discussed below that we finalized in the CY 2013 ESRD PPS final rule. For all measures except for the ICH CAHPS reporting measure, these proposed requirements would apply to the measures for PY 2016 and future payment years. For the ICH CAHPS measure, certain proposed expanded requirements would apply to PY 2016, and some additional proposed requirements would apply to PY 2017 and future payment years.

a. Expanded ICH CAHPS Reporting Measure

Patient-centered experience is an important measure of the quality of patient care. It is a component of the National Quality Strategy. The NQF endorses and the Measures Application Partnership supports a clinical measure on this topic, NQF #0258 [2] CAHPS In-Center Hemodialysis Survey, which is based on how facilities perform on the ICH CAHPS survey. In PY 2015, we continued to use a reporting measure related to the ICH CAHPS survey, requiring that facilities attest they had administered the survey according to the specifications set by the Agency for Healthcare Research and Quality (AHRQ), but not requiring the submission of survey data. We required that facilities attest by January 31, 2014, to administering the ICH CAHPS survey during the performance period (77 FR 67480 through 67481).

We are taking several steps to develop the baseline data necessary to propose and implement NQF #0258 as a clinical measure in the PY 2018 ESRD QIP. We expect to be able to certify ICH CAHPS survey vendors beginning in early CY 2014. We are also building the capacity to accept survey data; developing detailed specifications for administering the ICH–CAHPS survey in light of questions vendors asked about previous procedures; and developing specifications for submitting data to CMS, such as file specifications, structure and instructions that the survey vendors will use. We have taken these steps in order to make it possible for facilities to contract with third-party vendors to transfer survey data results to CMS, so that we might collect the baseline data necessary to propose and implement NQF #0258.

For PY 2016, we proposed that each facility arrange by July 2014 for a CMS-approved vendor to conduct the ICH CAHPS survey according to CMS (rather than AHRQ) specifications, available at the ICH CAHPS Web site (*https://ichcahps.org*). Facilities will need to register on the *https://ichcahps.org* Web site in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each facility must administer (via its vendor) the survey once during the performance period and, by 11:59 ET on January 28, 2015, report the survey data to CMS using the specifications on the ICH CAHPS Web site.

For PY 2017 and subsequent payment years, we proposed similar requirements except that each facility must arrange to have the survey administered twice during each performance period and must report the data (via its CMS-approved vendor) to CMS by the date specified on the ICH CAHPS Web site.

Although we have required that other types of providers, including home health agencies and acute care hospitals, administer and submit CAHPS survey data on a monthly, continuous basis, we recognize that there are generally low rates of turnover in dialysis-facility patient populations. For this reason, we do not see the same need to require facilities to administer the survey as frequently and, as proposed above, we would require facilities to administer the survey once during the performance period for PY 2016 (in order to allow facilities enough time to select a vendor) and twice for subsequent payment years. We believe that this frequency of survey administration will enable us to gather sufficient data to adopt in future rulemaking a clinical version of this

[2] Please note that the proposed rule initially included a typographical error, such that the measure was referred to as NQF #0285 instead of NQF #0258. We have revised the text here in response to a public comment, which is discussed below.

measure without unduly burdening facilities. The technical specifications for this proposed measure are located at *http://www.dialysisreports.org/pdf/esrd/public-measures/ICHCAHPS–2016NPRM.pdf.*

We requested comments on this proposal. The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters supported monitoring patients' experiences. However, these commenters stated that the ICH CAHPS survey is too burdensome and lengthy for patients to complete. Commenters suggested that the ICH CAHPS survey be divided into three parts, with each patient receiving one of these parts and a group of core questions.

Response: We do not agree that the ICH CAHPS survey is overly burdensome and we clarify that only 38 core survey questions are applicable to all respondents, plus 21 questions in the ''About You'' section. To be considered as complete, 19 of the 38 core questions must be answered. As we noted in the CY 2012 ESRD PPS final rule (76 FR 70269 through 70270) and the CY 2013 ESRD PPS final rule (77 FR 67480), we continue to believe that assessing the experiences of patients is vital to quality care. 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 ICH 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, patients may take a break during the administration of the survey or take the survey in multiple sittings if they feel that the number of questions is too great to answer at one time.

Additionally, there are no plans to change the measure specifications used in the AHRQ version, which received NQF endorsement in 2007. The ICH CAHPS survey underwent rigorous testing when it was being developed, and the testing refers to the survey in its entirety. The suggestion to parse the survey into three parts would make implementation too complex. In addition, the survey is designed to address many aspects of a patient's experience with in-center hemodialysis. Breaking the survey up into three separate components would mean that any single patient would not be asked about the full range of their experience.

Comment: One commenter sought clarification on the measure specifications for the ICH CAHPS measure. The commenter asked if the case minimum for the measure pertains to total patients, eligible patients, or respondents to the survey. Another commenter requested clarification on the 30-case minimum for the ICH CAHPS measure. One commenter wanted to know the period of time used to determine numbers of eligible patients treated (for example, between January and the end of April).

Response: The case minimum pertains to patients who are eligible for the survey, and patients over the age of eighteen with at least 3 months of experience on hemodialysis at their current facility are eligible. We further clarify that the performance period (for example, January through December 2014 for PY 2016) is the period of time that should be used to determine numbers of eligible patients.

Comment: One commenter did not agree that the target number of completed ICH CAHPS surveys should be 200. The commenter stated this target number makes no sense, regardless of clinic size, and should be removed.

Response: We selected 200 as the target number of completed surveys because we found that this was the number needed to reach a confidence interval of +/−0.07—a range that we believe ensures that facility scores will be accurate and comparable between facilities. We recognize that it will be difficult for smaller facilities to reach this target. We clarify that there are no penalties if a facility submits less than 200 complete surveys.

Comment: A few commenters raised concerns about the inclusion of homeless persons and nursing home patients with respect to eligibility for the ICH CAHPS survey because these patients may be difficult to contact for purposes of administering the survey.

Response: We are aware that it might be difficult to contact homeless and nursing home patients for any survey. However, these subgroups are important groups of people who may have different concerns than other dialysis patients. Although we have identified 200 completed surveys as a target response rate, there is no required minimum number of surveys that a facility must submit in order to satisfy the reporting requirements for the measure.

Comment: Several commenters stated that facilities should not be held accountable, leading to a penalty, for low response rates from such populations for which CMS's contact information may be inaccurate and/or out-of-date or based on the number of responses in the survey. Some commenters stated that facilities have no way to ensure that patients' contact information is as accurate and up-to-date as possible because the survey is administered by a third-party vendor. Other commenters did not support the ICH CAHPS measure specifications that require each patient to fill out at least half of the survey for the survey to count as complete. Commenters were also concerned because patients often skip or refuse to answer survey questions, and the commenters do not believe that facilities should be penalized for this.

Response: Facilities do not face any penalties for low-response rates. Survey vendors will receive contact information for patients sampled from a facility directly from CMS and its contractor, which will extract addresses and telephone numbers from CROWNWeb.

There are only 38 core survey questions that are applicable to all respondents, plus 21 questions in the ''About You'' section. To be considered as complete, 19 of the 38 core questions must be answered. Answering the survey is voluntary, and respondents may refuse to answer specific questions. With pre-notification by the vendor of the importance of their input, we hope that sampled patients will be willing to participate. Nevertheless, we clarify that facilities will not be penalized if they submit incomplete surveys.

Comment: Several commenters sought clarity on the ICH CAHPS measure specifications, which read that ''survey responses will not be shared with individual facilities, even if the respondent were to provide permission to do so.'' These commenters recommended that the specifications should clearly state that aggregate responses will be provided, but individual survey responses will not be shared.

Response: In an effort to protect the confidentiality of responses to the survey among this highly vulnerable population, in-center hemodialysis facilities must hire a third-party vendor to administer the survey. In addition, CMS will not allow vendors to share the responses of individual patients with in-center hemodialysis facilities. Vendors may provide aggregate results to facilities, but these results cannot include demographic data or other information that could be used to match patients and their survey responses. These measure specifications are consistent with the AHRQ specifications

for fielding the survey and handling the survey responses.

Comment: Several commenters did not support the proposal to adopt the ICH CAHPS measure because it is not appropriate to publicly publish scores that aggregate survey results when facilities have no means to impact responses to some of the questions. For example, cuts to the ESRD PPS payment rates may result in physicians spending less time with patients, and patients are also asked in the survey to comment on physicians that are not associated with the facility. Some commenters recommended including the physician component of the ICH CAHPS measure in the Physician Quality Reporting System instead of in the ESRD QIP.

Response: We believe that the survey results, in the aggregate, will be sufficient to promote quality improvement and, as we explain above, also believe that the interest in protecting patient anonymity and confidentiality outweighs the cost of making public individual survey responses. We also note that ICH CAHPS has been in the public domain since 2007, and dialysis facilities are already using the survey (with the ARHQ specifications) to meet the requirements for the PY 2014 ESRD QIP.

Questions about physicians are only one component of the ICH CAHPS survey, but we believe that the experience patients have with their physicians is critical to understanding and measuring their experience at the facility overall. We continue to believe that facilities can impact their performance on the physician component of the survey by encouraging physicians who see the facilities' patients to improve the quality of care they provide.

Comment: Many commenters discussed the impact of facility size on survey administration. Some commenters stated that small facilities would likely have low response rates that could skew results. Other commenters did not support the proposal to exclude facilities with fewer than 30 eligible patients from ICH CAHPS survey. These commenters stated that in CY 2011, nearly 20 percent of all in-center dialysis facilities would have been excluded from the measure; that CMS should evaluate patient experience of care in small facilities; and that CMS should develop further methodologies to collect reliable data from small facilities. Commenters also did not support the measure specifications for the ICH CAHPS measure. Specifically, these commenters noted that while the measure specifications require facilities with more than 200 patients to minimize overlap between the random sample of patients who receive each semi-annual survey, it will be difficult for facilities with close to 200 patients to minimize sampling overlap because many patients will likely be sampled in both of the bi-annual surveys.

Response: For our survey measures, we want to ensure that we are measuring true performance. In any measurement system there is a mixture of signal (true performance) and noise (random error). By using a case minimum of 30, we can increase reliability of the ICH CAHPS measure and the likelihood that it is measuring signal and not noise. Facilities with fewer than 30 eligible cases are excluded from the ICH CAHPS survey because results from these facilities might not be reliable. We recognize that when facilities have close to 200 patients, most of these patients will receive both of the semi-annual surveys in PY 2017 and future payment years. Nevertheless, these facilities should attempt to minimize overlapping patients by removing patients from the second survey if they were sampled in the first survey, and most facilities serve 99 or fewer unique patients per year.

Comment: Many commenters did not support the proposal to require facilities to administer the ICH CAHPS survey twice annually, starting in PY 2017, particularly in light of the proposed cuts to the ESRD PPS. Some of these commenters stated that it makes sense for hospitals to conduct the survey regularly because they generally do not treat the same patients more than once; however, dialysis facilities see the same patients over the course of the year, so there is no need to conduct a second survey. Commenters also stated that there are no data demonstrating that semi-annual surveys improve the validity of survey results. Additionally, many commenters did not support the proposal to administer the ICH CAHPS survey twice annually because doing so will lead to ''survey fatigue'' by decreasing the response rates to the ICH CAHPS survey, and other surveys administered by dialysis facilities, including the Kidney Disease Quality of Life-36 survey, which commenter states are required by the ESRD Conditions for Coverage (CfC) regulations. These commenters recommended fielding the survey once annually.

Response: We decided to require semi-annual administration of the survey in order to collect data about patients' experiences with dialysis care at different points in the calendar year, to ensure that patients could accurately recall their experience of care, and to ensure that survey responses were collected in timely fashion. Conducting the survey on an annual basis increases the likelihood of collecting outdated or inaccurate information, while making it more difficult to solicit information that accurately reflects the experiences of patients. Although we recognize that the requirement to conduct a second, semi-annual ICH CAHPS survey may decrease response rates to other surveys that facilities are required to complete (such as the Kidney Disease Quality of Life-36 survey), we believe that the drawbacks associated with the possibility of survey fatigue are outweighed by improvements in the reliability of the data collected through the ICH CAHPS survey.

Comment: Several commenters disagreed with the proposal to adopt the expanded ICH CAHPS measure because the survey is too expensive to administer.

Response: Although we acknowledge that there is a cost to administer the ICH CAHPS survey, we suggest that dialysis facilities compare several vendors before deciding on a vendor. We strongly believe that the information facilities gain from the ICH CAHPS survey outweighs the costs to administer the survey, because facilities can use this information to improve the care provided to patients with ESRD. Furthermore, as stated in the CY 2013 ESRD PPS final rule (77 FR 67481), ''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: Some commenters suggested that CMS redesign the survey to account for special populations (for example, low literacy, hearing and vision impaired, elderly, and physically handicapped). Other commenters stated that the ICH CAHPS survey should not be administered in languages other than English and Spanish, as proper translation of surveys requires a complicated forward and backward translation process, and it is unlikely that surveys conducted in other languages can be properly compared to surveys conducted in English and Spanish because of the complexity of the translation process.

Response: The survey administration procedures take into account the needs of special populations such as low literacy, hearing and vision impaired, elderly, and physically handicapped. Patients can get assistance in answering the survey as long as they, and not the assistor, actually answer the questions.

In addition, for telephone as well as in-person interviews, the interviewer will be instructed to permit respondents to take breaks as needed and to call back at another time if a respondent becomes fatigued. Finally, participation in the survey is completely voluntary on the part of the patients. They may refuse to participate or refuse to answer any questions they do not wish to answer. Facilities are not required to administer the survey in languages other than English and Spanish. However, CMS-approved vendors may use other approved translations that are authorized and developed by CMS.

Comment: A few commenters raised concerns about the administration of the survey and ways to ensure that sampled patients would/could complete the survey, especially those who may have lost their mail version of the survey or those with cognitive and/or language barriers.

Response: Responsiveness might vary by survey mode, language barriers, cognitive issues, literacy, and health issues. We believe that the ICH CAHPS measure is designed to maximize patient response rates while retaining its voluntary nature. Every sampled patient will receive a pre-notification letter from CMS (on its letterhead) prior to receipt of the mail survey or initial telephone call. This letter will describe the survey and the patient's role in providing feedback to improve the quality of care at the facility. The survey methodology also allows for assistance for patients who might have difficulty completing the survey.

The measure specifications suggest that survey vendors use current best practices to enhance response rates by (1) standardizing the survey materials; (2) improving readability; (3) allowing multiple contacts (up to 5) for follow-up in the telephone or mixed-mode; (4) offering call back times that are best suited for the sample patient; and/or (5) breaking up the survey over multiple calls.

In all three modes of administration (mail-only, telephone-only, and mixed modes), a pre-notification letter will include both email addresses and telephone numbers to call CMS or its ICH CAHPS contractor if the respondent has questions or problems with the survey. For the mail-only sample patients, cover letters will include the contact information of the CMS-approved survey vendors, who can replace lost surveys. Lost surveys should not be an issue for the telephone-only mode. For the other modes, sample patients will receive multiple surveys during the follow-up period or may contact the vendor for replacements.

Comment: A few commenters suggested making the survey available for patients online.

Response: We are aware that online surveys are popular, but this capability does not currently exist. We will continue to investigate new modes of administration, and in the meantime will continue with more traditional efforts to reach patients.

Comment: Many commenters expressed concerns that the ICH CAHPS survey only covers in-center hemodialysis patients. Many of these commenters recommended that CMS assess the experience of home dialysis patients and peritoneal dialysis patients as well.

Response: We thank commenters for their feedback. Eighty-nine percent of all ESRD patients receive in-center hemodialysis. Even those receiving peritoneal or home dialysis, have their initial care at an in-center hemodialysis facility. Therefore, this survey was specifically designed to capture the experience of in-center hemodialysis patients. Surveys for peritoneal and home dialysis patients may be considered for future development.

Comment: One commenter stated that there is a discrepancy between the proposed rule and the measure specifications for the ICH CAHPS measure. Specifically, the measure specifications establishes the survey periodicity for CY 2014 as ''twice annually,'' yet the proposed rule establishes the survey periodicity for CY 2014 as annually.

Response: We proposed that facilities would only have to administer the ICH CAHPS survey once in CY 2014. This is consistent with the measure specifications that appear at *https://ichcahps.org/Portals/0/ICH_DifferencesBtwAHRQandICHCAHPSSurveySpecs.pdf*.

Comment: One commenter noted that on page 40857, second column, subsection a, there is a typographical error. NQF #285 should be NQF #258.

Response: We thank the commenter for pointing out this typographical error. We have corrected it above.

Comment: Several commenters requested clarification about whether each facility will need to register on the *www.ichcahps.org* Web site, or if umbrella organizations that include a number of facilities will be able to authorize a selected vendor to administer the survey and submit data on behalf of each its facilities. These commenters stated that the contracting for this process will be centralized, and it would be inefficient for individual facilities to complete these steps when they could be done on an organization-wide basis. Concerns were also raised about having time to meet the system requirements for submitting ICH CAHPS data to CMS.

Response: Dialysis organizations may hire and authorize a single vendor to conduct the survey and submit data for all facilities under the corporate umbrella of the organization, but the corporate umbrella must report facility-level data to ensure that results can be attributed to individual facilities. The vendor may batch data from several facilities into a single zip file for submission.

Because third-party vendors are already conducting ICH CAHPS surveys on behalf of multi-facility organizations, we believe that the facilities will be able to timely meet the system requirements for administering the survey.

Comment: One commenter did not support the proposal to change the measure specifications for the ICH CAHPS measure from the AHRQ version to the CMS version. This commenter stated that doing so will make it hard to compare results between the two versions of the survey, and also cause confusion for facilities.

Response: Changes to the AHRQ measure specifications, which received NQF endorsement in 2007, are not substantive. Rather, the CMS measure specifications provide more details about the field operations and data submission in order to standardize the procedures used by third-party vendors. These non-substantive changes to the measure specifications were made in response to requests for this standardization. We have found that it is easier for vendors to administer the survey when they have detailed specifications, and we believe that this standardization helps ensure that the data will be comparable across all facilities.

For these reasons, we are finalizing the expanded ICH CAHPS reporting measure as proposed for the PY 2016 ESRD QIP and for future payment years. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/ICHCAHPS-2016FR.pdf*.

b. Revised Mineral Metabolism Reporting Measure

Adequate management of bone mineral metabolism and disease in patients with ESRD continues to be a high priority because it can cause severe consequences such as osteoporosis, osteomalacia, and hyperparathyroidism. The PY 2015 ESRD QIP has a reporting

measure focused on mineral metabolism (77 FR 67484 through 67487). We proposed two changes for PY 2016 and future payment years. First, when we finalized the measure in the CY 2013 ESRD PPS final rule, we inadvertently excluded home peritoneal dialysis patients from the measure specifications. For PY 2016 and future payment years, we proposed to include home peritoneal dialysis patients in the Mineral Metabolism reporting measure. Therefore, we proposed that a qualifying case for this measure will be defined as (i) an in-center Medicare patient who had been treated at least seven times by the facility; and (ii) a home dialysis Medicare patient for whom the facility submitted a claim at least once per month.

Second, if the proposed Hypercalcemia clinical measure (described below) is finalized based on public comment, then we believe it would be redundant, and unduly burdensome, for facilities to also continue reporting serum calcium levels as part of the Mineral Metabolism reporting measure. Accordingly, in light of our proposal to adopt the Hypercalcemia measure, we proposed to change the specifications for the Mineral Metabolism measure such that it no longer requires facilities to report serum calcium levels. We solicited comments on this proposal, and in particular on whether we should retain the reporting of serum calcium levels as part of the Mineral Metabolism reporting measure if the proposed Hypercalcemia measure was not finalized.

As described in more detail below (Proposed Minimum Data for Scoring Measures), we also proposed to eliminate the 11-case minimum for this measure, which was finalized in the CY 2013 ESRD PPS final rule (77 FR 67486). Because of the proposed revised case minimum, and because there are circumstances that might make it challenging for a facility to draw a sample from certain patients, such as those who are admitted to hospital during the month, we proposed that, in order to receive full points on this measure, facilities that treat 11 or more qualifying cases over the entire performance period will have to report at the lesser of the 50th percentile of facilities in CY 2013 or 97 percent per month, on a monthly basis, for each month of the performance period. We further proposed that facilities that treat fewer than 11 qualifying cases during the performance period will have to report on a monthly basis the specified levels for all but one qualifying case. If a facility only has one qualifying case during the entire performance period, a facility will have to attest to that fact in CROWNWeb by January 31 of the year following the performance period in order to avoid being scored on the measure. We made this proposal because we seek to ensure the highest quality of care regardless of facility size, and because we seek to mitigate cherry-picking by ensuring that one patient does not skew a facility's score (77 FR 67474).

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

Comment: Several commenters supported the proposal to include home peritoneal dialysis patients in the Mineral Metabolism reporting measure.

Response: We thank the commenters for their support.

Comment: Many commenters supported removing calcium from the reporting requirements of the Mineral Metabolism reporting measure if the Hypercalcemia measure is finalized, and retaining calcium in the Mineral Metabolism measure if the Hypercalcemia measure is not finalized.

Response: We thank the commenters for their support.

Comment: One commenter supported the proposal to modify the Mineral Metabolism measure and asked whether the revised Mineral Metabolism reporting measure would also include home hemodialysis patients.

Response: We thank the commenter for the support. We clarify that the measure includes home hemodialysis patients, as well as home peritoneal dialysis patients.

Comment: Some commenters stated the Mineral Metabolism reporting measure should include an exclusion for patients not on chronic dialysis to make the measure consistent with the anemia management reporting measure.

Response: We clarify that patients not on chronic dialysis have always been excluded from the Mineral Metabolism reporting measure, which is appropriate because the measure was designed for patients on chronic dialysis. We have updated the measure specifications to state this explicitly.

Comment: Several commenters noted that there is an inconsistency between the proposed rule and the measure specifications for the Mineral Metabolism reporting measure. The proposed rule states that ''if a facility only has 1 qualifying case during the entire performance period, a facility will have to attest to that fact in CROWNWeb by January 31 of the year following the performance period in order to avoid being scored on the measure.'' By contrast, the measure specifications state that ''fewer than 1 patient during the performance period who are (i) in-center Medicare patients who have been treated at least 7 times by the facility during the reporting month; or (ii) home dialysis Medicare patients for whom the facility submits a claim during the reporting month must attest to this fact in CROWNWeb to not be scored on this measure.''

Response: We thank commenters for identifying this discrepancy. We have changed the measure specifications to state that the case minimum is one eligible patient. Facilities with two or more eligible patients will be scored on the measure, and facilities with one eligible patient will be scored on the measure unless they attest to this fact in CROWNWeb. We made this proposal to enable us to gather data on patients in small facilities.

Comment: One commenter recommended that the Mineral Metabolism reporting measure specifications be modified to indicate that plasma and serum should both be acceptable blood samples for the measurement of calcium. The commenter stated that plasma testing is more stable and requires less manipulation, has been used since 2006, has been validated for most clinical chemistry analyzers, and has been deemed acceptable and equivalent by analyzer manufacturers.

Response: We disagree that the measure specification should be modified to include plasma calcium measurements. This issue was discussed at length during the April 2013 mineral bone disease TEP (*http://www.cms.gov/Medicare/End-Stage-Renal-Disease/CPMProject/index.html*). Overall, TEP members determined that there is a lack of strong evidence supporting the acceptance of measurements of serum phosphorus on plasma (vs. serum). Published literature indicates that the difference in phosphorus levels measured on plasma vs. serum are not trivial and may be as high as 10 percent.[3] Based on these observations, TEP members voted and unanimously recommended to keep the measure unchanged, such that facilities are required to report serum levels.

Comment: One commenter stated that the Mineral Metabolism measure will not improve patient care because it does not measure outcomes. The commenter recommended adopting an outcomes-based phosphorus measure in future payment years.

Response: As stated in the CY 2013 ESRD PPS final rule (77 FR 67486), we

[3] Carothers, JE et. al. Clinical Chemistry, volume 22, Issue 11, 1976 (Table 3).

continue to believe that the Mineral Metabolism reporting measure will help improve patient outcomes. Kidney Disease Improving Global Outcomes (KDIGO) recommends monthly measurements and emphasizes the importance of following trends versus single measurements, thus supporting relatively frequent measurements (for example, monthly).[4] There is evidence that extreme phosphorus levels may be associated with poor clinical outcomes. Monthly measurements will identify elevated levels of serum phosphorus and trigger therapeutic interventions, thus contributing to high-quality care.

Comment: Many commenters supported the inclusion of home dialysis patients in the Mineral Metabolism reporting measure. However, these commenters expressed concern that the inclusion of these patients will discourage home hemodialysis, force home dialysis patients to visit a facility too frequently or otherwise present greater challenges for regular blood draws, and cause difficulties for small facilities that only treat home dialysis patients.

Response: We disagree that the inclusion of home peritoneal dialysis patients in the Mineral Metabolism measure will force the patients to visit their dialysis facility too frequently, or otherwise discourage patients from receiving dialysis at home. Between May 2012 and March 2013, a large percentage of patients had blood testing performed each month. The percentage of patients with monthly testing varied by modality and specific blood test, but all populations provided data for between 72 percent and 89 percent of qualifying patients. Furthermore, the ESRD CfCs, implemented in October 2008, require monthly testing for some labs (for example, Albumin, Hemoglobin/Hematocrit at § 494.90(a)(2) and § 494.90(a)(4), respectively) and require that all patients (including home dialysis patients) see a practitioner (for example, a physician, physician's assistant, or nurse practitioner) at least monthly as specified at § 494.90(b)(4). Therefore, we do not believe that requiring monthly measurements of serum phosphorus will discourage patients from receiving dialysis at home, since the vast majority of home dialysis patients already receive monthly blood tests, and facilities are already required under the CfCs to conduct some other lab tests on a monthly basis.

Comment: One commenter stated that the language used to finalize the Mineral Metabolism reporting measure in the CY 2013 ESRD PPS was unclear about what was meant by ''monthly basis.'' The commenter asked whether this means the percent of complete months in which 96 percent of eligible patients were tested, or if this means the percent of eligible patients for that facility who had monthly testing in excess of 96 percent. The commenter also sought clarification with respect to the equation used to calculate scores on the Mineral Metabolism measure.

Response: By ''monthly basis,'' we mean meeting the reporting threshold for each month during the performance period. Facilities are scored on the measure based on the number of months in which the facility successfully meets this reporting threshold. Measure scores are not determined by the percent of months in which the facility meets this reporting threshold, but rather according to the equation below, which appears in the CY 2013 ESRD PPS final rule (77 FR 67506). We also affirm that this methodology will be used to calculate scores on the Mineral Metabolism measure in the PY 2015 and PY 2016 programs, as well as future payment years.

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

For the reasons stated above, and the reasons stated in section III.C.10 below, we are finalizing the Mineral Metabolism reporting measure for the PY 2016 ESRD QIP and for future payment years. Additionally, because we are finalizing the Hypercalcemia clinical measure (see Section III.C.3.b below), we are also finalizing the proposal to change the specifications for the Mineral Metabolism measure such that the measure no longer requires facilities to report serum calcium levels. Technical specifications for the revised Mineral Metabolism reporting measure can be found at: *http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Reporting-2016FR.pdf.*

c. Revised 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 for such management.'' In the CY 2013 ESRD PPS final rule, we finalized an Anemia Management reporting measure for the reasons stated in that final rule (77 FR 67491 through 67495). However, we inadvertently excluded home peritoneal patients from the measure specifications. For PY 2016 and future payment years, we proposed to include home peritoneal patients in the Anemia Management reporting measure. Therefore, we proposed that a qualifying case for this measure will be defined as (i) an in-center Medicare patient who had been treated at least seven times by the facility; and (ii) a home dialysis Medicare patient for whom the facility submitted a claim at least once per month.

We believe that there are circumstances that might make it challenging to draw a sample from certain patients. Therefore we proposed that, in order to receive full points on this measure, facilities that treat 11 or more qualifying cases over the entire performance period must report at the lesser of the 50th percentile of facilities in CY 2013 or 99 percent per month, on a monthly basis for each month of the performance period. In addition, we proposed that, in order to receive full points on this measure, facilities that treat fewer than 11 qualifying cases during the performance period must report on a monthly basis the specified levels for all but one qualifying case. If

[4] KDIGO recommends measurement of serum phosphorus every 1–3 months in Chapter 3, KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorders (CKD–MBD) Kidney International vol 76, supplement 113, August 2009.

a facility only has one qualifying case during the entire performance period, a facility will have to attest to that fact in CROWNWeb by January 31 of the year following the performance period in order to avoid being scored on the measure. We made this proposal because we seek to ensure the highest quality of care regardless of facility size, and because we seek to mitigate cherry-picking by ensuring that one patient does not skew a facility's score (77 FR 67474).

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

Comment: Many commenters supported the proposal to include home peritoneal dialysis patients in the Anemia Management reporting measure.

Response: We thank the commenters for their support.

Comment: Several commenters supported the inclusion of home peritoneal dialysis patients in the Anemia Management reporting measure. However, these commenters expressed some concern that the inclusion of these patients will discourage home hemodialysis, force home dialysis patients to visit a facility too frequently, and cause difficulties for small facilities that only treat home dialysis patients.

Response: We disagree that the inclusion of home peritoneal dialysis patients in the Anemia Management reporting measure will force the patients to visit their dialysis facility too frequently, or otherwise discourage patients from receiving dialysis at home. Most home dialysis patients, including peritoneal dialysis patients, receive blood testing on a monthly basis. Furthermore, the CfCs require monthly testing for some labs (for example, Albumin, Hemoglobin/Hematocrit at § 494.90(a)(2) and § 494.90(a)(4), respectively) and require that all patients (including home dialysis patients) see a practitioner (for example, a physician, physician's assistant, nurse practitioner) at least monthly as specified at § 494.90(b)(4). Therefore, we do not believe the inclusion of home peritoneal dialysis patients will discourage home dialysis, because most home dialysis patients already visit dialysis facilities for monthly blood tests, and because facilities are already required to conduct monthly hemoglobin/hematocrit tests for all dialysis patients.

Comment: Several commenters noted that there is an inconsistency between the proposed rule and the measure specifications for the Anemia Management reporting measure. The proposed rule states that ''if a facility only has 1 qualifying case during the entire performance period, a facility will have to attest to that fact in CROWNWeb by January 31 of the year following the performance period in order to avoid being scored on the measure.'' By contrast, the measure specifications state that ''fewer than 1 patient during the performance period who are (i) in-center Medicare patients who have been treated at least 7 times by the facility during the reporting month; or (ii) home dialysis Medicare patients for whom the facility submits a claim during the reporting month, must attest to this fact in CROWNWeb to not be scored on this measure.''

Response: We thank commenters for identifying this discrepancy. We have changed the measure specifications to state that the case minimum is one eligible patient. Facilities with two or more eligible patients will be scored on the measure, and facilities with one eligible patient will be scored on the measure until they attest to this in CROWNWeb. We made this proposal to enable us to gather data on patients in small facilities.

For these reasons, and the reasons stated in section III.C.10 below, we are finalizing the Anemia Management reporting measure as proposed for the PY 2016 ESRD QIP and for future payment years. Technical specifications for this proposed measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2016FR.pdf*.

3. New Measures for PY 2016 and Subsequent Payment Years of the ESRD QIP

As the program evolves, we believe it is important to continue to evaluate and expand the measures selected for the ESRD QIP. Therefore, for the PY 2016 ESRD QIP and future payment years, we proposed to adopt five new measures. The proposed new measures include two measures on anemia management, one measure on mineral metabolism, one measure on bloodstream infection monitoring, and one measure on comorbidities.

a. Anemia Management Clinical Measure Topic and Measures

Section 1881(h)(2)(A)(i) of the Act states that the measures specified for the ESRD QIP are required to include measures on ''anemia management that reflect the labeling approved by the Food and Drug Administration for such management.'' For PY 2016 and future payment years, we proposed to create a new anemia management clinical measure topic, which consists of one measure initially finalized in the PY 2012 ESRD QIP final rule and most recently finalized for PY 2015 and future PYs in the CY 2013 ESRD PPS final rule, and one new proposed measure, described below. We note that, like other measure topics, we proposed that the Anemia Management clinical measure topic consist only of clinical and not reporting measures.

i. Anemia Management: Hgb > 12

For the PY 2016 ESRD QIP and future payment years of the program, we proposed to include the current Hgb > 12 measure in a new Anemia Management Clinical measure topic. In the event that the Patient Informed Consent for Anemia Treatment measure described below is not finalized, we proposed to retain the Hgb > 12 measure as an independent measure. We solicited comments on this proposal.

We did not receive any comments on these proposals.

ii. Anemia of Chronic Kidney Disease: Patient Informed Consent for Anemia Treatment

This is a measure of the proportion of dialysis patients for whom a facility attests that risks, potential benefits, and alternative treatment options for anemia were evaluated, and that the patient participated in the decision-making regarding an anemia treatment strategy. We believe that this measure is consistent with recent changes to the FDA-approved labeling [5] for ESAs and Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Management Guidelines [6] that highlight the evolving understanding of risks associated with ESA therapy, as required in section 1881(h)(2)(A)(i) of the Act. We believe it is appropriate for facilities and physicians to ensure that steps are taken to make patients aware of those potential risks within the context of treatment for anemia. For these reasons, we proposed to adopt this measure (Anemia of Chronic Kidney Disease: Patient Informed Consent for Anemia Treatment) for the ESRD QIP in PY 2016 and future payment years of the program. In order to meet the requirements of this proposed measure, facilities must attest in CROWNWeb for each qualifying patient, on an annual basis, that informed consent was obtained from that patient, or that patient's legally authorized representative, during the performance period. We proposed that qualifying

[5] *http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm.*

[6] Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012 (2): 279–335.

cases for this measure would be defined as patients who received dialysis in the facility for 30 days or more. The proposed deadline for reporting these attestations for the PY 2016 ESRD QIP would be January 31, 2015, or, if that is not a regular business day, the first business day thereafter. Missing attestation data for a patient would be interpreted as failure to obtain informed consent from that patient.

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

Comment: Many commenters expressed a variety of concerns about the proposed Patient Informed Consent of Anemia Treatment clinical measure and did not support its adoption for the ESRD QIP. Some commenters stated that obtaining informed patient consent is already a standard of clinical care, and that the measure would therefore not promote quality care, but would instead add more, unnecessary recordkeeping. Other commenters stated that the informed consent measure would be duplicative and possibly inconsistent with the FDA's Risk Evaluation and Mitigation Strategy (REMS) for ESAs, which already requires physicians to discuss with patients the risks of ESA therapy. Other commenters expressed conflicting opinions about the proposed measure. One group of commenters stated that nephrologists, not dialysis facilities, prescribe ESAs, so it would be unreasonable to expect facilities to obtain informed consent from patients. A different group of commenters noted that obtaining informed patient consent is already an ESRD CfC for dialysis facilities, so it would be unnecessary for the ESRD QIP to adopt a measure on the topic.

Response: We appreciate the commenters' concerns. We continue to believe that this measure is a useful complement to the other anemia management measures currently used in the ESRD QIP, as those measures focus exclusively on hemoglobin levels and not the patient's knowledge of the risks and benefits of anemia treatment. We also believe that it is essential to provide patients with this information, in light of the lack of scientific evidence regarding ESAs and ideal hemoglobin levels in this patient population. Additionally, we disagree that this measures and the FDA REMS accomplish the same goal. The FDA REMS program is focused on ensuring that patients are aware of the risks associated with aspects of ESA use in overall anemia management, particularly in the setting of cancer chemotherapy. The informed consent measure, by contrast, would require facilities to provide a balanced discussion of both the risks and the potential benefits of a contemplated treatment.

However, we agree with commenters who noted that providing informed consent is already a standard of care that is at least partially regulated through the ESRD CfCs. We do not want to create additional recordkeeping requirements for facilities when there is already an existing standard that facilities are required to meet. For this reason, we are not finalizing the Patient Informed Consent for Anemia Treatment clinical measure at this time. Because we are not finalizing this measure, we are also not finalizing the proposed Anemia Management Clinical measure topic. Instead, the Hemoglobin Greater Than 12 g/dL clinical measure will remain an independent clinical measure, unassociated with a clinical measure topic, as it has in previous payment years. Technical specifications for the Hemoglobin Greater Than 12 g/dL measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-HGB-2016FR.pdf*.

b. Hypercalcemia

Section 1881(h)(2)(A)(iii)(II) 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). Many studies have associated disorders of mineral metabolism with mortality, fractures, cardiovascular disease, and other morbidities. Therefore, we believe it is critical to adopt a clinical measure that encourages adequate management of bone mineral metabolism and disease in patients with ESRD.

Elevated serum calcium level (or hypercalcemia) has been shown to be significantly associated with increased all-cause mortality in patients with advanced CKD. Both KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD–MBD) and the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) support maintaining serum calcium levels within reference ranges. Hypercalcemia is also a proxy for vascular and/or valvular calcification [7] [8] and subsequent risk for cardiovascular deaths. We previously proposed a hypercalcemia clinical measure for the PY 2015 ESRD QIP (77 FR 40973 through 40974), but decided not to finalize the measure because we lacked baseline data that could be used to calculate performance standards, achievement thresholds, and benchmarks (77 FR 67490 through 67491). We now possess enough baseline data to calculate these values. Therefore, we proposed to adopt the NQF-endorsed measure NQF #1454: Proportion of Patients with Hypercalcemia, for PY 2016 and future payment years of the ESRD QIP.

The proposed Hypercalcemia 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.) In order to enable us to calculate this measure, each facility will be required to enter in CROWNWeb, on a monthly basis, an uncorrected calcium level for each in-center and home dialysis patient over the age of eighteen.

Performance on this measure is expressed as a proportion of patient-months for which the 3-month rolling average exceeds 10.2 mg/dL. The numerator is the total number of eligible patient-months where the 3-month rolling average is greater than 10.2 mg/dL, and the denominator is the total number of eligible patient-months. We proposed that facilities would begin to submit data on this measure based on January 2014 uncorrected serum calcium levels but that we would calculate the first 3-month rolling average for each eligible patient in March 2014 using January, February, and March 2014 data. We would then calculate a new 3-month rolling average each successive eligible patient-month (April through December measure calculations) by dropping the oldest month's data and using instead the newest month's data in the 3-month period. The facility's performance will be determined by calculating the proportion of the 3-month averages calculated monthly (March through December, each time using the latest 3

[7] Wang A, Woo J, Law C, et al. Cardiac Valve Calcification as an Important Predictor for All-Cause Mortality and Cardiovascular Mortality in Long-Term Peritoneal Dialysis Patients: A Prospective Study. J Am. S. Nephrology 2011 (14/1): 159–168.

[8] Wang A, Ho S, Wang M, et al. Cardiac Valvular Calcification as a Marker of Atherosclerosis and Arterial Calcification in End-stage Renal Disease. JAMA 2005 (165/3): 327–332.

months of data) for all eligible patients that was greater than 10.2 mg/dL.

Because we proposed to adopt this measure not only for PY 2016, but also for subsequent payment years, we also proposed that, beginning with the PY 2017 program, we would measure hypercalcemia beginning in January of the applicable performance period. This will allow us to have a 3-month rolling average for all months in the performance period. We 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.

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

Comment: One commenter supported the proposal to adopt the hypercalcemia measure because ''this measure represents an incentive for maintaining this important standard of care and protecting patients'' in light of the ''intention to include oral drugs, such as phosphorus binders, in the PPS in 2016.'' The commenter also stated that there is no clinical rationale for needing a full year of baseline data for improvement and achievement scoring.

Response: We thank the commenter for the support.

Comment: Several commenters strongly supported the inclusion of mineral metabolism measures in the ESRD QIP, including the proposal to adopt the hypercalcemia measure. These commenters also supported the adoption of other mineral metabolism measures (for example, PTH and phosphorus), in future payment years because oral drugs used to regulate mineral metabolism are moving from Medicare Part D to the ESRD PPS bundled payment in CY 2016.

Response: We thank the commenters for their support. Additionally, we agree that we should explore other measures to assess mineral metabolism for future payment years. We are currently developing such measures, and will continue to do so.

Comment: Many commenters supported the proposal to adopt the hypercalcemia measure. However, some of these commenters stated that patients who present with other non-ESRD conditions that may cause hypercalcemia should be excluded from the 3-month rolling average. Commenters also stated that patients treated fewer than seven times by a facility should be excluded from the measure. Additionally, one commenter noted that the 10.2 mg/dL threshold used to evaluate the hypercalcemia measure is higher than the KDOQI and KDIGO guidelines, which recommend a threshold of 9.5 mg/dL. This commenter prefers the 9.5 threshold, but supports the adoption of the hypercalcemia measure because having an upper target for calcium is a valuable addition to the ESRD QIP.

Response: We thank the commenters for the support. While we acknowledge that calcium levels in dialysis patients might be impacted by conditions unrelated to ESRD, we also believe it is appropriate to monitor and minimize the prevalence of hypercalcemia in all patients with ESRD, since mineral and bone disorder are highly prevalent in this population, and because some dialysis-related treatments impact serum calcium levels.

We further note that patients are included in the denominator only if they are on dialysis for at least 90 days as of the first day of the most recent month of the ''measurement period'' (that is, the 3-month period used to calculate the rolling average for the measure) and are in the facility for at least 30 days as of the last day of the most recent month of the measurement period. These NQF-endorsed exclusion criteria will exclude the vast majority of in-center patients who are treated fewer than seven times by a facility. However, the NQF-endorsed exclusion criteria are broad enough to include home dialysis patients. We believe that the NQF-endorsed exclusion criteria are more appropriate because they will not exclude home dialysis patients, who are rarely treated at a facility seven or more times in a month.

Finally, the 10.2 threshold is consistent with KDIGO guideline 4.1.2 [2009] ''In patients with CKD stages 3–5D, we suggest maintaining serum calcium in the normal range,'' since 10.2 mg/dL is considered the upper limit of the normal range in the majority of clinical laboratories. This threshold is also consistent with the value discussed and supported by the 2006 TEP. The hypercalcemia measure using the 10.2 threshold was developed by the 2010 TEP as summarized in the final TEP report posted by CMS at *http://www.cms.gov/Medicare/End-Stage-Renal-Disease/CPMProject/index.html*.

Comment: Several commenters did not support the proposal to adopt the hypercalcemia measure. These commenters stated that this metric is not the best measure in the mineral metabolism domain to impact patient outcomes, in the absence of clinical metrics for other related mineral disturbances, such as phosphorus and PTH. Some of these commenters recommended adopting the hypercalcemia measure as a reporting measure.

Response: We believe that the hypercalcemia measure is the best measure supported by current evidence available for implementation in the ESRD QIP at this time. CMS has convened three discrete TEPs since 2006 charged with developing quality measures related to management of bone and mineral disorders in chronic dialysis patients. The 3-month rolling average hypercalcemia measure is the first outcome measure developed in this topic area that has received NQF endorsement. The measure is important because it addresses a potential healthcare-associated condition, hypercalcemia, that may result from treatments chosen by dialysis providers to treat CKD-related bone disease. However, we are currently exploring the feasibility of adopting in the future additional measures to address PTH monitoring to ensure that dialysis patients' bone and mineral disease laboratory outcomes are monitored at a frequency consistent with clinical consensus guidelines.

Comment: Some commenters did not support the proposal to adopt the hypercalcemia measure because there is no consensus that the measure is appropriate. These commenters also stated that the measure should only apply to Medicare patients because CMS should not collect data on patients who are not enrolled in Medicare. Commenters recommended that calcium and phosphorus data continue to be collected via the mineral metabolism reporting measure.

Response: The Hypercalcemia measure (NQF# 1454) has been endorsed by the NQF, and we believe that this endorsement reflects broad consensus that the measure is appropriate for assessing hypercalcemia within the ESRD population. In addition, the collection of all-patient data on this measure allows us to assess the quality of care provided to Medicare patients with ESRD, in part, by analyzing how that care compares to the quality of care provided to the ESRD population overall. Because we are finalizing the adoption of the Hypercalcemia measure for the ESRD QIP, facilities will not be required to submit calcium data for the Mineral Metabolism reporting measure.

Comment: One commenter did not support the proposal to adopt the hypercalcemia measure because there is

no evidence that facilities are not adequately managing hypercalcemia, and because there is no agreement on how calcium should be adjusted (if at all) for albumin levels.

Response: The published literature indicates that large numbers of patients with ESRD are affected by hypercalcemia.[9] [10] [11] [12] [13] In addition, patient-level analysis of CROWNWeb data collected for July 2012 shows that of 441,681 patients, 81.9 percent had uncorrected serum calcium reported during the month, 59.8 percent met the denominator for this proposed measure, and 3.0 percent had hypercalcemia based on a rolling-average from May 2012 through July 2012. We agree that there is lack of agreement on the need to correct serum calcium for serum albumin concentration. Furthermore, there is lack of agreement on the accuracy of different available methods for correction of serum calcium for albumin concentration. We are therefore using uncorrected calcium to score the Hypercalcemia clinical measure, instead of scoring the measure on the basis of corrected calcium.

Comment: Several commenters did not support the proposal to adopt the hypercalcemia measure because it may lead to unintended consequences (for example, sudden cardiac death) and because it will incentivize facilities to decrease calcium levels in patients with serum calcium levels near 10.2 mg/dL.

Response: Although patients with serum calcium concentrations below the lower limit of normal may be at increased risk for cardiac arrhythmias, the available literature reviewed by KDIGO suggests that the risk of hypocalcemia occurs below 8.4 mg/dl calcium concentration, if at all. While facilities are incentivized to prevent patients from developing extremely high levels of calcium, we believe the threshold is sufficiently high that it is unlikely to incentivize facilities to cause hypocalcemia in patients. Therefore we do not anticipate an increased risk for sudden death, provided that clinicians properly monitor calcium levels.

Comment: One commenter did not support the proposal to adopt the Hypercalcemia measure for a number of reasons: (1) The measure should exclude patients not on dialysis for at least 90 days to ensure that the 3-month rolling average is calculated using a consistent methodology; (2) the measure should provide a method for calculating a 3-month rolling average when data is only reported for months 1 and 3; and (3) the measure should specify that values were obtained during the current dialysis facility admission, and that samples must be obtained before hemodialysis treatment. The commenter recommends retaining the Mineral Metabolism reporting measure (to include reporting of serum calcium) until these issues are addressed.

Response: We will respond to each issue in turn.

First, the measure excludes patients not on dialysis for less than 90 days, as described in the proposed measure specifications. Patients are included in the denominator if they are 18 years or older as of the first day of the most recent month of the measurement period, are on dialysis for at least 90 days as of the first day of the most recent month of the measurement period, are in the facility for at least 30 days as of the last day of the most recent month of the measurement period, and have at least one serum calcium measurement within the measurement period.

Second, the patient must have at least one serum calcium measurement in the three month period. If the patient only had one serum calcium measurement in the three month period, then the average serum calcium would be that value. If the patient only had serum calcium measurement for months 1 and 3 within the three month period, then the average would only use these two values.

Third, the measure specifies that only patients who have been at the facility for at least 30 days should be included. In addition, this measure uses serum calcium concentrations reported in CROWNWeb. CROWNWeb data dictionary directions specify reporting of pre-dialysis serum calcium only. While not stated in the measure specifications, it is well understood that the vast majority of blood samples for serum calcium testing are drawn before the patient receives hemodialysis treatment on a particular treatment day.

Comment: Several commenters did not support the proposal to adopt the Hypercalcemia measure. Commenters stated that CMS has not collected a full year of data that would support the performance standards, achievement thresholds, and benchmarks for the measure. These commenters stated that having at least one year of reporting data is a core criterion for moving structural reporting measures to clinical measures. Some of the commenters recommended adopting the Hypercalcemia measure as a reporting measure.

Response: As stated in the CY 2013 ESRD PPS final rule (77 FR 67488), we believe that achievement thresholds, benchmarks, and performance standards should be based on a full year of data whenever possible. However, we also believe that in certain circumstances it is not practical or necessary to use a full year of baseline data. In this case, we only have data for the Hypercalcemia measure starting in May 2012 because that was when CROWNWeb was rolled out nationally. In this case, we believe that it is appropriate to use 7 months of baseline data because serum calcium levels are not subject to seasonal variations, and because the 7-month time window offers a consistent representation of national facility performance. Based on CROWNWeb data, monthly patient-level uncorrected serum calcium averages were stable during May 2012 through March 2013, with averages ranging from 8.99 mg/dL to 9.06 mg/dL.

Comment: One commenter did not support the proposal to adopt the Hypercalcemia measure because manually reporting calcium values is overly burdensome.

Response: We do not agree that entering patients' calcium phosphorus levels into CROWNWeb on a monthly basis is overly burdensome. The Mineral Metabolism measure finalized in the CY 2012 ESRD PPS final rule (76 FR 70271) required facilities to enter this information, so the Hypercalcemia measure does not impose any additional burden for facilities.

Comment: One commenter expressed concerns that CROWNWeb will not be able to accurately capture data needed to calculate the Hypercalcemia measure because it cannot handle situations when a patient switches modalities in the middle of a month, and because CROWNWeb is lacking data for roughly 10 percent of patients.

Response: We recognize that CROWNWeb is currently experiencing issues if a patient switches modalities during a clinical month and the facility attempts to indicate this through the submission of batch data. This is a

[9] National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. American Journal of Kidney Disease 2003 42:S1–S202 (suppl 3).

[10] Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group: KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD–MBD). Kidney International 2009 76 (Suppl 113): S1–S130.

[11] Block GA, Klassen PS, Lazarus JM, et al. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. Journal of the American Society of Nephrology: JASN 2004 15:2208–18.

[12] Young EW, Albert JM, Satayathum S, et al. Predictors and consequences of altered mineral metabolism: the Dialysis Outcomes and Practice Patterns Study. Kidney international 2005 67:1179–87.

[13] Kalantar-Zadeh K, Kuwae N, Regidor DL, et al. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. Kidney international 2006 70:771–80.

serious concern, and we are working to address it. However, this issue does not affect patient data when facilities manually enter the data. We therefore recommend that facilities manually enter patient data when patients switch modalities during a clinical month. Furthermore, we are currently conducting an analysis to determine what percentage of patient data are missing data in CROWNWeb. We recognize that CROWNWeb should not lack data for a high percentage of patients. Nevertheless, we continue to believe that CROWNWeb possesses valid data for the vast majority of patients, and we continue to affirm that facilities are responsible for ensuring that patient data are accurately reflected in CROWNWeb. For these reasons, we believe it is appropriate to use CROWNWeb as the primary data source for the Hypercalcemia clinical measure.

For these reasons, we are finalizing the Hypercalcemia clinical measure (NQF #1454) as proposed for the PY 2016 ESRD QIP and for future payment years. Technical specifications for this measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Hypercalcemia-2016FR.pdf*

c. Use of Iron Therapy for Pediatric Patients Reporting Measure

Section 1881(h)(2)(A)(i) states that the ESRD QIP must include measures on ''anemia management that reflect the labeling approved by the Food and Drug Administration for such management.'' Appropriate anemia management requires the presence of sufficient stores of iron.[14] Iron deficiency is a leading cause of non-response to ESA therapy, and several studies suggest that providing oral or IV iron is effective in correcting iron deficiency in the pediatric population.[15] [16] Pediatric patients have previously been excluded from all anemia management measures, limiting the participation of dialysis facilities with substantial numbers of pediatric patients in the ESRD QIP. In an effort to address this issue, and account for the quality of care dialysis facilities provide to pediatric patients, we proposed to adopt a pediatric iron therapy measure for the ESRD QIP in PY 2016 and future payment years of the program.

We considered proposing an NQF-endorsed clinical measure on the use of iron therapy for pediatric patients as part of the proposed Anemia Management clinical measure topic (NQF #1433: Use of Iron Therapy for Pediatric Patients). This measure is an assessment of the percentage of all pediatric hemodialysis and peritoneal dialysis patients who received IV iron or were prescribed oral iron within three months of attaining the following conditions: (i) Patient had hemoglobin less than 11.0 g/dL; (ii) patient had simultaneous values of serum ferritin concentration less than 11.0; and (iii) patient's transferrin saturation (TSAT) was less than 20 percent. Upon investigation, we discovered that there were not enough patients who would qualify for this measure to establish reliable baseline data that would allow us to propose to adopt this measure as a clinical measure for PY 2016. We also note that the clinical measure currently presents other issues related to the minimum number of cases that would need to be reported for scoring, and we are considering the use of an adjuster that could be applied where the sample size is small. While we continue to consider these and other issues related to the adoption of a pediatric iron therapy clinical measure, we proposed a related reporting measure for PY 2016 and future payment years in order to acquire a sufficient amount of baseline data for the development of a clinical measure in the future.

For PY 2016 and future payment years, we proposed that facilities must enter in CROWNWeb on a quarterly basis, for each qualifying case (defined in the next sentence): (i) Patient admit/discharge date; (ii) hemoglobin levels; (iii) serum ferritin levels; (iv) TSAT percentages; (v) the dates that the lab measurements were taken for items (ii)–(iv); (vi) intravenous IV iron received or oral iron prescribed (if applicable); and (vii) the date that the IV iron was received or oral iron was prescribed (if applicable). We proposed that qualifying cases for this measure would be defined as in-center and home dialysis patients under the age of eighteen.

We proposed that each facility must report data on the Use of Iron Therapy for Pediatric Patients measure if it treats one or more qualifying cases during the performance period. Because this reporting measure requires that a facility enter data in CROWNWeb only once per quarter for each patient, we believe that the burden is appropriate and will not unduly impact small facilities, since it is proportionate to the number of patients that facilities treat. However, for the same reasons stated in the final description of the PY 2014 ESRD QIP Mineral Metabolism measure (which had a one patient minimum) (77 FR 67472 through 67474), we proposed that, in order to receive full points on this measure, facilities that treat 11 or more qualifying cases over the performance period will have to report at the lesser of the 50th percentile of facilities in CY 2013 or 97 percent per quarter, for each quarter of the performance period. We proposed that facilities that treat fewer than 11 qualifying cases during the performance period will have to report on a quarterly basis the specified data elements for all but one qualifying case. If a facility only has one qualifying case during the entire performance period, a facility will have to attest to that fact in CROWNWeb by January 31 of the year following the performance period in order to avoid being scored on the measure.

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

Comment: Several commenters expressed concerns about the proposal to adopt the pediatric iron therapy reporting measure. Some commenters recommended that facilities should only be required to report that they prescribed oral iron therapy or administered IV iron, since patients typically take over-the-counter iron supplements and the facility would not be able to verify that patients obtained non-prescription medications. Other commenters stated that the measure would unduly burden pediatric facilities, which are typically small and do not use batch data submissions.

Response: We thank commenters for raising these concerns. We will consider alternate implementation of quality reporting for pediatric patients and facilities relating to iron therapy through future rulemaking. Independent of these concerns, we conducted an analysis of the scope and impact of the proposed pediatric iron therapy measure. Over the course of the analysis, we determined that fewer than 100 patients would be eligible for this measure if it was adopted as a clinical measure. We also determined that facilities would not be required to report data for many of these patients because the proposed measure specifications for the reporting measure excluded facilities with one or fewer eligible patients. The purpose of adopting the reporting measure would have been to collect the baseline data needed to adopt a clinical measure in future

[14] Seeherunvong W, Rubio L, Abitbol CL, et al. Identification of poor responders to erythropoietin among children undergoing hemodialysis. J Pediatr 2001 (138/5):710–714.

[15] Warady BA, Zobrist RH, Wu J, Finan E. Sodium ferric gluconate complex therapy in anemic children on hemodialysis. Pediatr Nephrol 20: 1320–7, 2005.

[16] Frankenfield DL, Neu AM, Warady BA, et al. Anemia in pediatric hemodialysis patients: results from the 2001 Clinical Performance Measures Project. Kidney International 64:1120–4, 2003.

payment years, but our analysis suggests that this would not be feasible. These data were not available through CROWNWeb at the time the measure was proposed. Accordingly, we are not finalizing this measure for the ESRD QIP.

Comment: Several commenters supported the proposal to adopt the Pediatric Iron Therapy reporting measure because it is important for measures in the ESRD QIP to cover pediatric patients.

Response: We appreciate the commenters' support. However, we have concluded that it is not feasible to adopt the measure because very few patients would be eligible for the measure.

For the reasons noted above, we are not finalizing the Pediatric Iron Therapy reporting measure at this time. However, we will continue to investigate measures on anemia management for pediatric patients, and we intend to adopt a measure on this topic in future payment years.

d. NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure

Healthcare-acquired infections (HAI) are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities. Bloodstream infections are a pressing concern in a population where individuals are frequently immunocompromised and depend on regular vascular access to facilitate dialysis therapy. In a national effort to reduce infection rates, CMS has partnered with the CDC to encourage facilities to report to the NHSN as a way to track and facilitate action intended to reduce HAIs. The NHSN is a secure, internet-based surveillance system that is 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 continue to believe that accurately reporting dialysis events to the NHSN by these facilities supports national goals for patient safety, particularly goals for the reduction of HAIs. In addition, we believe that undertaking other activities designed to reduce the number of HAIs supports national goals for patient safety. For further information regarding the NHSN's dialysis event reporting protocols, please see *http://www.cdc.gov/nhsn/dialysis/index.html.*

We have worked during the past 2 years to help dialysis facilities become familiar with the NHSN system through the adoption of an NHSN Dialysis Event reporting measure. We now believe that facilities are sufficiently versed in reporting this measure to the NHSN. In light of the importance of monitoring and preventing infections in the ESRD population, and because a clinical measure would have a greater impact on clinical practice by holding facilities accountable for their actual performance, we proposed to replace the NHSN Dialysis Event reporting measure that we adopted in the CY 2013 ESRD PPS final rule (77 FR 67481 through 67484) with a new clinical measure for PY 2016 and future payment years. This proposed measure, NHSN Bloodstream Infection in Hemodialysis Outpatients, is based closely on NQF #1460 in that it evaluates the number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.

We proposed that facilities must submit 12 months of accurately reported dialysis event data (defined in the next sentence) to NHSN on a quarterly basis. In order to ensure that a facility submits data that can be used to identify the source of bloodstream infections, to preserve the internal validity of bloodstream infection data, and to help prevent future bloodstream infections, we proposed to define ''accurately reported dialysis event data'' as data reported by facilities that follow the NHSN enrollment and training guidelines specified by the CDC (available at *http://www.cdc.gov/nhsn/dialysis/enroll.html* and *http://www.cdc.gov/nhsn/Training/dialysis/index.html*), according to the reporting requirements specified within the NHSN Dialysis Event Protocol. (This protocol, which facilities are already using to meet the requirements of the NHSN Dialysis Event reporting measure, includes information about IV antimicrobial starts and evidence of vascular access site infection, as well as information about the presence of a bloodstream infection.)

Additionally, we proposed that each quarter's data would be due 3 months after the end of that quarter. For example, data from January 1 through March 31, 2014 would need to be entered by June 30, 2014; data from April 1 through June 30, 2014 would need to be submitted by September 30, 2014; data from July 1 through September 30, 2014 would need to be submitted by December 31, 2014; and data from October 1 through December 31, 2014, would need to be submitted by March 31, 2015. If facilities do not report 12 months of these data according to the requirements and the deadlines specified above, we proposed that they would receive a score of zero on the measure. We also proposed that facilities with a CCN open date after January 1, 2014 will be excluded from the measure. We note that in previous payment years we have awarded partial credit to facilities that submitted less than 12 months of data to encourage them to enroll in and report data in the NHSN system. However, we proposed to require 12 months of data on this clinical measure because infection rates vary through different seasons of the year.

We note that this proposed measure only applies to facilities treating in-center hemodialysis patients (both adult and pediatric). We will determine whether a facility treats in-center patients by referencing the facility's information in the Standard Information Management System and CROWNWeb.

We recognize that the CDC has published Core Interventions for BSI Prevention in Dialysis, which are listed at *http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html.* We encourage facilities to adopt the nine listed interventions in order to help prevent infections, but did not propose to require facilities to adopt any of these interventions at this time.

We requested comments on this proposal, and in particular on the issue of whether it is appropriate at this time to convert the current NHSN Dialysis Event Reporting measure into a clinical measure. The comments we received on these proposals and our responses are set forth below.

Comment: Several commenters supported the proposal to adopt the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure. These commenters stated that the monitoring of bloodstream infections and the adoption of CDC's core prevention interventions will reduce healthcare acquired infections in the ESRD patient population.

Response: We thank the commenters for their support.

Comment: Several commenters did not support the proposal to adopt the NHSN clinical measure because they believe that the measure does not reflect actual patient-exposure time each month. Specifically, these commenters stated that using a monthly census on the first two working days of the month ignores patient hospitalization during the month, and can be adversely impacted by an influx of new patients after the first two working days of the month.

Response: CDC has conducted pilot validation work with a group of dialysis facilities and found that the census on the first two working days of the month was an accurate predictor of the entire month's census. The alternative of counting denominator data on a daily basis has been required in inpatient settings, but was determined by CDC to be unacceptably burdensome for the dialysis facility setting because this setting has a relatively stable patient population. Although patients with ESRD may be hospitalized at various times during a month, we have no reason to believe this would systematically be more likely to occur at a certain time relative to the first two working days of the month. Similarly, we are unaware of admission or transfer patterns whereby there is an increased likelihood of patient influx after the first two working days of the month.

Comment: Many commenters expressed concerns that the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure will misattribute infections to a dialysis facility. Some of these commenters stated that the measurement of positive blood cultures is not specific enough to detect HAIs contracted at another facility, and may include blood cultures associated with another site or contaminated samples. Commenters also raised concerns that these types of issues will result in an overestimate of the number of dialysis-related bloodstream infections, limit the capacity to develop reliable benchmark data, and may increase the possibility that facilities will be improperly penalized.

Other commenters stated that elderly, newly diagnosed dialysis patients with other chronic conditions and wounds are particularly likely to have infections that are unrelated to vascular access. Some commenters worried that infections in these patients will be inappropriately attributed to dialysis facilities because the NHSN measure does not focus on access-related bloodstream infections. Commenters also expressed concerns that the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure does not risk adjust for common comorbidities in the ESRD patient population.

Another commenter stated that the rate of positive blood cultures should be interpreted in the context of the facility's rate of empiric antibiotic treatment, also recorded by NHSN, since some physicians and facilities may treat empirically rather than on the basis of culture results.

Several commenters stated that culture results needed to designate the event as a bloodstream infection for NHSN reporting purposes are frequently not available to facilities. Therefore, between-facility differences in NHSN-reported BSI rates currently reflect differences not in infection rates, but rather in the availability and capture of blood culture results. Given this, the commenters believe that the measure will incentivize under-reporting of blood culture results, thereby undoing the great benefit that the current NHSN reporting metric has afforded dialysis facilities.

One commenter stated that sufficient knowledge and infrastructure does not exist to determine the type of vascular access to which the infection was related. This commenter further stated that the TEP that reviewed the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure concluded that the ''vascular access infection CPMs should not be used for reimbursement purposes.''

Commenters provided several recommendations in light of these perceived issues. Some commenters recommended retaining the NHSN reporting measure until these technical issues are resolved. Other commenters stated that it would be inappropriate to adopt the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure under any circumstances. Another commenter recommended adopting, in a staggered manner, three alternative HAI measures: Local access site infection, access-related bloodstream infection, and vascular access infection.

Response: We do not believe that misattribution is a significant enough issue to warrant a delay in the adoption of the NHSN clinical measure. The NHSH Bloodstream Infection in Hemodialysis Outpatients clinical measure tracks infection events that present real dangers to patients. We believe that tracking these infection events and rewarding facilities for minimizing these events is of critical importance to protecting patient safety and improving the quality of care provided to patients with ESRD.

First, NQF endorsed a bloodstream infection measure (NQF #1460, the measure upon which the proposed NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure is based) because bloodstream infections can be objectively identified. By contrast, NQF raised concerns about an access-related bloodstream infection measure because determining the source of infections (for example, determining whether an infection was related to vascular access) requires subjective assessments. The NHSH Bloodstream Infection in Hemodialysis Outpatients clinical measure avoids this subjectivity by including all positive blood cultures. This makes it simpler and more reliable than an access-related bloodstream infection measure. While we recognize that the NHSH Bloodstream Infection in Hemodialysis Outpatients clinical measure may occasionally misattribute bloodstream infections to dialysis facilities, we believe that the measure's objectivity, simplicity, and reliability make it the most appropriate measure for assessing facility performance. NHSN relies upon use of standard definitions to ensure that infection events are reported in the same manner across facilities. The vast majority of reported bloodstream infection events represent true, HAIs that are not the result of misclassification or misattribution. Therefore, considering the benefits to patients associated with strong incentives to reduce bloodstream infections, we believe that these technical issues are not significant enough to warrant a delay in adopting the NHSH Bloodstream Infection in Hemodialysis Outpatients clinical measure. CDC will continue to assess the possibility that certain facility-related factors could systematically overestimate infection rates, and it will consider risk-adjusting the measure to take these factors into account.

Second, our goal is to eliminate all preventable HAIs, including those in elderly patients and patients with certain comorbidities. Therefore, we do not believe it is appropriate to risk-adjust the measure to account for those patient characteristics.

Third, regardless of whether antibiotics are started before culture results become available, facilities are required to report positive blood culture results to NHSN. We recognize that additional information reported to NHSN, including antibiotic starts, provide useful contextual information to help interpret rates and facilitate prevention efforts. We believe that this information is important for identifying strategies to reduce bloodstream infections.

Fourth, with respect to concerns about between-facility differences in NHSN-reported BSI rates, we are legitimately concerned about this issue of differential capture rate and the potential impact it could have on valid inter-facility comparisons. Facilities are expected to follow the NHSN reporting protocol, which includes reporting all positive blood cultures drawn from their patients in the outpatient setting or within one calendar day after a hospital admission. In both of these scenarios, facilities should have access to blood

culture results to properly diagnose and treat patients under their care, and to include in the patient's medical record. Although results of blood cultures that were drawn outside of the dialysis center can sometimes be challenging to retrieve, facilities should be working to develop systems to enable complete capture of all positive blood cultures that meet reporting criteria.

Fifth, we agree with the commenters' concerns about determining the type of vascular access to which the infection was related, and we reiterate that NQF endorsed a bloodstream infection measure and not an access-related bloodstream infection measure. The NQF endorsement process includes an expert review assessing the feasibility of implementing of the measure. The NQF determined that the infrastructure and clinical expertise needed to determine the source of bloodstream infections do exist in the dialysis-facility setting. Therefore, the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure only requires facilities to report positive blood culture results. It does not involve a clinical diagnosis of infection, nor does it rely upon a determination of vascular access-relatedness or identification of the access to which the infection is related. When an event is reported to NHSN, all vascular accesses the patient has in place at the time of the event are reported. The user is not asked to attribute the event to a particular access. This is consistent with the recommendations of the TEP that the commenter cited.

Finally, we appreciate the commenters' recommendations. In light of the responses detailed above, and the urgent need to provide facilities with strong incentives to improve patient safety, we believe that the technical issues raised by commenters are not significant enough to warrant a delay in the adoption of the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure.

Comment: Many commenters expressed concerns about the methodology used to score the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure. Some commenters did not support the proposal to use CY 2014 as the performance period for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure. These commenters stated that under the proposed timeline, a facility will not be able to determine whether it is meeting the goals of the measures or still need to improve. Other commenters urged CMS to wait to penalize facilities until there are established performance standards, until facilities have a chance to adopt practices that demonstrably reduce infection rates, and until CMS has collected the data needed to calculate improvement scores. Other commenters did not support the proposal to use CY 2014 as the performance period and the baseline period for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, and to define the performance standard as the 50th percentile of facility performance in CY 2014. These commenters stated that this methodology guarantees a 50-percent ''failure rate,'' which is inconsistent with quality improvement approaches to medicine. In light of these concerns, some commenters recommended postponing the adoption of the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure until CMS has collected one year of baseline data.

Response: We appreciate the commenters' concerns about penalizing facilities for their performance on the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure before we have collected the data needed to establish both the achievement and improvement performance standards. We also recognize that, in so doing, we are deviating somewhat from the scoring methodology used in the PY 2014 and PY 2015 programs. However, as stated in the PY 2016 proposed rule (78 FR 40863), we believe it is important to begin assessing facilities on the number of these events as soon as possible, rather than on merely whether they report these events, because of the abnormally large impact HAIs have upon patients and the healthcare industry.

Furthermore, when calculating the minimum TPS facilities need to achieve in order to avoid a payment reduction, we set the number low enough that a facility can meet the minimum TPS even if it receives zero achievement points on the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, as long as it meets or exceeds the performance standard for each of the other finalized clinical measures and scores 5 points on each of the finalized reporting measures. We did this to balance our policy goal to provide facilities with strong incentives to improve patient safety as soon as possible against our recognition that we will not initially have enough data to award improvement points to facilities. In some circumstances, a facility may score zero points on the NHSN Bloodstream Infection in Hemodialysis Outpatients and receive a payment reduction. Nevertheless, the payment reduction a facility would receive in these circumstances (using the scoring methodology we are finalizing for the measure) would necessarily be no more than the payment reduction it would have received if the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure was not included in the minimum TPS calculations. Therefore, we strongly believe that these considerations should alleviate concerns associated with the atypical scoring methodology.

Comment: One commenter approved of CMS's support of CDC's core prevention interventions, but stated that CMS should require facilities to follow core interventions 7 and 8 (that is (i) the use of alcohol-based chlorhexidine >0.5 percent, the first line skin antiseptic for central line insertions and dressing changes, and (ii) reducing risk of intraluminal biofilm by ''scrubbing hubs'' prior to accession or disconnection).

Response: We thank the commenter for the support. We continue to encourage facilities to adopt all of CDC's core prevention interventions. However, they are not required under the ESRD QIP because we do not believe it is feasible at this time to design a performance measure that would accurately evaluate facility compliance.

Comment: One commenter raised concerns that the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, as proposed, will unduly penalize small facilities because these facilities will be disproportionately impacted by a small number of infections. Instead, the commenter recommends using the Standardized Infection Rate risk-adjustment method, along with the development of a publicized data validation process for NHSN data.

Response: As stated in the proposed measure specifications, the measure will be calculated using a Standardized Infection Ratio with adjustment for volume of exposure to address this issue. We also agree with the need for a publicized data validation process for the NHSN data. As stated in the PY 2016 ESRD QIP proposed rule (78 FR 40872), we are considering a feasibility study for validating NHSN data, and we will publicize the data validation process after the conclusion of the feasibility study.

Comment: Several commenters did not support the proposal that facilities must submit 12 months of data or receive a score of 0 on the NHSN measure. These commenters stated that facilities cannot improve in such an all-or-nothing environment.

Response: We disagree that the requirement to report 12 months of NHSN data is an unreasonable expectation. Facilities began reporting NHSN data for the PY 2014 program during CY 2012, so they will have had two years of experience at the beginning of the performance period for the PY 2016 program. We strongly believe that two years is a sufficient amount of time for facilities to become acclimated to the NHSN system. We also note that it would be inappropriate to score facilities on less than 12 months of data because HAIs are subject to seasonal variability. Furthermore, given the critical importance of reducing HAIs and the NHSN system's capacity to address this pressing issue, we believe that it is appropriate to provide facilities with the strongest possible incentives to report NHSN data.

Comment: One commenter did not support the proposal to adopt the NHSN clinical measure because NHSN was intended to be a surveillance system, not for scoring facilities on the ESRD QIP.

Response: We believe that the NHSN system can be used for the purposes of incentivizing quality improvement. HAIs are implicated in significant clinical problems for patients, and they are an important source of increased medical costs. Given the importance of HAIs for patients and providers, we strongly believe that reducing HAIs is a central pillar in efforts to improve the quality of healthcare offered in the dialysis setting, and we continue to believe that facilities have the strongest incentive to improve when their performance is linked to payment. Furthermore, we note that facilities are scored based on their performance on NHSN infection measures in the Hospital Value Based Purchasing Program.

Comment: One commenter recommends aligning the Vascular Access Type measure topic and census requirement for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure to reduce administrative burden. Commenter notes that the Vascular Access Type measure topic is based on the last treatment of the month, while the NHSN census is based on the ESRD facility's first two working days of the month.

Response: We appreciate the comment, and will further investigate whether the divergent dates for the two measures increases the reporting burden for facilities.

Comment: One commenter did not agree with CMS's position that the urgency of reducing bloodstream infections warrants the adoption of the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure before two years of baseline data are available to calculate achievement and improvement scores. The commenter stated that central venous catheters present the greatest risk for bloodstream infections in the ESRD patient population, and that the ESRD QIP already has a measure that addresses this issue (Vascular Access Type—Catheter greater than 90 Days).

Response: According to the 2012 Annual Data Report of the United States Renal Data System, hemodialysis patients experienced an adjusted hospitalization rate of 103 per 1,000 due to vascular access infection in 2010. We recognize that these rates have declined since 2005, but we believe they are still unacceptably high. Additionally, rates of adjusted hospitalizations due to bacteremia/sepsis in hemodialysis patients have increased significantly since 2000, rising to 116 per 1,000 in 2010.[17] These and other indicators have led to the inclusion of ESRD facilities in the Assistant Secretary for Health's National Action Plan to Prevent Health Care-Associated Infections, and the inclusion of dialysis facilities in this report reflects the urgency of reducing HAIs in patients with ESRD. We agree with the commenter's observation that central venous catheters present the greatest risk for bloodstream infections in the ESRD patient population. However, considering that these rates increased at same time as the Fistula First Breakthrough Initiative sought to reduce the use of catheters, we do not believe that the Vascular Access Type measure topic is sufficient to reduce rates of HAIs. Additionally, for the reasons stated above, we believe the significance of HAIs warrants adopting a clinical measure before we have collected the baseline data needed to calculate achievement and improvement scores. Therefore, we strongly believe that Vascular Access Type measure topic and the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure are complimentary, not duplicative, because they address infections in different and equally valid ways.

Comment: Some commenters did not support the proposal to adopt the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure because the measure is dependent upon voluntary reporting of data that is often subjective. These commenters stated that the identification of positive bloodstream infections often relies upon subjective assessments of whether a bacteremia is access-related. The commenters believed that facilities will be less likely to identify and report positive bloodstream infections if they will be financially penalized for doing so.

Response: The NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure is an objective measure based solely on the presence of a positive blood culture. Although NHSN collects information on access-relatedness to provide additional information that is of use for prevention purposes, the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure does not rely upon assessments of whether the bloodstream infection was access-related. There may still be perceived disincentives to conduct thorough surveillance to identify all positive blood cultures that meet the bloodstream infection definitional criteria. For this reason, it is important that the data be validated in a rigorous manner, and we are in the process of evaluating the feasibility of launching a pilot program to validate NHSN data.

For these reasons, we are finalizing the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure for the PY 2016 ESRD QIP and for future payment years. The technical specifications for this measure are located at *http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNBloodstreamInfection-2016FR.pdf*.

e. Comorbidity Reporting Measure

The NQF endorsed a clinical measure for Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (#0369) in 2008, and a clinical measure for Standardized Hospitalization Ratio for Admissions (#1463) in 2011. We have long been interested in adding a Standardized Mortality Ratio (SMR) measure and a Standardized Hospitalization Ratio (SHR) measure to the ESRD QIP. As articulated in the CY 2013 ESRD PPS final rule, ''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'' (77 FR 67496). Similarly, we continue to believe that 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

[17] United States Renal Data System, 2012 USRDS Annual Data Report, Volume 2: Atlas of End-Stage Renal Disease in the United States, pg. 240.

care in other settings, such as hospitals'' (77 FR 67497).

Although we believe that SHR and SMR capture important indicators of morbidity and mortality, we are considering whether and how we might be able to adopt them through future rulemaking in a way that properly takes into account the effect that comorbidities have on hospitalization and mortality rates for the ESRD population. We also acknowledge concerns raised by commenters in the past that the NQF-endorsed SMR and SHR measures are not adequately risk-adjusted (77 FR 67496). Currently, information about patient comorbidities is collected by CMS via the Medical Evidence Reporting Form 2728, which is typically only submitted by facilities to CMS when a new patient first begins to receive dialysis treatment. We also use Form 2728 to capture the date of first dialysis in order to help determine patient exclusions for all of the clinical measures finalized in the PY 2013 ESRD PPS final rule. However, facilities are not required to update this form, which makes it difficult to capture information about comorbidities that develop after the initiation of dialysis treatment. We acknowledge the concerns of commenters who stated that ''there is currently no mechanism either for correcting or updating patient comorbidity data on CMS' Medical Evidence Reporting Form 2728, and these comorbidities affect the calculation of the measure'' (76 FR 70267).

We proposed to adopt a Comorbidity reporting measure for the PY 2016 ESRD QIP and future payment years of the ESRD QIP. The purpose of this measure is two-fold. First, the proposed reporting measure offers a mechanism for collecting annual information about patient comorbidities, thereby providing a reliable source of data that we can use to develop a risk-adjustment methodology for the SHR and SMR clinical measures, should we propose to adopt such measures in the future. Second, the reporting measure will make it possible to improve our understanding of the risk factors that contribute to morbidity and mortality in the ESRD patient population. The data we gather will enable us to develop risk-adjustment methodologies for possible use in calculating the SHR and SMR measures, should we propose to adopt those measures in the future, and therefore more reliably calculate expected hospitalization and mortality rates in future payment years of the ESRD QIP. When we examine updated data on comorbidities, we will determine the appropriateness of including that data as additional risk-adjustment factors for the SMR and SHR measures by considering the extent to which each comorbidity may be influenced by the quality of dialysis facility care, as opposed to factors outside of a facility's control.

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 section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed, so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

NQF has not endorsed a measure for updating comorbidity information for patients with ESRD. We have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and we are proposing this measure under the authority of 1881(h)(2)(B)(ii) of the Act. We believe that the proposed measure's potential to improve clinical understanding and practice outweighs the minimal burden it would impose upon facilities. Additionally, we believe that this measure will provide data that is currently unavailable through Form 2728 because the measure accounts for the most recent information about patient risk factors, which may change over time as a patient continues receiving dialysis.

For this proposed reporting measure, we proposed each facility will annually update in CROWNWeb up to 24 comorbidities, or indicate ''none of the above,'' for each qualifying case. For the purposes of this measure, we proposed to define a ''qualifying case'' as a hemodialysis or peritoneal dialysis patient being treated at the facility as of December 31 of the performance period, according to admit and discharge dates entered into CROWNWeb. In fulfilling this reporting requirement, facilities would select one or more of the following for each qualifying case.

• Congestive heart failure	• Diabetes, on oral medications	• Drug dependence
• Atherosclerotic heart disease (ASHD)	• Diabetes, without medications	• Inability to ambulate
• Other cardiac disease	• Diabetic retinopathy	• Inability to transfer
• Cerebrovascular disease (CVA, TIA)	• Chronic obstructive pulmonary disease	• Needs assistance with daily activities
• Peripheral vascular disease	• Tobacco use (current smoker)	• Institutionalization—Assisted Living
• History of hypertension	• Malignant neoplasm, Cancer	• Institutionalization—Nursing Home
• Amputation	• Toxic nephropathy	• Institutionalization—Other Institution
• Diabetes, currently on insulin	• Alcohol dependence	• Non-renal congenital abnormality
• None of the above		

Therefore, to receive full points on this measure, we proposed that facilities would be required to provide the updates in CROWNWeb by January 31, 2015, or, if that is not a regular business day, the first business day thereafter. While we proposed to require facilities to report a single annual update per patient, we encourage facilities to update this information more frequently in order to more closely monitor their patients' risk factors, and to improve the quality of the data.

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

Comment: While several commenters supported the proposal to adopt the Comorbidity reporting measure and the decision to collect more information before adopting the SMR and SHR measures, many commenters did not support the proposal. Several commenters stated that they did not think the Comorbidity reporting measure was a quality measure and expressed a concern that it had never been developed nor endorsed by a consensus-based organization or reviewed by the MAP. Commenters also stated that CMS should either use the ESRD CfCs or revise Form 2728 to accomplish this data collection, rather

than using the ESRD QIP for this purpose.

Response: We appreciate the many comments we received on the Comorbidity reporting measure. As a result of the significant concerns expressed about the measure, we have decided not to finalize the measure at this time. We will consider whether there is a better way to update this important comorbidity information, including the suggestion to collect comorbidity data under the CfCs, in the future.

For these reasons, we are not finalizing the Comorbidity reporting measure as proposed for the PY 2016 ESRD QIP and for future payment years.

4. Other Measures Under Development

As part of our effort to continuously improve the ESRD QIP, we continue to work on developing additional robust measures that provide valid assessments of the quality of care furnished by facilities to patients with ESRD. We are considering the feasibility of developing quality measures in other topic areas (for example, blood transfusions, kidney transplantation, quality of life, and health information technology) for quality improvement at the point of care as well as for the electronic exchange of information in support of care coordination across providers and settings. Additional areas of potential interest include residual renal function, complications associated with ESRD, and frequently comorbid conditions (for example, diabetes and heart disease).

We requested comments 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: Many commenters provided recommendations on potential areas of future measurement. Some commenters urged CMS to adopt measures on patient education (covering, for example, renal replacement therapies, diet, and access placements), health information technology, kidney transplants, fluid management, blood transfusions, quality of life, care coordination, symptom management, clinical depression, pain screening, dyspnea, advanced care planning, emergency department use, 30-day hospital readmissions, use of home dialysis, hospitalization rates, and mortality rates. Other commenters urged CMS to not adopt measures on blood transfusions, hospitalization rates, mortality rates, 30-day hospitalization readmissions, quality of life, kidney transplants, and care coordination.

Response: We thank the commenters for their recommendations and will consider them as we develop our policies for future years of the ESRD QIP.

Comment: Many commenters urged CMS to adopt a hemoglobin measure that establishes a minimum safe hemoglobin level for patients. These commenters stated that the use of the Hemoglobin Greater Than 12 g/dL measure has led to an increase in transfusions, which are not covered in the ESRD PPS bundled payment but remain an expense for Medicare. Some commenters believe that there is a consensus in the field that keeping hemoglobin levels above 10 g/dL yields optimal patient outcomes.

Response: Using a Hemoglobin Less Than 10 g/dL measure without a corresponding measure that targeted high hemoglobin levels might place patients at increased risk for complications of aggressive ESA therapy. Furthermore, we note that randomized, controlled trials targeting patients to higher, rather than lower hemoglobin levels, or comparing the effect of ESAs against a placebo have indicated an increased risk of myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and overall mortality, and in patients with a history of cancer, tumor progression or recurrence. Because we cannot yet identify which patients would be included in this subset (and accordingly exclude them from the specifications of a Hemoglobin Less Than 10g/dL measure) we have concluded that it is not appropriate at this time to include such a measure in the ESRD QIP. Finally, we note that our rationale for removing the Hemoglobin Less Than 10 g/dL was published in the PY 2013 ESRD QIP proposed rule (76 FR 40519), and we believe those concerns remain sufficiently valid to merit not reintroducing the measure to the ESRD QIP at this time.

5. Scoring for the PY 2016 ESRD QIP and Future Payment Years

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. We believe that the methodology set forth in the CY 2013 ESRD PPS final rule incentivizes facilities to meet the goals of the ESRD QIP; therefore, with the exception of the proposed changes further discussed in the applicable section below, we proposed to adopt a scoring methodology for the PY 2016 ESRD QIP and future payment years that is nearly identical to the one finalized in the CY 2013 ESRD PPS final rule. To the extent that the scoring methodology differs, those differences are discussed below.

Comment: Many commenters recommended adding a provision to the rule to exempt facilities forced to close temporarily due to natural disaster or other extenuating circumstances from the requirements of all of the clinical and reporting measures (and the NHSN measure in particular). These commenters stated that such a provision exists in the Hospital Inpatient Quality Reporting Program. The commenters stated that adopting a similar policy for the ESRD QIP would allow facilities to avoid payment reductions due to circumstances they cannot control.

Response: We agree that there are times when facilities are unable to submit required quality data due to extraordinary circumstances that are not within their control, and we do not wish to penalize facilities for such circumstances or unduly increase their burden during these times. We are developing a disaster/extraordinary circumstances exception process, and we intend to propose to adopt such a process in future rulemaking.

6. Performance Period for the PY 2016 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a year, and that the performance period occur prior to the beginning of such year. In the CY 2013 ESRD PPS final rule, we finalized a performance period of CY 2013. We stated our belief that, for most measures, 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. For the reasons outlined in the CY 2013 ESRD PPS final rule (77 FR 67500), we have determined for PY 2016 that CY 2014 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 renal dialysis services furnished on January 1, 2016. Therefore, for the PY 2016 ESRD QIP, we proposed to establish CY 2014 as the performance period for all of the measures.

We requested comment on this proposal. We did not receive any comments on this proposal. We will, therefore, finalize that CY 2014 is the performance period for the PY 2016 ESRD QIP.

7. Performance Standards for the PY 2016 ESRD QIP and Future Payment Years

We proposed to adopt performance standards for the PY 2016 ESRD QIP measures that are similar to what we finalized in the CY 2013 ESRD PPS final rule. Section 1881(h)(4)(A) 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 Medicare payment reduction.

We received several comments on performance standards for the PY 2016 ESRD QIP and future payment years. The comments and our responses are set forth below.

Comment: Many commenters registered their concern with CMS's reliance on CROWNWeb data to establish performance benchmarks for achievement and improvement, particularly for the Hypercalcemia measure. These commenters stated that CROWNWeb is unreliable because (1) frequent changes to the business requirements have resulted in an inconsistent set of rules under which data are collected, making the data collected unreliable for setting performance standards and benchmarks; (2) CROWNWeb collects less than 100% of facility data, and a facility could be found not to meet the ESRD QIP performance standard because the CROWNWeb system ''kicks out'' a particular patient and/or data for a particular patient; (3) CROWNWeb defects open the possibility of ''gaming the system'' by manually and preferentially excluding the data for patients who fail to meet a particular goal; and (4) there is still a problem with accurate reconciliation with dialysis census data and the patient counts in CROWNWeb, which could result in the misattribution of patients to facilities. The commenters recommended that CROWNWeb should not be relied upon for setting performance standards and benchmarks or to collect individual patient-level data until (1) facility and CROWNWeb patient attribution lists are identical; (2) only 1 percent of the data are ''kicked out'' by CROWNWeb; and (3) clear business rules remain in place for at least one year to allow for the consistent collection data before the data are used for the ESRD QIP. Commenters also recommended that (1) CMS establish a CROWNWeb Help Desk to assist them in real time to resolve roster data discrepancies; (2) new data definitions be shared with the provider community for comment well in advance of including them in CROWNWeb; (3) CMS initiate a formal quality assessment and process improvement program that would field-test each CROWNWeb update before it is scheduled for general release; and (4) current CROWNWeb data not be shared for the purpose of measure development with CMS TEPs until and unless the recorded data have been carefully evaluated for completeness, accuracy, and reliability.

Response: We appreciate commenters' concerns about CROWNWeb and we welcome the opportunity to respond. We will address each issue in turn.

First, CROWNWeb has been updated six times since the national rollout in June 2012. We recognize that facilities received revised information for entering data with every release of CROWNWeb. Nevertheless, we note that the clinical fields in the single user interface and batch submissions have stayed the same. We believe that this continuity in the clinical fields has minimized data inconsistencies resulting from changes to the business requirements, and we will continue to correct and standardize the business requirements for data submission, collection, and reporting.

Second, CROWNWeb does not ''kick out'' patients or data once the patients have been entered into the CROWNWeb. Rather, patient data (such as, demographic information, clinical values, and information about vascular access) may not be allowed into CROWNWeb via the batch submission process if CROWNWeb determines that the data are inconsistent or invalid. Facilities entering data manually do not experience such issues, and we note that electronic data interchange (EDI) users are able to view and correct data that do not pass validations testing. We have already implemented two successful patches to alleviate CROWNWeb systems barriers to EDI, and we will continue to release patches to address additional areas of concern. Nevertheless, we affirm that facilities are responsible for ensuring that their patient censuses and patient clinical data in CROWNWeb is complete and accurate.

Third, we understand there are concerns about ''gaming the system,'' possibly due to the fact that facilities are not required to enter clinical data elements in order to proceed in the CROWNWeb system. We do not believe this is a system defect; in certain instances, it might not be appropriate to enter such data, and the system is not designed to make these determinations. Additionally, we are not aware of any defects that allow facilities to preferentially exclude patients. If facilities and submission organizations are aware of other defects, we encourage them to report this to the QualityNet Helpdesk or on EDI Data Discrepancy Support calls. If we receive such reports, we will investigate them immediately and prioritize patches for the next available CROWNWeb patch release.

Fourth, we are aware that CROWNWeb is currently experiencing some issues related to the attribution of patients to facilities. We are in the process of implementing new business requirements that should address this known defect. We continue to encourage facilities to ensure that their patient censuses are accurately reflected in CROWNWeb.

With respect to commenters' recommendations for improving the accuracy of CROWNWeb data, we agree that facility attribution lists should match patient censuses in CROWNWeb. As stated above, we are actively working to resolve this issue, and we encourage facilities to review their patient censuses in CROWNWeb to ensure that they match their attribution lists. Additionally, we agree that CROWNWeb should minimize the amount of accurate data that does not pass validation testing while ensuring that inaccurate data is not used to calculate scores on ESRD QIP clinical performance measures. As stated above, we affirm that facilities are responsible for ensuring that patient data is accurately reflected in CROWNWeb while we continue to improve the EDI submission process. Furthermore, we do not agree that business rules need to remain in place for one year before the data can be used to calculate scores on ESRD QIP clinical performance measures, as long as changes to the business rules are not significant enough to render data from the baseline period incomparable with data from the performance period. Finally, we note that facilities are able to report concerns about roster-data discrepancies to the QualityNet helpdesk. We note that new data definitions are regularly provided to the ESRD community.

We appreciate the recommendation to not share CROWNWeb data with any CMS TEPs due to concerns about completeness, accuracy, and reliability. We will consider these concerns before sharing CROWNWeb data with CMS TEPs in the future. We also appreciate

the recommendation to field-test CROWNWeb updates before they are scheduled for general release, and we are working on a process that would allow users and ''beta testers'' to test system functionalities in real-world settings.

Comment: One commenter did not support the addition of other measures to the ESRD QIP until concerns about the program's complexity and the reliability of CROWNWeb are alleviated.

Response: We appreciate the commenter's concerns about the complexity of the ESRD QIP and the reliability of CROWNWeb. We make every effort (e.g., through National Provider Calls, CROWN Memos, and other educational programs) to ensure that facilities receive the information they need to understand the ESRD QIP. We also work diligently to make reporting requirements and measurement methodologies as simple as possible. Additionally, we appreciate the commenter's concerns about the reliability of CROWNWeb, and we are working to address related concerns that have been raised by the ESRD community. However, given the fact that facilities are able to ensure that their data is accurately represented in CROWNWeb at any time, as well as the fact that CMS and its contractors check the validity of CROWNWeb data when calculating measure scores, we believe that there are processes in place to ensure that technical issues with CROWNWeb do not impact the measure scores that facilities receive. We therefore do not believe it is appropriate or necessary to postpone programmatic developments until these technical issues are completely resolved.

Comment: Several commenters asked CMS to provide sufficient data and explanation to allow the kidney care community to understand the methodology underlying the models used to estimate ESRD QIP payment adjustments and the minimum TPS. These commenters stated that without this data, it is difficult to know the assumptions CMS uses in its modeling and to offer meaningful comments on the proposed rule.

Response: We appreciate commenters' request. We will make publicly available facility-level data that is used to estimate ESRD QIP payment adjustments and the minimum TPS. Information used to estimate these values in the CY 2014 ESRD PPS proposed rule will be released by December 31, 2013. Information used to estimate these values in proposed rules for future payment years will be released within two weeks of the publication of the applicable proposed rule. However, since this data is preliminary, individual facility identifiers will be removed before the data is released so that it will not be possible to connect estimated measure scores to individual facilities. Additionally, final data used to determine finalized ESRD QIP payment adjustments and the finalized minimum TPS will continue to be posted on a CMS Web site every year in December.

Comment: Some commenters noted that many of the measure specifications list SIMS as a data source. These commenters sought clarity on this, as SIMS has been decommissioned.

Response: We thank commenters for noting this discrepancy. When the proposed rule was published, it was not clear that SIMS would be decommissioned. We have updated the final measure specifications to reflect the fact that SIMS has been decommissioned.

a. Clinical Measure Performance Standards

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we proposed for PY 2016 to set the performance standards (both achievement and improvement) based on the national performance rate (that is, the 50th percentile) of facility performance in CY 2012, except as specified below.

With respect to the proposed NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, we proposed to begin data collection beginning with CY 2014 events. We do not have data prior to CY 2014 for purposes of setting a performance standard based on the national performance rate of facility performance in CY 2012. For that reason, we proposed that the performance standard for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure for PY 2016 be the 50th percentile of the national performance rate on the measure during CY 2014. Because we lack the baseline data needed to calculate an improvement score, we also proposed that, for PY 2016, facilities be scored only on achievement for this measure, and not on the basis of improvement. Although we recognize that with other measures that lacked baseline data we instituted a reporting measure to ensure that both an achievement and improvement score could be assessed, we believe that it is appropriate, in this case, to adopt a clinical measure without the baseline data necessary for an improvement score. Hospital Acquired Infections (HAIs) are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities, costing patient lives and billions of dollars. CMS has recognized that reducing HAIs is critically important to the Agency's three main goals of improving healthcare, improving health, and reducing healthcare costs. Because of the abnormally great impact HAIs have upon patients and the healthcare industry, we believe it is important to begin assessing facilities on the number of these events as soon as possible, rather than on merely whether they report these events. Additionally, the NHSN measure has been a reporting measure since PY 2014, which will give facilities 2 years to report data before they are scored on the data results. Thus, although we do not yet have complete baseline data to give improvement scores in PY 2016, we believe it is appropriate to implement this measure using only achievement scores because of the urgency in reducing these events and the time facilities have had to prepare themselves for such a measure. Finally, we proposed that facilities would receive a score of zero on the NHSN clinical measure if they do not submit 12 months of data, as defined in Section III.C.3.d above, and by the deadlines specified in Section III.C.3.d above.

For the proposed Patient Informed Consent for Anemia Treatment, we stated that we believed that facilities should meet the standard 100 percent of the time. However, we recognized that unexpected events might make a 100 percent standard difficult to meet, so we proposed that facilities should be allowed to meet the standard for less than 100 percent of their patients. Because prior data are unavailable for the establishment of a performance standard, benchmark, and achievement threshold, we developed a methodology to determine appropriate achievement standards. As described in Section III.C.10 of the proposed rule, we proposed that a small facility adjuster would be applied to facilities with between 11 and 25 qualifying patients. Since facilities with between 11 and 25 patients would be subject to the favorable scoring modifications applied by the small-facility adjuster, these facilities would have an easier time achieving the proposed achievement standards. Therefore, the minimum number of cases a facility may have and not benefit from a small-facility adjuster would be 26. We calculated that if a facility with 26 cases failed to obtain consent for two qualifying cases, it would have obtained consent 92 percent

of the time (rounded). If the facility failed to obtain consent for one case, it would have obtained consent 96 percent of the time (rounded). We believed that these values (92 and 96 percent) encourage a high consistency of care for patients with ESRD that is reasonably attainable by all facilities, while accounting for the possibility that facilities would be unable to obtain informed consent for reasons beyond their control. Therefore, we proposed that the achievement threshold be defined as obtaining informed consent for 92 percent of qualifying cases during the performance period, and that the benchmark would be defined as obtaining informed consent for 96 percent of such cases. Furthermore, we proposed to calculate the proposed performance standard using the average of the benchmark and achievement threshold, which is 94 percent. We sought comments on this performance standard.

Because we lack the baseline data needed to calculate improvement scores for the Patient Informed Consent for Anemia Treatment measure, we also proposed that for PY 2016, facilities be scored only on achievement for this measure, and not on the basis of improvement. We recognized that with other measures where we lacked baseline data, we adopted a reporting measure to ensure that both an achievement and improvement score could be assessed. However, we stated that we believe that it is appropriate, in this case, to adopt a clinical measure without the baseline data necessary for an improvement score. Anemia management is a topic highlighted in the ESRD QIP authorizing statute, requiring measures that reflect labeling approved by the Food and Drug Administration. (See section 1881(h)(2)(A) of the Act.) The inclusion of the topic in statue highlights its importance to CMS and to dialysis patients. ESA labeling has changed over time as additional safety information has become available, and the informed consent process is designed to ensure that the most current safety information is communicated to patients before ESAs are administered. In addition, obtaining informed consent for anemia treatment is a standard of practice that should already be in place at dialysis facilities, so facilities should already have procedures in place to support the measure. Thus, although we did not yet have complete baseline data to give improvement scores in PY 2016, we stated that we believed it would be appropriate to implement this measure using only achievement scores because of the importance of providing patients with current information about the risks and benefits of anemia therapy, and because this is already a standard clinical practice.

For the proposed Hypercalcemia measure, the first month that we can use to establish the baseline is May 2012. This is because the Hypercalcemia measure relies on CROWNWeb as its data source, CROWNWeb was first rolled out nationally in May 2012, and data submitted to CROWNWeb before that time is considered test or pilot data. For that reason, we proposed to set the performance standard as the 50th percentile of national performance from May 2012 through November 2012.

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

Comment: Several commenters stated that measures should have at least one year of reporting data available using consistent, well-defined data elements before being adopted as clinical measures.

Response: As stated in the CY 2013 ESRD PPS final rule (77 FR 67488), we believe that achievement thresholds, benchmarks, and performance standards should be based on a full year of data whenever possible. However, we also believe that, in certain circumstances, it not practical or necessary to use a full year of baseline data. For example, as stated in the proposed rule, we believe the clinical importance of reducing HAIs warrants the adoption of the NHSN clinical measure without a full year of baseline data. Similarly, we believe that it is appropriate to use seven months of baseline data for the Hypercalcemia measure because serum calcium levels are not subject to seasonal variations, and because the seven-month time window offers a reliable representation of national facility performance.

Comment: Several commenters stated that measures that lack the baseline data to calculate achievement and improvement scores should not be part of the ESRD QIP.

Response: Although we believe that achievement and improvement scores should generally be based on two years of baseline data, we also believe that other considerations may warrant the adoption of clinical measures before this baseline data is available. In particular, we believe that the urgency of addressing substantial gaps in the quality of clinical care may outweigh the benefits associated with using two years of baseline data if these gaps present safety concerns for patients. Given the significant increases in healthcare acquired infections in dialysis patients discussed above, we believe the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure meets this criterion. As we explained above, we have taken steps to minimize the financial impact on facilities associated with adopting this measure in the PY 2016 ESRD QIP, and we will propose to award both achievement and improvement points to facilities on this measure as soon as the baseline data is available. We also note that the ESRD QIP has used reporting measures since the PY 2014 program. These measures are not scored on the basis of achievement and improvement. Rather, they exist in order to help facilities become familiar with different reporting mechanisms, ensure that facilities capture data that can improve the quality of care they provide, and collect the baseline data needed to calculate achievement and improvement scores.

Comment: One commenter approved of the ESRD QIP overall. However, the commenter urged CMS to use measures that have been tested for reliability and validity, and that all clinical data should be retrieved from a single source.

Response: We thank the commenter and affirm that all the measures in the ESRD QIP have been tested for reliability and validity. With respect to the suggestion that we limit clinical data to a single data collection source, it is infeasible at this time to collect all ESRD QIP data from a single source. Although we are mindful of the reporting burden for facilities, we strive to make use of existing data collection systems, and we consider the benefits and drawbacks of collecting data in different reporting systems.

After consideration of the comments, we are finalizing the following performance standards for all of the PY 2016 clinical measures, except the Patient Informed Consent for Anemia Management clinical measure. We are not finalizing a performance standard for the Patient Informed Consent for Anemia Management clinical measure because we are not adopting that measure for the ESRD QIP.

b. Performance Standards for Clinical Measures

TABLE 8—FINALIZED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2016 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA [18]

Measure	Performance Standard
Vascular Access Type:	
%Fistula	62.3%
%Catheter	10.6%
Kt/V:	
Adult Hemodialysis.	93.4%
Adult Peritoneal Dialysis.	85.7%
Pediatric Hemodialysis.	93% [1]
Hemoglobin > 12 g/dL	0%
Hypercalcemia	1.7%
NHSN Bloodstream Infection in Hemodialysis Outpatients.	50th percentile of eligible facilities' performance during the performance period.

[1] According to the most recent data available, the performance standard for the Kt/V Pediatric Hemodialysis Adequacy measure is 91.9%. Because this is lower than the performance standard of 93% from the PY 2015 ESRD QIP, we are finalizing a performance standard of 93%.

If the final numerical values for the PY 2016 performance standards are worse than PY 2015 for a measure, then we proposed to substitute the PY 2015 performance standard for that measure. We stated our belief that the ESRD QIP should not have lower standards than in previous years.

We requested comment on this proposal. We did not receive any comments on this proposal. Using the most recent available data, we determined that the performance standard for the Kt/V Pediatric Hemodialysis Adequacy measure is 91.9%. Because this is lower than the performance standard of 93 percent from the PY 2015 ESRD QIP, we are finalizing a performance standard of 93 percent for the PY 2016 ESRD QIP. The finalized performance standards for the PY 2016 ESRD QIP clinical measures are set forth above in Table 8.

[18] Medicare claims data from 2012 were used to calculate the performance standard for the Hemoglobin > 12 g/dL, Dialysis Adequacy, and Vascular Access Type clinical measures. CROWNWeb data from May 2012 through December 2012 were used to estimate the performance standard for the Hypercalcemia clinical measure.

c. Performance Standards for Reporting Measures

For the proposed ICH CAHPS reporting measure, we proposed to set the performance standard for PY 2016 as the facility's successful submission, by January 28, 2015, of ICH CAHPS survey data collected during the performance period in accordance with the measure CMS specifications at *https://ichcahps.org*. For PY 2017 and future payment years, we proposed that the PY 2016 performance standard continue except that, in each performance period, facilities are required to submit data from the two surveys conducted during the performance period, rather than one, and that the survey data must be submitted by the dates specified by CMS at *https://ichcahps.org*.

For the proposed Mineral Metabolism reporting measure, we proposed to set the performance standard as successfully reporting the measure for the number of qualifying cases specified in Section III.C.2.b for each month of the 12-month duration of the performance period.

For the proposed Anemia Management reporting measure, we proposed to set the performance standard as successfully reporting the measure for the number of qualifying cases specified in Section III.C.2.c for each month of the 12-month duration of the performance period.

For the proposed Anemia Management: Pediatric Iron Therapy reporting measure, we proposed to set the performance standard as successfully reporting for each qualifying case each quarter the following: (i) patient admit/discharge date; (ii) hemoglobin levels; (iii) serum ferritin levels; (iv) TSAT percentages; (v) the dates that the lab measurements were taken for items (ii)–(iv); (vi) intravenous IV iron prescribed or oral iron prescribed (if applicable); and (vii) the date that the IV iron or oral iron was prescribed (if applicable).

For the proposed Comorbidity reporting measure, we proposed to set the performance standard as successfully updating in CROWNWeb at least once during the performance period for each qualifying case, the patient's comorbidities. We also proposed that the update be entered into CROWNWeb by the January 31 following the conclusion of the performance period or, if that is not a regular business day, the first business day thereafter.

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 except for the Anemia Management: Pediatric Iron Therapy and the Comorbidity reporting measures, which we are not finalizing for adoption in the ESRD QIP.

8. Scoring for the PY 2016 ESRD QIP Measures

In order to assess whether a facility has met the performance standards, we finalized a methodology for the PY 2014 ESRD QIP under which we separately score each clinical and reporting measure. We score facilities based on an achievement and improvement scoring methodology for the purposes of assessing their performance on the clinical measures (76 FR 70272 through 70273). We proposed to use a similar methodology for the purposes of scoring facility performance on each of the clinical measures for the PY 2016 ESRD QIP and future payment years, except that we proposed that there will only be an achievement score for the NHSN Bloodstream Infection in Hemodialysis Outpatients and Patient Informed Consent for Anemia Treatment clinical measures, because data are not available to calculate an improvement score.

In determining a facility's achievement score for the PY 2016 program and future payment years, we proposed to continue using the current methodology described above, under which facilities would receive points along an achievement range based on their performance during the proposed performance period for each measure, which we define as a scale between the achievement threshold and the benchmark explained below. We proposed to define the achievement threshold for each of the proposed clinical measures as the 15th percentile of the national performance rate during CY 2012, except as otherwise specified below for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, the Patient Informed Consent for Anemia Treatment clinical measure, and the Hypercalcemia clinical measure. We believe that this achievement threshold will provide an incentive for facilities to continuously improve their performance, while not reducing incentives to facilities that score at or above the national performance rate for the clinical measures (77 FR 67503). We proposed to define the benchmark as the 90th percentile of the national performance rate during CY 2012, except as proposed below for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent for Anemia Treatment clinical measure, because it represents a

demonstrably high but achievable standard of quality that the high performing facilities reached.

For the proposed NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, we proposed that the achievement threshold and benchmark be the 15th and 90th percentiles, respectively, of national performance during CY 2014.

For the proposed Patient Informed Consent for Anemia Treatment clinical measure, and for the reasons described in Section III.C.7.a, we proposed that the achievement threshold be defined as obtaining informed consent for 92 percent of qualifying cases during the performance period, and that the benchmark be defined as obtaining informed consent for 96 percent of such cases.

For the reasons described above, the first month that we can use to establish the baseline for the proposed Hypercalcemia measure is May 2012. Therefore, we proposed to set the achievement threshold as the 15th percentile of national performance and the benchmark as the 90th percentile of national performance from May 2012 through November 2012.

With the exception of the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent Anemia Treatment clinical measure, we proposed that facilities 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 performance on the measure during CY 2013. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2014 (the proposed performance period) to its performance rate on the measure during CY 2013. Because we lack the baseline data needed to calculate improvement scores for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent for Anemia Treatment clinical measure, we proposed that facilities will not receive improvement scores for these measures for PY 2016.

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

Comment: Several commenters supported the achievement/improvement scoring methodology that is carried over from the PY 2015 program.

Response: We thank the commenters for their support.

Comment: Several commenters believed that the achievement/improvement scoring methodology is inappropriate for measures with compressed performance ranges. These commenters stated that in such cases, noncompliance for a single patient can easily result in a facility receiving 0 points instead of 10, resulting in a standard of perfection that is impossible to meet. In such cases, the commenters recommended giving a facility a pass for one noncompliant patient or otherwise altering the scoring methodology to award higher scores to facilities with very few noncompliant patients..

Response: We recognize that measures with compressed performance scores, such as the Hemoglobin Greater Than 12 g/dL measure, present special challenges for the achievement/improvement methodology finalized in the CY 2013 ESRD PPS final rule. We will consider the commenters' suggestion as we work to address these challenges in future payment years.

Comment: One commenter recommended that new facilities should be scored the first year they are open on all of the clinical and reporting measures, and that their scores should be publicly reported, but that they should not be eligible to receive a payment reduction. The commenter stated that this is a fair way to handle new facilities, because they will have to post a Performance Score Certificate, but they would not experience adverse financial consequences.

Response: We appreciate the commenter's concerns about the difficulties new facilities face when meeting the requirements of the ESRD QIP. It is because of these concerns that facilities with CCN open dates after July 1 of the performance period are excluded from the reporting measures and are therefore not eligible to receive a TPS. However, we disagree that it is unfair for a facility to be eligible for a payment reduction if it has a CCN open date before July 1 of the performance period because we believe that 6 months is enough time to become familiarized with the ESRD QIP requirements, and because we believe that financial incentives provide the strongest enticement to improve the quality of care provided to patients with ESRD.

Comment: One commenter recommended that facilities be given a monthly report that previews the facility's performance rate on each of the measures in the ESRD QIP. The commenter believes this would provide facilities with a better opportunity to monitor and improve performance.

Response: We appreciate the commenter's request for CMS to provide timely information about facilities' performance on the ESRD QIP. However, we believe that offering a monthly preview of a facility's performance rate may not provide an accurate estimate of a facility's actual score during the performance period. Most clinical measures require at least four months of data, and a monthly preview may not include enough data for the first several months. Additionally, case minimums for the clinical and reporting measures are based on numbers of patients treated during the performance period, so it would not be possible to determine if a facility were eligible to receive a score on each of the measures until the conclusion of the performance period. Furthermore, attestations through CROWNWeb are due by January 31 of the year following the performance period, and this information could not be incorporated into the monthly reporting.

After consideration of the comments, we are finalizing the achievement thresholds, benchmarks, and improvement thresholds for the PY 2016 ESRD QIP clinical measures that are listed below. We are not finalizing achievement thresholds, benchmarks, and improvement thresholds for the Informed Consent for Anemia Management clinical measure because we are not adopting that measure for the ESRD QIP. We have calculated the numerical values for the achievement threshold and benchmarks based on data from the dates described above; we will calculate the numerical values for the improvement thresholds (where applicable) based on individual facilities' data from CY 2013. The numerical values for the achievement thresholds and benchmarks for the PY 2016 ESRD QIP clinical measures are set forth below in Table 9.

TABLE 9—FINALIZED ACHIEVEMENT THRESHOLDS AND BENCHMARKS FOR THE PY 2016 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA [19]

Measure	Achievement threshold	Benchmark
%Fistula	49.9%	77.0%
%Catheter	19.9%	2.8%
Kt/V:		
Adult Hemodialysis	86%[1]	97.4%
Adult, Peritoneal Dialysis	67.8%	94.8%
Pediatric Hemodialysis	83%[2]	97.1%
Hemoglobin > 12 g/dL	1.2%	0%
Hypercalcemia	5.4%	0%
NHSN Bloodstream Infection in Hemodialysis Outpatients.	15th percentile of eligible facilities' performance during the performance period.	90th percentile of eligible facilities' performance during the performance period.

[1] According to the most recent data available, the achievement threshold for the Adult Hemodialysis Adequacy measure is 85.6%. Because this is lower than the achievement threshold of 86% from the PY 2015 ESRD QIP, we are finalizing an achievement threshold of 86%.

[2] According to the most recent data available, the achievement threshold for the Pediatric Hemodialysis Adequacy measure is 71.3%. Because this is lower than the achievement threshold of 83% from the PY 2015 ESRD QIP, we are finalizing an achievement threshold of 83%.

We proposed that if the final PY 2016 numerical values for the achievement thresholds and benchmarks are worse than PY 2015 for a given measure, we will substitute the PY 2015 achievement thresholds and benchmarks 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. We did not receive any comments on this proposal. Using the most recent available data, we determined that the achievement threshold for the Kt/V Adult Hemodialysis Adequacy measure is 85.6 percent. Because this is lower than the achievement threshold of 86 percent from the PY 2015 ESRD QIP, we are finalizing an achievement threshold of 86 percent for the PY 2016 ESRD QIP. Using the most recent available data, we determined that the achievement threshold for the Kt/V Pediatric Hemodialysis Adequacy measure is 71.3 percent. Because this is lower than the achievement threshold of 83 percent from the PY 2015 ESRD QIP, we are finalizing an achievement threshold of 83 percent for the PY 2016 ESRD QIP. We will, therefore, finalize the achievement thresholds and benchmarks set forth above in Table 9 for the PY 2016 ESRD QIP clinical measures.

a. Scoring Facility Performance on Clinical Measures Based on Achievement

Using the same methodology we finalized in the CY 2013 ESRD PPS final rule, we proposed to award between 0 and 10 points for each of the proposed clinical measures (77 FR 67504). As noted, we proposed that the score for each of these clinical measures will be based upon the higher of an achievement or improvement score on each of the clinical measures, except for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent for Anemia Treatment clinical measure, which we proposed to score on achievement alone. For purposes of calculating achievement scores for the clinical measures, we proposed to base the score on where a facility's performance rate falls relative to the achievement threshold and the benchmark for that measure. (Performance standards do not enter into the calculation of improvement or achievement scores.) Identical to what we finalized in the CY 2013 ESRD PPS final rule, we proposed that if a facility's performance rate during the performance period is:

- Equal to or greater than the benchmark, then the facility would receive 10 points for achievement;
- Less than the achievement threshold, then the facility would receive 0 points for achievement; or
- Equal to or greater than the achievement threshold, but below the benchmark, then 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 for a clinical measure based on a linear scale distributing all points proportionately between the achievement threshold and the benchmark, so that the interval in the performance between the score for 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.

We did not receive any comments on this proposal. Therefore, we are finalizing the achievement scoring methodology for the PY 2016 ESRD QIP and future payment years, with the exception of the Informed Consent for Anemia Management clinical measure, because we are not adopting that measure for the ESRD QIP.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

Using the same methodology we have previously finalized for the ESRD QIP, we proposed that facilities would earn between 0 and 9 points for each of the clinical measures that will have an improvement score (that is, all clinical measures except the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent for Anemia Treatment), based on how much their performance on the measure during CY 2014 improved from their performance on the measure during CY 2013 (77 FR 67504). A specific improvement range for each measure would be established for each facility. We proposed that if a facility's performance rate on a measure during the performance period is:

- Less than the improvement threshold, then the facility would receive 0 points for improvement; or
- Equal to or greater than the improvement threshold, but below the benchmark, then the following formula would be used to derive the improvement score:

[10 * ((Facility performance period rate—Improvement threshold)/(Benchmark—Improvement

[19] Medicare claims data from 2012 were used to calculate the achievement threshold and benchmark for the Hemoglobin > 12 g/dL, Dialysis Adequacy, and Vascular Access Type clinical measures. CROWNWeb data from May 2012 through December 2012 were used to estimate the percentiles for the Hypercalcemia clinical measure.

threshold))]—.5, with all scores rounded to the nearest integer, with half rounded up.

Note that if the facility score is equal to or greater than the benchmark, then it would receive 10 points on the measure based on the achievement score methodology discussed above.

We did not receive any comments on this proposal. We will therefore finalize the improvement scoring methodology for the PY 2016 ESRD QIP and future payment years with the exception of the Informed Consent for Anemia Management clinical measure, because we are not adopting that measure for the ESRD QIP.

c. Calculating Facility Performance on Reporting Measures

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

With respect to the proposed Anemia Management reporting measure and the proposed Mineral Metabolism reporting measure, we proposed to award points to facilities using the same formula that we finalized in the CY 2013 ESRD PPS final rule for Mineral Metabolism and Anemia Management (77 FR 67506):

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

With respect to the proposed Use of Iron Therapy for Pediatric Patients reporting measure, we proposed to award points to facilities using the following formula:

$$\frac{\textit{Number of Quarters Facility Successfully Reports}}{\textit{Number of Quarters in the Performance Period Facility has CCN}}\ x\ 10$$

We proposed to score the Pediatric Iron Therapy measure differently than the proposed Anemia Management reporting measure and the proposed Mineral Metabolism reporting measure because it requires quarterly rather than monthly reporting; therefore, scoring based on monthly reporting rates is not feasible.

With respect to the proposed ICH CAHPS reporting measure and Comorbidity reporting measure, we proposed that a facility receive a score of 10 points if it satisfies the performance standard for the measure, and 0 points if it does not. We proposed to score these reporting measures differently than the other reporting measures because these measures require annual or biannual reporting, and therefore scoring based on monthly or quarterly reporting rates is not feasible.

We requested comments on the proposed methodology for scoring the PY 2016 ESRD QIP reporting measures. We did not receive any comments on this proposal. We will, therefore, finalize the scoring methodology for the reporting measures as proposed, with the exception of the Pediatric Iron Therapy and Comorbidity reporting measures, because we are not adopting those measures for the ESRD QIP.

9. Weighting the PY 2016 ESRD QIP Measures and Calculating the PY 2016 ESRD QIP Total Performance Score

Section 1881(h)(3)(A)(iii) of the Act provides that the methodology for calculating the facility TPS shall include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that 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 2016 ESRD QIP measures for purposes of calculating the TPS, we considered two criteria: (1) the number of measures we proposed to include in the PY 2016 ESRD QIP; and (2) the National Quality Strategy priorities.

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

In the CY 2013 ESRD PPS final rule, we established a methodology for deriving the overall scores for measure topics (77 FR 67507). For the reasons described in the CY 2013 ESRD PPS final rule, we proposed to use the same methodology in PY 2016 and future payment years to calculate the scores for the three measure topics. After calculating the individual measure scores within a measure topic, we proposed to calculate a measure topic score using the following steps: (i) Dividing the number of patients in the denominator of each measure by the sum of the number of patients in each denominator for all of the applicable measures in the measure topic; (ii) multiplying that figure by the facility's score on the measure; (iii) summing the results achieved for each measure; and (iv) 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 (as discussed below), then that measure would not be included in the measure topic score for that facility. Only one measure within the measure topic needs to have enough cases to be scored in order for the measure topic to be scored and included in the calculation of the TPS. We also proposed that the measure topic score would be equal to one clinical measure in the calculation of the TPS. For an additional explanation, see the examples provided at 77 FR 67507.

We did not receive any comments on this proposal. We will therefore finalize this methodology of weighting individual measure scores to derive a measure topic score for the PY 2016 ESRD QIP and future payment years with the exception of the Anemia Management Clinical measure topic, because we are not adopting that measure topic for the ESRD QIP.

b. Weighting the Total Performance Score

We continue to believe that weighting the clinical measures/measure topics equally will incentivize facilities to improve and achieve high levels of

performance across all of these measures, resulting in overall improvement in the quality of care provided to patients with ESRD. We also continue to believe that, while the reporting measures are valuable, the clinical measures evaluate actual patient outcomes and therefore justify a higher combined weight (77 FR 67506 through 67508). For the reasons outlined in the CY 2013 ESRD PPS final rule, we proposed to continue weighting clinical measures as 75 percent and reporting measures as 25 percent of the TPS. We requested comments on this proposed methodology for weighting the clinical and reporting measures.

We have also considered the issue of awarding a TPS to facilities that do not report data on the proposed minimum number of cases with respect to one or more of the measures or measure topics. For the reasons stated in the CY 2013 ESRD PPS final rule, for PY 2016 and future payment years, we proposed to continue to require a facility to have at least one clinical and one reporting measure score to receive a TPS (77 FR 67508). We requested comments on our proposals to require a facility to be eligible for a score on at least one reporting and one clinical measure in order to receive a TPS.

Finally, we proposed that the TPSs be rounded to the nearest integer, with half of an integer being rounded up. We requested comments on this proposal. For further examples regarding measure and TPS calculations, we refer readers to the figures below.

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

Comment: Several commenters supported the proposed methodology for weighting measures in the TPS.

Response: We thank the commenters for their support.

Comment: One commenter did not support the adoption of the Hypercalcemia measure because hypercalcemia might not be an important clinical indicator, and the measure would dilute the effectiveness of the ESRD QIP by reducing the weight of other clinical measures. Other commenters did not support the adoption of the Hypercalcemia measure but recommended weighting it at 10 percent of the TPS if the measure was adopted.

Response: Given commenters' concerns about the clinical significance of the Hypercalcemia measure (see Section III.C.3.b above), particularly because the measure does not incorporate other indicators of mineral metabolism, we agree with the recommendation to decrease the measure's weight in the TPS. We note that if the Hypercalcemia measure were weighted at 10 percent of the TPS, and the clinical measures continued to comprise 75 percent of the TPS overall, then the weight of the Hypercalcemia measure would be receive roughly two-thirds the weight of the four other clinical measures. We believe that decreasing the Hypercalcemia measure's weight by one-third appropriately reflects the fact that in the absence of other information about mineral management, the Hypercalcemia measure is less clinically significant than the other clinical measures.

Therefore, for PY 2016 and future payment years, we are finalizing that the Hypercalcemia measure will weighted at two-thirds the weight of the other clinical measures, and that the clinical measures will continue to constitute 75 percent of the TPS. If a facility is not eligible for one or more of the clinical measures, we are finalizing that the Hypercalcemia measure will still be weighted at two-thirds the weight of the other clinical measures, and that the other measures will be equally weighted, such that the clinical measures comprise 75 percent of the TPS.

Comment: Several commenters did not support either the proposal to equally weight all clinical measures or the proposal to equally weight all reporting measures. These commenters expressed concerns that this methodology over-weights new measures and may not place enough emphasis on measures that have the most clinical importance. The commenters recommended establishing a set of weighting principles that take into account (1) how long the measure has been included in the ESRD QIP; (2) whether room for improvement exists; (3) the measure's clinical significance; and (4) the number of patients affected by the measure. The commenters also recommended that CMS should collaborate with the MAP to determine measure weights.

Response: We agree that it is not appropriate to equally weight all of the clinical measures if their clinical significance is not equal. That is why we are reducing the weight of the Hypercalcemia clinical measure, as explained above. Using this criterion, we do not agree that the reporting measures should be weighted differently because the reporting measures have similar clinical significance.

Furthermore, we appreciate the recommended principles for weighting the measures' contribution to the TPS. We will consider these recommendations in future rulemaking except for the recommendation to collaborate with the MAP on measure weighting.

Although the MAP provides input on measures under consideration, its statutorily authorized function does not include commenting on Medicare quality incentive program implementation policy.

Comment: One commenter recommended that the clinical measures should constitute 90 percent of the TPS and the reporting measures should constitute 10 percent. The commenter stated that the ESRD QIP should evaluate providers' performance rather than their ability to track and report information, and that a 90 percent/10 percent weighting methodology would accomplish that.

Response: We agree that it is important to weight the clinical measures significantly more than the reporting measures because the clinical measures evaluate provider's clinical performance, rather than their ability to track and report information. However, we also believe that the reporting measures should carry enough weight to provide facilities with an incentive to report data to CMS. We are finalizing 5 clinical measures/measure topics and 3 reporting measures. Since this ratio is not significantly different than our proposal to adopt 6 clinical measures/measure topics and 5 reporting measures we continue to believe that the 75 percent/25 percent distribution appropriately balances the need to incentivize performance with the need to incentive the reporting of data.

For these reasons, we are finalizing that the clinical measures will be weighted at 75 percent of the TPS and that the reporting measures will be weighted at 25 percent of the TPS. We are also finalizing that the Hypercalcemia clinical measure will be weighted at two-thirds the weight of the other clinical measures, and that the reporting measures will be weighted equally.

c. Examples of the PY 2016 ESRD QIP Scoring Methodology

In this section, we provide examples to illustrate the scoring methodology for PY 2016. Figures 1–3 illustrate the scoring for the Vascular Access Type—Fistula measure. Figure 1 shows Facility A's performance on the measure. Note that for this example, the facility has performed very well. The example benchmark (the 90th percentile of performance nationally in CY 2012) calculated for this clinical measure is 77 percent, and the example achievement threshold (which is the 15th percentile

of performance nationally in CY 2012) is 50 percent. Therefore, Facility A's performance of 86 percent on the clinical measure during the performance period exceeds the benchmark of 77 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

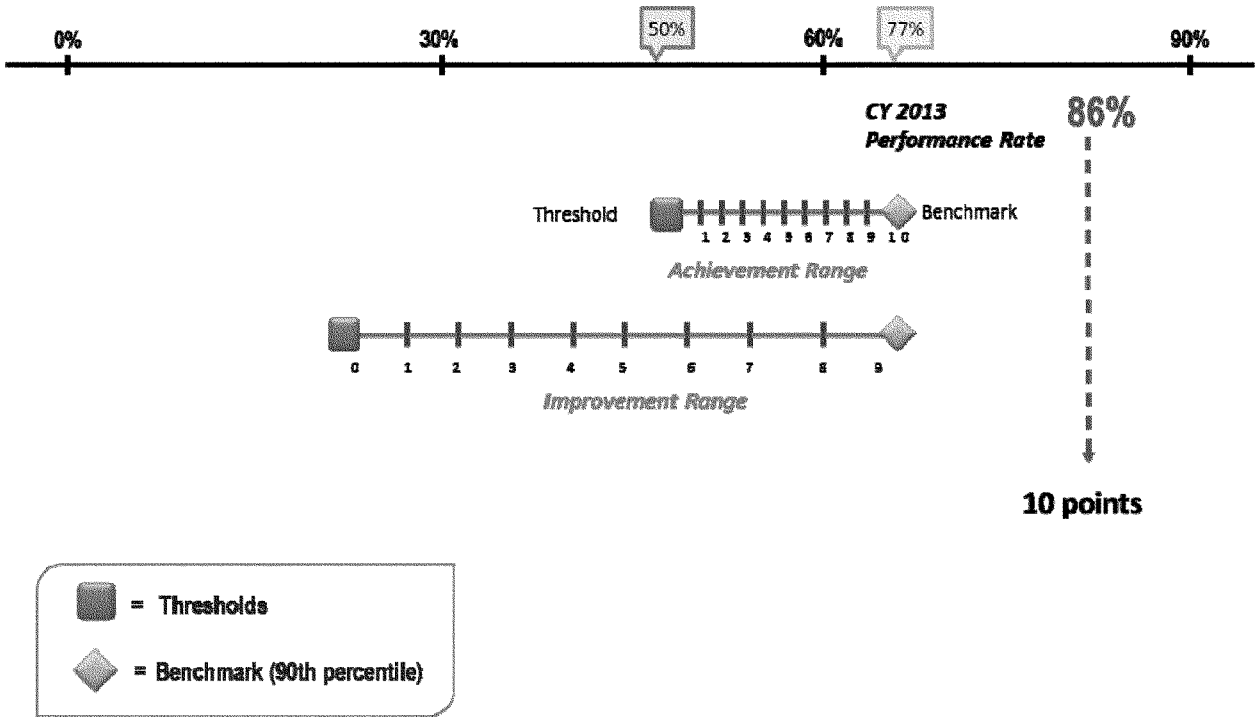


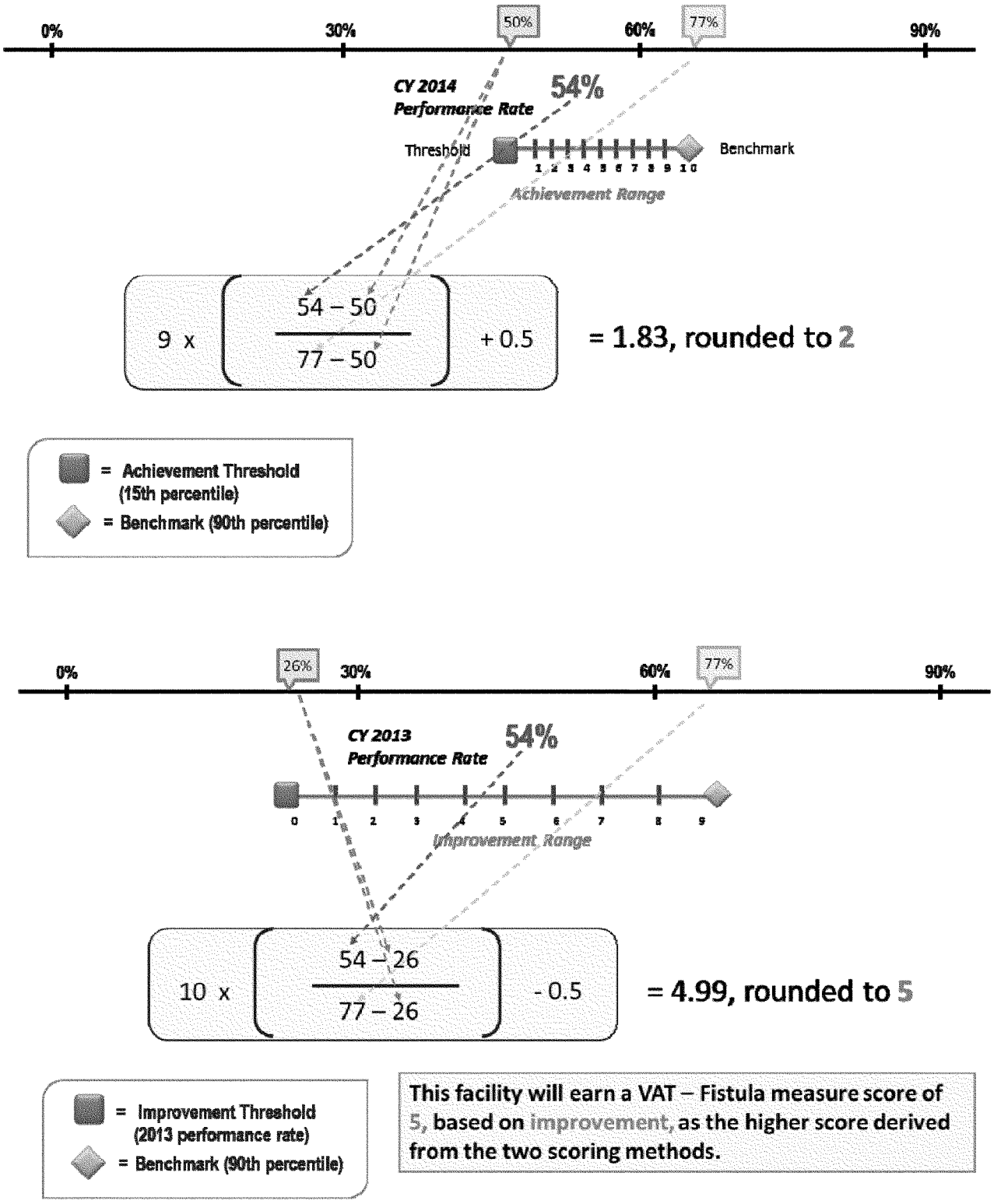
Figure 2 shows an example of scoring for another facility, Facility B. As illustrated below, the facility's performance on the Vascular Access Type—Fistula measure improved from 26 percent in CY 2013 to 54 percent during the performance period. The achievement threshold is 50 percent and the achievement benchmark is 77 percent. Because the facility's performance during the performance period is within the achievement range and the improvement range, we must calculate the improvement and achievement scores to determine the Vascular Access Type—Fistula measure.

To calculate the achievement score, we would apply the formula discussed above. The result of this formula for this example is [9 * ((54—50)/(77—50))] + .5, which equals 1.83, and we round to the nearest integer, which is 2.

Likewise, to calculate the improvement score, we apply the improvement formula discussed above. The result of this formula for this is example is [10 * ((54—26)/(77—26))]—.5, which equals 4.99 and we round to the nearest integer, which is 5.

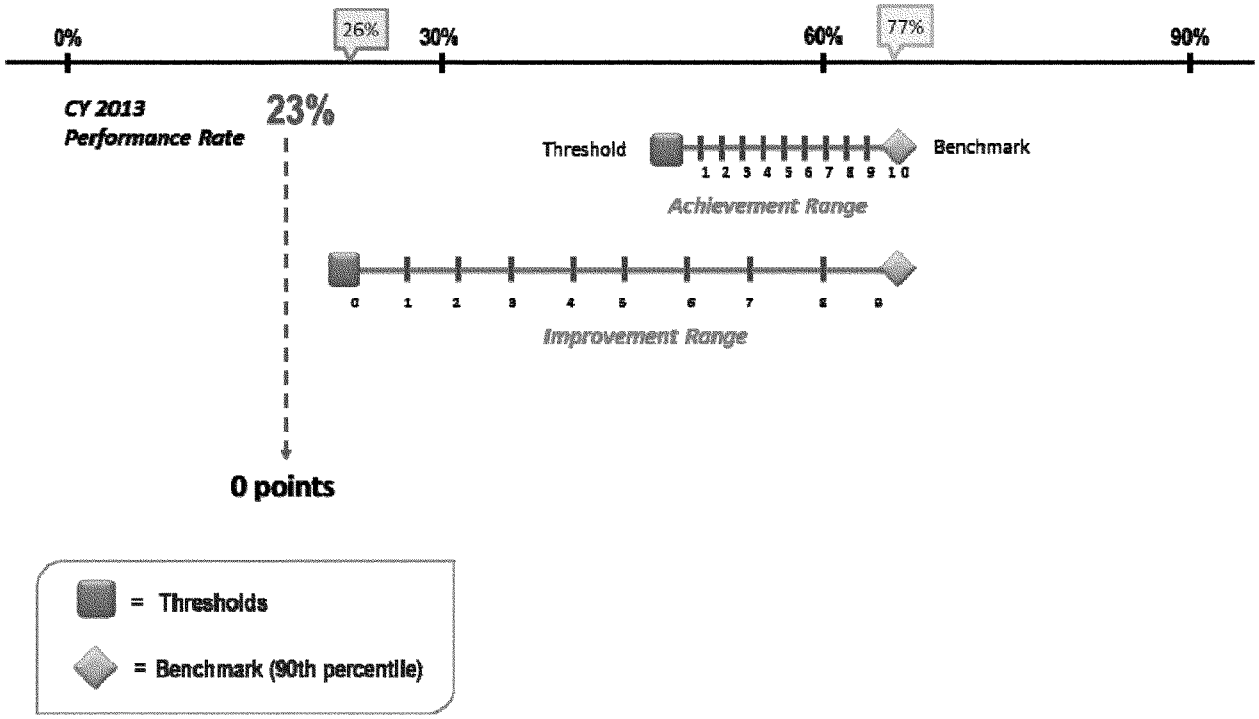
Therefore, for the Vascular Access Type—Fistula measure, Facility B's achievement score is 3, and its improvement score is 5. We award Facility B the higher of the two scores for this clinical measure. Thus, Facility B's score on this measure is 5.

Figure 2



In Figure 3, Facility C's performance on the Vascular Access Type—Fistula measure drops from 26 percent in CY 2013 to 23 percent during the performance period, a decline of 3 percent. Because Facility C's performance during the performance period falls below the achievement threshold of 26 percent, it receives 0 points for achievement. Facility C also receives 0 points for improvement, because its performance during the performance period was lower than its performance during CY 2013. Therefore, in this example, Facility C would receive 0 points for the Vascular Access Type—Fistula measure.

Figure 3



The methods 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 discussed earlier.)

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

Total Performance Score = [(.161 * Vascular Access Type Measure Topic) + (.161 * Kt/V Dialysis Adequacy Measure Topic) + (.161 * Hemoglobin Greater Than 12 g/dL) + (.107 * Hypercalcemia Measure) + (.161 * NHSN Bloodstream Infection in Hemodialysis Outpatients) + (.083 * ICH CAHPS Survey Reporting Measure) + (.083 * Mineral Metabolism Reporting Measure) + (.083 * Anemia Management Reporting Measure)] * 10.

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

The formula changes in the event that a facility does not receive a score on a particular measure. If, for example, a facility did not receive a score (that is, did not have enough qualifying cases) on the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, then the facility's TPS would be calculated as follows:

Total Performance Score = [(.205 * Vascular Access Type Measure Topic) + (.205 * Kt/V Dialysis Adequacy Measure Topic) + (.205 * Hemoglobin Greater Than 12 g/dL) + (.137 * Hypercalcemia) + (.083 * ICH CAHPS Survey Reporting Measure) + (.083 * Mineral Metabolism Reporting Measure) + (.083 * Anemia Management Reporting Measure)] * 10.

Again, the TPS would be rounded to the nearest integer (and any individual measure values ending in .5 would be rounded to the next higher integer).

If, for example, a facility did not receive a score (that is, did not have enough qualifying cases) on the Hypercalcemia clinical measure, then the facility's TPS would be calculated as follows:

Total Performance Score = [(.188 * Vascular Access Type Measure Topic) + (.188 * Kt/V Dialysis Adequacy Measure Topic) + (.188 * Hemoglobin Greater Than 12 g/dL) + (.188 * NHSN Bloodstream Infection in Hemodialysis Outpatients) + (.083 * ICH CAHPS Survey Reporting Measure) + (.083 * Mineral Metabolism Reporting Measure) + (.083 * Anemia Management Reporting Measure)] * 10.

If a facility is eligible for only two of the reporting measures, then the facility's TPS would be calculated as follows:

Total Performance Score = [(.161 * Vascular Access Type Measure Topic) + (.161 * Kt/V Dialysis Adequacy Measure Topic) + (.161 * Hemoglobin Greater Than 12 g/dL) + (.107 * Hypercalcemia Measure) + (.161 * NHSN Bloodstream Infection in Hemodialysis Outpatients) + (.125 * ICH CAHPS Survey Reporting Measure) + (.125 * Anemia Management Reporting Measure)] * 10.

Again, the TPS would be rounded to the nearest integer (and any individual measure values ending in .5 would be rounded to the next higher integer).

10. Minimum Data for Scoring Measures for the PY 2016 ESRD QIP and Future Payment Years

For the same reasons described in the CY 2013 ESRD PPS final rule (77 FR 67510 through 67512), for PY 2016 and future payment years, we proposed to only score facilities on clinical and reporting measures for which they have a minimum number of qualifying cases during the performance period. For PY 2016 and future payment years, we proposed that a facility must have a threshold of at least 11 qualifying cases for the entire performance period in order to be scored on a clinical measure. We proposed that reporting measures other than ICH CAHPS will have a threshold of one qualifying case during the performance period. The 11-qualifying case minimum was intended to reduce burden on facilities with

limited qualifying cases for earlier reporting measures (77 FR 67480, 67483, 67486 and 67493). We proposed to set the reporting measure case minimums at one because we plan to use data to permit future implementation of clinical measures. If patients in small facilities are systematically excluded, then we will not be able to gather the robust data we need to support the performance standard, benchmark, and achievement threshold calculations in future payment years. For those reasons, we proposed that the case minimum for all reporting measures except for ICH CAHPS be one.

For the proposed expanded ICH CAHPS reporting measure, we proposed that facilities with fewer than 30 qualifying cases during the performance period not be scored on the measure. In the CY 2013 ESRD PPS final rule, we excluded facilities with 10 or fewer adult in-center hemodialysis patients from the ICH CAHPS measure because we recognized that, for many small dialysis facilities, hiring a third-party administrator to fulfill the ICH CAHPS survey requirements would have been impractical or prohibitively costly (77 FR 67480). As we move toward developing a clinical measure, we have determined that the survey results are more reliable if there are at least 30 surveys submitted per facility. Therefore, we proposed that for PY 2016 and future payment years, facilities that treat fewer than 30 qualifying cases (defined as adult in-center hemodialysis patients) during the performance period will be excluded from this measure. We further proposed that we will consider a facility to have met the 30-patient threshold unless it affirmatively attests in CROWNWeb by January 31 of the year prior to the year in which payment reductions will be made (for example, January 31, 2015, for the PY 2016 ESRD QIP) that it treated 29 or fewer adult in-center hemodialysis patients during the performance period.

For the same reasons described in the CY 2013 ESRD PPS final rule (77 FR 67510 through 67512), for PY 2016 and future payment years, we proposed to apply to each clinical measure score for which a facility has between 11 and 25 qualifying cases the same adjustment factor we finalized in the CY 2013 ESRD PPS final rule (77 FR 67511). We solicited public comment on these proposals.

For the PY 2016 ESRD QIP and future payment years, we also proposed to continue to begin counting the number of months or quarters, as applicable, for which a facility is open on the first day of the month after the facility's CCN open date. With the exception of the ICH CAHPS expanded reporting measure, we proposed that only facilities with a CCN open date before July 1, 2014, be scored on the proposed reporting measures. Under the specifications for the proposed ICH CAHPS reporting measure, facilities would need to administer the survey (via a CMS-approved, third-party vendor) during the performance period. Because arranging such an agreement takes time, we proposed that only facilities with a CCN open date before January 1 of the performance period to be scored on this measure. Additionally, we proposed that facilities with CCN open dates after January 1, 2014 will not be scored on the NHSN. We note that in previous payment years we have awarded partial credit to facilities that submitted less than 12 months of data to encourage them to enroll in and report data in the NHSN system. However, we proposed to collect 12 months of data on this clinical measure because infection rates vary through different seasons of the year.

As discussed above, we proposed that a facility will not receive a TPS unless it receives a score on at least one clinical and one reporting measure. We noted that finalizing this proposal would result in facilities not being eligible for a payment reduction for the PY 2016 ESRD QIP and future payment years if they have a CCN open date on or after July 1 of the performance period (CY 2014 for the PY 2016 ESRD QIP).

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

Comment: Several commenters supported the proposed performance standards for the reporting measures, including the 30-case minimum for the ICH CAHPS reporting measure.

Response: We thank the commenters for their support.

Comment: Several commenters did not support the proposed reporting threshold of 97 and 99 percent for the Mineral Metabolism and Anemia Management reporting measures. These commenters stated that the threshold will unduly penalize small facilities. The commenters did not believe that that this possibility is mitigated by the alternative threshold of the 50th percentile of facility reporting in CY 2013, or by the requirement for facilities with fewer than 11 patients to report for all but one patient.

Response: We disagree that the proposed reporting threshold for the mineral metabolism and anemia management reporting measures unduly penalizes small facilities. In proposing that facilities with between 10 and 2 eligible patients must report monthly serum phosphorus and hemoglobin/hematocrit levels for all but one patient, we effectively created a reporting threshold of 90 percent for facilities with 10 patients, and a reporting threshold of less than 90 percent for facilities with 9 or fewer patients. Because facilities with fewer than 11 patients must meet lower reporting thresholds than facilities with more than 11 patients, we believe that this provision adequately addresses the possibility that a small facility will not be able to report data for certain patients for reasons that are beyond the facility's control.

Comment: Several commenters recommended applying a consistent case minimum (of either 11 or 26) to all ESRD QIP measures.

Response: We disagree that it is appropriate to establish a consistent case minimum for all of the ESRD QIP measures. As stated in the CY 2014 ESRD PPS proposed rule (78 FR 40871), we proposed to ''set the reporting measure case minimums at one because we plan to use data to permit future implementation of clinical measures. If patients in small facilities are systematically excluded, then we will not be able to gather the robust data we need to support the performance standard, benchmark, and achievement threshold calculations in future payment years.'' Additionally, due to the considerations about the reliability of ICH CAHPS data discussed above, we decided that 30 was the appropriate case minimum for the ICH CAHPS reporting measure. We therefore do not believe that an 11- or 26-case minimum is appropriate for any of the reporting measures.

As stated in the CY 2013 ESRD PPS final rule (77 FR 67510 through 67511), we adopted an 11-case minimum for the clinical measures based on the minimum number of cases needed to protect patient privacy, which could be compromised by the public reporting of data for small facilities. Given our goal to encourage quality improvement, we want to ensure the full participation of as many facilities as possible in the program. We therefore do not believe that a 26 case minimum is appropriate for the clinical measures.

Comment: One commenter expressed concerns that the 11-case minimum for the clinical measures excludes virtually all of the pediatric dialysis facilities from participation in the ESRD QIP. The commenter recognizes the this case minimum is important for the purposes of protecting patient confidentiality, but the commenter remained concerned that

pediatric facilities will not have an opportunity to use the ESRD QIP to improve performance.

Response: We are cognizant of the issues relating to inclusion of pediatric dialysis facilities in the ESRD QIP and continue to consider pathways to ensure that they are not excluded from participation. We appreciate the commenter's concerns and will continue to consider new pathways for incorporating pediatric dialysis facilities in the ESRD QIP.

Comment: Some commenters did not support the proposal to use the small-facility adjuster for facilities with 11 to 26 patients. These commenters stated that (1) the volatility associated with small sample sizes may create unintended and harmful consequences for facilities; (2) the methodology to adjust results for small samples sizes is complex and opaque; and (3) very small differences in both sample size and SE (x_i) can cause the achievement score to ''jump'' from 10 to 0 points (or vice versa).

Response: We do not agree that the small-facility adjuster will create harmful consequences for facilities, or that small differences in sample size and SE (x_i) can result in significant disparities in measure scores. While we recognize that the adjustment methodology is complex, we disagree that it is opaque. First, as illustrated below, the proposed small facility adjuster could only improve a facility's individual component score and will not create unintended and harmful consequences for small facilities (or facilities of any size). Second, the adjuster is transparent and straightforward, in that the adjustment explicitly depends on a facility's size (number of patients eligible for the measure), the unadjusted measure rate, and the standard error for that measure at the facility, which quantifies the amount of uncertainty in the unadjusted measure rate. Thirdly, even with small differences in both sample size and SE (x_i), the adjustment will still be applied in favor of the facility, and it is impossible for a facility's measure score to be reduced as a result of the application of the adjuster. The following example illustrates how the small facility adjustment impacts the achievement score for the AV fistula measure.

Facility B (% AVF Fistula)

- Unadjusted Measure (x_B) = 55%
- Achievement Threshold = 50%
- Benchmark = 77%
- Patients (n_B) = 12
- Standard Error ($SE(x_B)$) = 25%
- C = 26

Unadjusted Achievement Score:

$$9 * \frac{\textbf{Performance Rate} - \textbf{Achievement Threshold}}{\textbf{Benchmark} - \textbf{Achievement Threshold}} + 0.5 = 9 * \frac{55 - 50}{77 - 50} + 0.5 = 2.17, \text{ rounds to } \mathbf{2}.$$

Small facility adjustment:

- Calculation steps:
  - Weight $w_B = 1 - \frac{n_B}{C} = 1 - \frac{12}{26} = 0.54$
  - Adjusted Measure $t_B = x_B + w_B * SE(x_B)$

$$= 55\% + 0.54 * 25\%$$
$$= 55\% + 13.5\%$$
$$= 68.5\%, \textbf{ rounds to } \mathbf{69\%}$$

Adjusted Achievement Score:

$$9 * \frac{69 - 50}{77 - 50} + 0.5 = 6.8, \text{ rounds to } \mathbf{7}.$$

In the example above, the small-facility adjustment increased the AV fistula performance rate from 55 percent to 69 percent and the achievement score from 2 to 7.

For these reasons, we are finalizing as proposed the minimum data requirements for scoring measures for the PY 2016 ESRD QIP and future payment years.

11. Payment Reductions for the PY 2016 ESRD QIP and Future Payment Years

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 TPSs receive the largest payment reductions. For PY 2016, we proposed that a facility would not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) it performed at the performance standard for each clinical measure; (ii) it received zero points for each clinical measure that did not have a numerical value for the performance standard published with the PY 2016 final rule; and (iii) it received five points for each reporting measure. We requested comments on these proposals.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. For PY 2016 and future payment years, we proposed that the payment reduction scale be the same as the PY 2015 ESRD QIP (77 FR 67514 through 67516). We proposed that, for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. As we stated in the CY 2012 ESRD PPS final rule, we believe that such a sliding scale will incentivize facilities to meet the performance standards established and continue to improve their performance; even if a facility fails to achieve the minimum TPS, such a facility will still be incentivized to strive for and attain better performance rates in order to reduce the percentage of its payment reduction (76 FR 70281).

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

Comment: Several commenters supported the payment reduction scale. However, these commenters remained concerned that ''when a facility has a small number of patients, its TPS can be quickly reduced, causing financial harm to the facility.''

Response: We are aware that small facilities are more susceptible to the effects of outliers, due to their small sample sizes, and that this creates a real potential for them to be unfairly scored on measures in the ESRD QIP. It is for this reason that the ESRD QIP includes a small facility adjustment on the clinical measures for facilities that treat between 11 and 25 patients. We continue to believe that this adjustment provides a fairer and more precise way to account for the effects of outliers that could otherwise impact a small facility's TPS.

For the reasons stated above, we are finalizing our proposals for calculating payment reductions for PY 2016 and future payment years. Based on this approach, the minimum TPS for PY 2016 is 54 points. Facilities failing to meet this minimum will receive payment reductions in the amounts indicated in Table 10 below.

TABLE 10—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2016 BASED ON THE MOST RECENTLY AVAILABLE DATA [20]

Total performance score	Reduction (percent)
100–54	0
53–44	0.5
43–34	1.0
33–24	1.5
23–0	2.0

12. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data-validation program in CY 2013 for the ESRD QIP, and we are now in the process of procuring the services of a data-validation contractor, who will be tasked with validating a national sample of facilities' records as they report CY 2013 data to CROWNWeb. The first priority will be to develop a methodology for validating data submitted to CROWNWeb under the pilot data-validation program; once this methodology has been developed, CMS will publicize it through a CROWN Memo and solicit public comment. As part of the CY 2013 ESRD QIP PPS final rule (77 FR 67522 through 67523), we finalized a requirement to sample approximately 10 records from 750 randomly selected facilities; these facilities will have 60 days to comply once they receive requests for records. We proposed to extend this pilot data-validation program to include analysis of data submitted to CROWNWeb during CY 2014. For the PY 2016 ESRD QIP, sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. Additionally, we proposed to reduce the annual random sample size from 750 to 300. We believe that this smaller sample size will still yield a sufficiently precise estimate of ESRD QIP reliability while imposing a smaller burden on ESRD QIP-eligible facilities and CMS alike. We proposed to extend our policy that no facility will receive a payment reduction resulting from the validation process for CY 2014 during PY 2016. Once we have gathered additional information based on these initial validation efforts, we will propose further procedures for validating data submitted in future years of the ESRD QIP. These procedures may include a method for scoring facilities based on the accuracy of the data they submit to CROWNWeb, and a method to assign penalties for submitting inaccurate data. We solicited comments on these proposals.

We are also considering a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module. Although this is still in the early stages of development, we anticipate that this study may incorporate the methodology used by CMS's Hospital Inpatient Quality Reporting Program (77 FR 53539 through 53553), as well as additional input from CDC. The feasibility study will likely: (i) Estimate the burden and associated costs to ESRD QIP-eligible facilities for participating in an NHSN validation program; (ii) assess the costs to CMS to implement an NHSN validation program on a statistically relevant scale; and (iii) develop and test a protocol to validate NHSN data in nine ESRD QIP-eligible facilities. Facilities would be selected on a voluntary basis. Based on the results of this study, we intend to propose more detailed requirements for validating NHSN data used in the ESRD QIP in the future.

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

Comment: Several commenters urged CMS to validate NHSN data and to publish the processes that will be used for data validation.

Response: As noted above, we are considering a feasibility study for validating NHSN data submitted by facilities. If we proceed with the study, then we will publish the process used to validate NHSN data before the study is conducted.

Comment: Several commenters supported the proposal to extend the data-validation pilot, to reduce the sample size from 750 to 300 facilities, and to not penalize facilities for submitting invalid data (particularly until CROWNWeb is fully functional). These commenters also appreciated the opportunity to comment on future validations methodologies. However, some commenters urged CMS to reimburse facilities for staff time, as

[20] Medicare claims data from 2012 were used to calculate the achievement threshold, benchmark, and performance standard for the Hemoglobin > 12 g/dL, Dialysis Adequacy, and Vascular Access Type clinical measures. CROWNWeb data from May 2012 through December 2012 were used to estimate the percentiles for the Hypercalcemia clinical measure.

well as for costs associated with copying and mailing patient records.

Response: We thank the commenter for the support. Additionally, we note that CMS has not historically reimbursed provider staff or contractors for staff time spent in connection with copying and mailing patient records, and we believe these costs are minimal in comparison with the value of validating data used in the ESRD QIP.

For the reasons stated above, we are finalizing our proposal to extend the data validation pilot as proposed, and we will post the methodology, procedures and results of the PY 2016 pilot on *http://www.dialysisreports.org.*

13. Scoring Facilities Whose Ownership Has Changed

During PY 2012 (our first implementation year for the ESRD QIP), facilities requested guidance regarding how a change in ownership affects any applicable ESRD QIP payment reductions. Starting with the implementation of the PY 2015 ESRD QIP (the performance period of which is CY 2013), the application of an ESRD QIP payment reduction depended on whether the facility retained its CCN after the ownership transfer. If the facility's CCN remained the same after the facility was transferred, then we considered the facility to be the same facility (despite the change in ownership) for the purposes of the ESRD QIP, and we applied any ESRD QIP payment reductions that would have applied to the transferor to the transferee. Likewise, as long as the facility retained the same CCN, we calculated 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 received a new CCN as a result of a change in ownership, then we treated the facility as a new facility for purposes of the ESRD QIP based on the new facility's CCN open date. We believe that these policies are the most operationally efficient, and will allow facilities the greatest amount of certainty when they change ownership. We proposed to continue applying these rules during the PY 2016 ESRD QIP and future years of the program, and we requested public comments on this proposal.

We did not receive any comments on this proposal. Therefore, we are finalizing our proposals for scoring facilities whose ownership has changed for the PY 2016 ESRD QIP and for future payment years.

14. Public Reporting Requirements

Section 1881(h)(6)(A) of the Act requires the Secretary to establish procedures for making information available to the public about facility performance under the ESRD QIP, including information on the TPS (along with appropriate comparisons of facilities to the national average with respect to such scores) and 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 publication. In addition, section 1881(h)(6)(C) of the Act requires the Secretary to provide each facility with a certificate containing its TPS 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 a 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, thereby establishing procedures for facilities to review the information to be made public and for informing the public through facility-posted certificates. We proposed to maintain the public reporting requirements as finalized in the CY 2013 ESRD PPS final rule, except regarding the timing of when facilities must post their certificates.

For PYs prior to PY 2014, we required facilities to post certificates within 5 business days of us making these certificates available for download from *dialysisreports.org* in accordance with section 1881(h)(6)(C) of the Act. (77 FR 67516 and 76 FR 637) In the CY 2013 ESRD PPS final rule, we noted that many individuals responsible for posting the certificates were away on holiday during the December time period when certificates typically become available, and finalized that, beginning in PY 2014, a facility must post copies of its certificates by the first business day after January 1 of the payment year. (77 FR 67517) We also noted that certificates are typically available for download on or around December 15 of each year, and stated that we believe that this two week time period is enough to allow facilities to post them.

Since the CY 2013 ESRD PPS final rule was finalized, we have noted that a posting deadline of the first business day after January 1 could create difficulties for facilities if it were ever the case that certificates were not available for download in the typical timeframe. We want to ensure that facilities have adequate time to post certificates as required in this circumstance, and that the required timing accommodates the December holidays. Therefore, we proposed that, beginning in CY 2014, facilities must post certificates within fifteen business days of CMS making these certificates available for download from *dialysisreports.org* in accordance with section 1881(h)(6)(C) of the Act.

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

Comment: Several commenters supported the public-reporting proposal to require facilities to post performance score certificates fifteen business days after they are made available.

Response: We thank the commenters for the support.

For this reason, we are finalizing the public reporting requirements as proposed for the PY 2016 ESRD QIP and for future payment years.

IV. Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME)

A. Background

1. Background for DME

Title XVIII of the Social Security Act (the Act) governs the administration of the Medicare program. The statute provides coverage for broad categories of benefits, including, but not limited to, inpatient and outpatient hospital care, skilled nursing facility care, home health care, physician services, and DME. ''Medical and other health services,'' which is defined under section 1861(s)(6) of the Act to include DME, is a separate Medicare Part B benefit for which payment is authorized by section 1832 of the Act. In accordance with section 1861(n) of the Act, the term ''durable medical equipment'' includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the beneficiary's home, including an institution used as his or her home other than an institution that meets the requirements of section 1861(e)(1) or section 1819(a)(1) of the Act.

Section 1834(a) of the Act, as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100–203, sets forth the payment rules for DME furnished on or after January 1, 1989. The Medicare payment amount for a DME item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary's coinsurance for such items is generally equal to 20 percent of the

lesser of the actual charge or the fee schedule amount for the item once the deductible is met. The fee schedule amounts are generally calculated using average allowed charges from a base period and then increased by annual update factors. Sections 1834(a)(2) through (a)(7) of the Act set forth separate classes of DME and separate payment rules for each class. The six classes of items are: inexpensive and other routinely purchased DME; items requiring frequent and substantial servicing; customized items; oxygen and oxygen equipment; other covered items (other than DME); and other items of DME, also referred to as capped rental items. The class for inexpensive and other routinely purchased DME also includes accessories used in conjunction with nebulizers, aspirators, continuous positive airway pressure devices and respiratory assist devices. Items of DME fall under the class for other items of DME (capped rental items) if they do not meet the definitions established in the statute and regulations for the other classes of DME.

2. Medicare Guidance and Rulemaking Regarding Definition of Routinely Purchased DME

On July 14, 1988, CMS issued a program memorandum containing guidance for carriers to follow in developing a data base that would be used in identifying other routinely purchased DME for the purpose of implementing section 1834(a)(2)(A)(ii) of the Act. For the purpose of identifying routinely purchased items, the carriers were instructed via the program memorandum to ''compute the unduplicated count of beneficiaries who purchased the item, by Health Care Financing Administration (HCFA) Common Procedure Coding System (HCPCS) code (now the Healthcare Common Procedure Coding System), and a count of those who only rented the item during the 7/1/86–6/30/87 period.'' The carriers were instructed to include purchase of new and used items and beneficiaries who purchased an item that was initially rented in the count of beneficiaries who purchased the item. The carriers made determinations regarding whether DME furnished during this period would be rented (non-capped) or purchased based on which payment method was more economical.

In November 1988, CMS revised Part 3 (Claims Process) of the Medicare Carriers Manual (HCFA Pub. 14–3) via transmittal number 1279, by adding section 5102 and detailed instructions for implementation of the fee schedules and payment classes for DME mandated by section 4062 of OBRA 87. The new implementing instructions were effective for services furnished on or after January 1, 1989. Section 5102.1.A.2 indicated that carriers would be provided with a listing of the equipment in the routinely purchased DME category. The initial classifications were implemented on January 1, 1989, in accordance with the program instructions, and included a listing of HCPCS codes for base equipment such as canes and walkers, as well as HCPCS codes for replacement accessories such as cane tips, walker leg extensions, and power wheelchair batteries for use with medically necessary, patient-owned base equipment (canes, walkers, and power wheelchairs). In the case of expensive accessories that were not routinely purchased during July 1986 through June 1987, such as a wheelchair attachment to convert any wheelchair to one arm drive, these items fell under the listing of HCPCS codes for capped rental items. Medicare payment for DME extends to payment for replacement of essential accessories used with patient-owned equipment or accessories, attachments, or options that modify base equipment, such as the addition of elevating leg rests to a manual wheelchair.

The Medicare definition of routinely purchased equipment under 42 CFR § 414.220(a)(2) specifies that routinely purchased equipment means ''equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. This definition was promulgated via an interim final rule (IFC) on December 7, 1992 (57 FR 57675), remaining consistent with Medicare program guidance in effect beginning in 1988 and discussed above, and finalized on July 10, 1995 (60 FR 35492). In the preamble of the 1992 IFC (57 FR 57679), we discussed how items were classified as routinely purchased DME based on data from July 1986 through June 1987, ''in the absence of a statutory directive that defines the period for determining which items are routinely purchased.'' CMS indicated that it ''selected the period July 1, 1986 through June 30, 1987, because it is the same 12-month period required by section 1834(a)(2)(B)(i) of the Act for calculating the base fee schedule amount for routinely purchased equipment.'' (57 FR 57679) This period was therefore established as the period from which data was used for identifying the items that had been acquired on a purchase basis 75 percent of the time or more under the Medicare rent/purchase program.

3. Payment for Inexpensive or Routinely Purchased Items and Capped Rental Items

Under § 414.220(b), payment for inexpensive or routinely purchased DME is made on a purchase or rental basis, with total payments being limited to the purchase fee schedule amount for the item. If an item is initially rented and then purchased, the allowed purchase charge is based on the lower of the actual charge or fee schedule amount for purchase of the item minus the cumulative allowed charge for previously paid rental claims. Under § 414.229(f), payment for capped rental items is made on a monthly rental basis for up to 13 months of continuous use. The supplier must transfer title to the equipment to the beneficiary on the first day following the 13th month of continuous use.

B. Current Issues

Concerns have been raised about the application of the definition of and payment for routinely purchased DME, as it applies to expensive DME accessories. For example, recently one manufacturer of a new, expensive wheelchair accessory, included under a HCPCS code that would result in a corresponding Medicare fee schedule amount of approximately $3,000, if purchased, questioned why the HCPCS code describing their product was classified as capped rental DME. They pointed out that codes added to the HCPCS in recent years for other similar and more expensive wheelchair accessories costing $4,000 to $10,000 were classified as routinely purchased DME even though the items were not purchased under Medicare during the period specified in § 414.220(b). As a result, we began a review of expensive items that have been classified as routinely purchased equipment since 1989, that is, new codes added to the HCPCS after 1989 for items costing more than $150, to address this apparent inconsistency.

As a result of this review, we found some codes that are not classified consistent with the regulatory definition of routinely purchased equipment at section § 414.220(a)(2). We found that HCPCS codes added after 1989 for expensive, durable accessories used with base equipment, such as wheelchairs, have been classified as routinely purchased equipment. While section 1834(a)(2)(A)(iii) of the Act and 42 CFR § 414.220(a)(3) of the regulations allow payment for the purchase of accessories used in conjunction with

nebulizers, aspirators, continuous positive airway pressure devices (CPAP), other items covered under the DME benefit, including DME other than nebulizers, aspirators, CPAP devices, respiratory assist devices and accessories used in conjunction with those items, are paid for in accordance with the rules at section 1834(a) of the Act and are classified under sections 1834(a)(3) thru (7) of the Act as inexpensive and other routinely purchased DME, items requiring frequent and substantial servicing, certain customized items, oxygen and oxygen equipment, other covered items other than DME, or other covered items of DME.

Additionally, we found that in some cases, expensive items of DME were classified as routinely purchased based on information suggesting that payers other than Medicare were routinely making payment for the items on a purchase basis. We believe that classifying an item as routinely purchased equipment based on data and information from other payers for the purposes of implementing § 414.220(b) is inappropriate because other payers do not operate under the same payment rules as Medicare. Other payers may decide to purchase expensive items for reasons other than achieving a more economical alternative to rental, the basis Medicare contractors used in deciding whether to purchase items during July 1986 through June 1987. In other cases, expensive items of DME were classified as routinely purchased equipment based on requests from manufacturers of equipment primarily used by Medicaid beneficiaries. We do not believe we should classify an item as routinely purchased equipment for the purposes of implementing § 414.220(b) of the Medicare regulations based on how this might affect other payers such as Medicaid state agencies because such classifications are not consistent with the regulations. After reviewing this issue, we do not think the regulation supports the classification of expensive DME as routinely purchased equipment based on whether other payers routinely pay for the item on a purchase basis or how manufacturers would prefer that other payers pay for the item. The classification of HCPCS codes for expensive equipment added after 1989 as routinely purchased equipment based on this kind of information does not comply with the Medicare definition of routinely purchased equipment and defeats a fundamental purpose of the capped rental payment methodology to avoid paying the full purchase price of costly equipment when used only a short time.

DME and accessories used in conjunction with DME are paid for under the DME benefit and in accordance with the rules at section 1834(a) of the Act. In the proposed rule (78 FR 40874), we proposed to clarify the existing definition of routinely purchased equipment at § 414.220(a)(2) and provide notice that certain HCPCS codes for DME and DME accessories added to the HCPCS after 1989 that are currently classified as routinely purchased equipment would be reclassified as capped rental items (see Table 11 below). Under our proposal, this would apply to all expensive items for which Medicare claims data from July 1986 through June 1987 does not exist or does not indicate that the item was acquired by purchase on a national basis at least 75 percent of the time. In the case of expensive accessories that are furnished for use with complex rehabilitative power wheelchairs, we proposed that the purchase option for complex rehabilitative power wheelchairs at section 1834(a)(7)(A)(iii) of the Act would also apply to these accessories. For any wheelchair accessory classified as a capped rental item and furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be used as part of the complex rehabilitative power wheelchair), the supplier must give the beneficiary the option of purchasing these accessories at the time they are furnished. These items would be considered as part of the complex rehabilitative power wheelchair and associated purchase option set forth at § 414.229(a)(5).

We also solicited comments on the effective date(s) for reclassifying items previously classified as routinely purchased equipment to the capped rental payment class in order to be in compliance with current regulations. (78 FR 40874) Given that some items (HCPCS codes) may be included in the Round 2 and/or Round 1 Recompete phases of the competitive bidding program (CBP), we indicated we do not believe we could change the classification for items furnished under these programs until the contracts awarded based on these competitions expire on July 1, 2016, and January 1, 2017, respectively, regardless of whether the item is provided in an area subject to competitive bidding or not. We proposed that the reclassification of items previously classified as routinely purchased equipment to the capped rental payment class be effective January 1, 2014, for all items that are not included in either a Round 2 or Round 1 Recompete CBP established in accordance with § 414.400. For any item currently under a Round 2 CBP, instead of a January 1, 2014, effective date we proposed July 1, 2016, for these reclassifications, which would apply to all items furnished in all areas of the country, with the exception of items furnished in a Round 1 Recompete CBP. For items furnished in a Round 1 Recompete CBP, we proposed an effective date of January 1, 2017, which would only apply to items furnished in the nine Round 1 Recompete areas. Therefore, we proposed to generally base the effective dates on when the CBPs end. To summarize, the proposed effective dates for the reclassifications of these items from the routinely purchased DME class to the capped rental DME class would be:

- January 1, 2014, for items furnished in all areas of the country if the item is not included in Round 2 or Round 1 Recompete CBP;
- July 1, 2016, for items furnished in all areas of the country if the item is included in a Round 2 CBP and not a Round 1 Recompete CBP and for items included in a Round 1 Recompete CBP but furnished in an area other than one of the 9 Round 1 Recompete areas; and
- January 1, 2017, for items included in a Round 1 Recompete CBP and furnished in one of the nine Round 1 Recompete areas.

We noted that this implementation strategy would allow the item to be moved to the payment class for capped rental items at the same time in all areas of the country without disrupting CBPs currently underway. For Round 1 Recompete items furnished in nine areas of the country for the six-month period from July 1, 2016, thru December 31, 2016, Medicare payment would be on a capped rental basis in all parts of the country other than these nine areas.

Alternatively, we noted the effective date for the reclassifications could be January 1, 2014, for all items paid under the fee schedule (78 FR 40875). In other words, the reclassification would not affect payments for items furnished under the Round 2 or Round 1 Recompete CBPs in the respective competitive bidding areas (CBAs) until the contract entered into under these programs expire on July 1, 2016, and January 1, 2017, respectively. However, such an alternative would result in an extensive two and a half year period from January 2014 through June 2016, where Medicare payment would be on a capped rental basis for the items in half of the country (non-CBAs) and on a purchase basis in the other half of the country (109 Round 2 and/or Round 1 Recompete CBAs). We believed that this

bifurcation in payment classifications would create confusion and would be difficult to implement, but we solicited comments on this alternative implementation strategy.

For this final rule, we have identified 78 HCPCS codes that will require reclassification from the inexpensive or routinely purchased DME payment class to the capped rental DME payment class (78 FR 40875 through 40876). The codes are shown in Table 11 below. As shown in Table 11, Column A of the table shows the type of DME, Columns B and C indicate the HCPCS level II codes and the short descriptor. The long descriptor for each code is available at *http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html*.

As shown in Column A, the majority of codes relate to manual wheelchairs and wheelchair accessories. In the case of accessories used with complex rehabilitative power wheelchairs, the purchase option for complex rehabilitative power wheelchairs applies to these accessories because they are part of the complex rehabilitative power wheelchair.

TABLE 11—ROUTINELY PURCHASED ITEMS RECLASSIFIED TO CAPPED RENTAL

Group category	HCPCS	Descriptor
Automatic External Defibrillator	K0607	Repl battery for AED.
Canes/Crutches	E0117	Underarm spring assist crutch.
Glucose Monitor	E0620	Capillary blood skin piercing device laser.
High Frequency Chest Wall Oscillation Device (HFCWO)	A7025	Replace chest compress vest.
Hospital Beds/Accessories	E0300	Enclosed ped crib hosp grade.
Misc. DMEPOS	A4639	Infrared ht sys replacement pad.
	E0762	Trans elec jt stim dev sys.
	E1700	Jaw motion rehab system.
Nebulizers & Related Drugs	K0730	Ctrl dose inh drug deliv system.
* * *	*	* * *
Other Neuromuscular Stimulators	E0740	Incontinence treatment system.
	E0764	Functional neuromuscular stimulation.
Pneumatic Compression Device	E0656	Segmental pneumatic trunk.
	E0657	Segmental pneumatic chest.
Power Operated Vehicles (POV)	E0984	Add pwr tiller.
* * *	*	* * *
Speech Generating Devices	E2500	SGD digitized pre-rec <= 8 min.
	E2502	SGD prerec msg >8 min <= 20 min.
	E2504	SGD prerec msg >20 min <= 40 min.
	E2506	SGD prerec msg > 40 min.
	E2508	SGD spelling phys contact.
	E2510	SGD w multi methods messg/access.
Support Surfaces	E0197 *	Air pressure pad for mattress.
	E0198	Water pressure pad for mattress.
Traction Equipment	E0849	Cervical pneum traction equip.
	E0855	Cervical traction equipment.
	E0856	Cervical collar w air bladder.
Walkers	E0140 *	Walker w trunk support.
	E0144	Enclosed walker w rear seat.
	E0149 *	Heavy duty wheeled walker.
Wheelchairs Manual	E1161	Manual adult wc w tiltinspac.
	E1232	Folding ped wc tilt-in-space.
	E1233	Rig ped wc tltnspc w/o seat.
	E1234	Fld ped wc tltnspc w/o seat.
	E1235	Rigid ped wc adjustable.
	E1236	Folding ped wc adjustable.
	E1237	Rgd ped wc adjstabl w/o seat.
	E1238	Fld ped wc adjstabl w/o seat.
Wheelchairs Options/Accessories		
	E0985 *	W/c seat lift mechanism.
	E0986	Man w/c push-rim pow assist.
	E1002 ∧	Pwr seat tilt.
	E1003 ∧	Pwr seat recline.
	E1004 ∧	Pwr seat recline mech.
	E1005 ∧	Pwr seat recline pwr.
	E1006 ∧	Pwr seat combo w/o shear.
	E1007 ∧	Pwr seat combo w/shear.
	E1008 ∧	Pwr seat combo pwr shear.
	E1010 ∧	Add pwr leg elevation.
	E1014	Reclining back add ped w/c.
	E1020 *	Residual limb support system.
	E1028 *	W/c manual swingaway.
	E1029	W/c vent tray fixed.
	E1030 ∧	W/c vent tray gimbaled.
	E2227	Gear reduction drive wheel.
	E2228 *	Mwc acc, wheelchair brake.
	E2310 ∧	Electro connect btw control.
	E2311 ∧	Electro connect btw 2 sys.

TABLE 11—ROUTINELY PURCHASED ITEMS RECLASSIFIED TO CAPPED RENTAL—Continued

Group category	HCPCS	Descriptor
	E2312 ∧	Mini-prop remote joystick.
	E2313 ∧	PWC harness, expand control.
	E2321 ∧	Hand interface joystick.
	E2322 ∧	Mult mech switches.
	E2325 ∧	Sip and puff interface.
	E2326 ∧	Breath tube kit.
	E2327 ∧	Head control interface mech.
	E2328 ∧	Head/extremity control interface.
	E2329 ∧	Head control interface nonproportional.
	E2330 ∧	Head control proximity switch.
	E2351 ∧	Electronic SGD interface.
	E2368 *	Pwr wc drivewheel motor replace.
	E2369 *	Pwr wc drivewheel gear box replace.
	E2370 *	Pwr wc dr wh motor/gear comb.
	E2373 ∧	Hand/chin ctrl spec joystick.
	E2374 ∧	Hand/chin ctrl std joystick.
	E2375 *	Non-expandable controller.
	E2376 ∧	Expandable controller, replace.
	E2377 ∧	Expandable controller, initial.
	E2378	Pw actuator replacement.
	K0015 *	Detach non-adjus hght armrst.
	K0070 *	Rear whl complete pneum tire.
Wheelchairs Seating	E0955 *	Cushioned headrest.

* Effective July 1, 2016. If the item is furnished in CBAs in accordance with contracts entered into as part of the Round 1 Recompete of DMEPOS CBP, then effective January 1, 2017.
∧ Item billable with Complex Rehabilitative Power Wheelchair codes K0835—K0864.
** Code E0760 not included in final list based on comments received on proposed list.
*** Code E0457 not included in final list as code has been made invalid for Medicare effective January 1, 2014.

In summary, we provided notice that certain HCPCS codes we proposed would be reclassified as capped rental items. We invited comments on this section.

C. Responses to Comments on the Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME)

We received approximately 172 comments regarding the clarification of the definition of Routinely Purchased DME. CMS received comments from DME suppliers, manufacturers, professional, state and national trade associations, physicians, physical therapists (PTs), speech pathologists, occupational therapists (OTs), beneficiaries and their caregivers, the Veterans Administration (VA), and a state government representative. The comments and our responses are summarized below.

Comment: Several commenters noted the clarification of the definition of routinely purchased durable medical equipment relies on 1986/87 as the base year and instead suggested using 2010/11 as a base year for determining new items classified under routinely purchased category.

Response: We do not agree with this comment. In this final rule, we are not revising the definition given our longstanding interpretation regarding section 1834(a)(2) of the Act. Although there have been numerous amendments to section 1834(a) over the years to address payment of certain DME, there have been no amendments to revise the definition of routinely purchased DME. Payment on a capped rental basis avoids lump sum purchases of expensive equipment that is only needed on a short term basis and is more economical than purchase. If the equipment is needed on a long term basis, beneficiaries will take over ownership following 13 months of continuous use. In addition, we did not propose to revise the base period in the definition for routinely purchased DME at 42 CFR § 414.220(a)(2). We are therefore not adopting this suggestion to revise the base period for the definition of routinely purchased DME equipment under 42 CFR § 414.220(a)(2).

Comment: Many commenters contended that reclassifying certain codes from the routinely purchased DME category to capped rental DME would result in additional administrative burden for suppliers. Commenters reacted unfavorably to repeated billings for monthly rental claims for as long as the item is medically necessary up until title transfers at the end of the 13th month rental period.

Response: While we understand certain billing procedures for capped rental items differ from and may be more administratively burdensome than billing procedures for routinely purchased items, this does not negate the fact that items must be classified in accordance with the rules of the statute and regulations.

Comment: One commenter requested a delay in the implementation of the reclassification of the list of codes in our table from routinely purchased DME to capped rental DME. The commenter stated that more time is needed to educate practitioners and patients along with receipt of adequate program guidance. Another comment from a manufacturer requested a substantial delay in implementation of the capped rental system for Speech Generating Devices (SGDs).

Response: Items that are not in compliance with the existing definition of routinely purchased DME will be classified as capped rental items and paid for in accordance with the rules set forth in 42 CFR 414.229 for items not currently included in a CBP that are furnished on or after April 1, 2014. The dates for re-classification of items affected by this rule that are currently included in a CBP will be discussed later in the preamble. We do not agree with the comment that a substantial delay in implementation of the reclassification of SGDs is necessary. Suppliers and practitioners will have more than three months to become familiar with payment rules and billing procedures related to capped rental

items and to prepare for this change in classification. In addition, this change in classification only affects payments for these items on or after April 1, 2014. We recognize that consumers, occupational and physical therapists and disability advocacy groups have expressed concerns with these changes to acquisition policy for some durable medical equipment which persons with disabilities rely upon, including specialized wheelchairs and speech generating devices. Although we do not anticipate disruptions resulting from the transition from purchase to a capped rental, we understand the important role that this technology plays in maximizing the independence of persons with disabilities and their ability to direct their own care. Accordingly, CMS is committed to carefully monitoring beneficiary access using real-time claims data to ensure that there isn't an adverse impact.

Comment: Several commenters noted some of the codes proposed for reclassification include the term ''replacement only'', such as code E2376 Expandable controller, replacement and K0607 Automatic external defibrillator part; thus, the codes are most likely submitted for payment for beneficiary owned DME instead of DME owned by the supplier during a 13-month capped rental period. Commenters felt it was unrealistic to expect a supplier to rent these items and disable the patient owned equipment should the beneficiary become ineligible for Medicare payment. Another commenter mentioned that some of the transitioning codes are not covered or have lower utilization under Medicare.

Response: We do not agree with these comments. The statute does not differentiate between items paid for under the DME benefit that are base equipment versus items paid for under the DME benefit that are replacement parts for base equipment. With the exception of drugs, which are paid in accordance with a separate payment methodology, all items covered under the DME benefit category are subject to the payment rules mandated by section 1834(a) of the Act. An item is not classified based on utilization, and, under our regulation at 42 CFR 414.229(f), if the beneficiary needs the item for 13 continuous months, title to the item is transferred to the beneficiary after 13 months. Lastly, our review of the codes for reclassification from routinely purchased DME to capped rental indicates coverage under Medicare although the extent of coverage differs by item.

Comment: One commenter noted several of the listed codes have limited coverage under Medicare and so continuing to pay on a lump sum purchase basis for these items will have a minimal impact on Medicare expenditures.

Response: The statute does not provide direction or discretion to classify items under section 1834(a)(2) thru (7) of the Act based on magnitude of expenditures.

Comment: Numerous commenters opposed reclassifying the HCPCS codes for pediatric manual wheelchairs (codes E1232–E1238) and manual tilt in space wheelchairs (code E1161) from the payment class for inexpensive or routinely purchased items to the payment class for capped rental items. Some commenters stated many adult tilt in space wheelchair users require customization of equipment and require adjustment to reflect their unique postural and mobility needs. The commenters stated a concern that payment on a rental basis for these items will increase the risk for orthopedic deformities due to improper support, increase the risk of pressure sores from poorly managed skin integrity, and will contribute to overall costs of medical care. Many commenters stated these items are used for chronic conditions or permanent disabilities, such as quadriplegia, paraplegia, multiple sclerosis, head and spinal injuries, requiring wheelchairs and wheelchair accessories that are constructed of components that are not mass produced which reduces the profit margin compared to the furnishing of power mobility and acute adult manual wheelchairs.

Response: Claims for ''youth'' or ''pediatric'' wheelchairs were submitted using HCPCS code E1091 (Youth Wheelchair, Any Type) from July 1986 through June 1987, and this equipment was paid on a purchase basis 25 percent of the time during this time. This is well below the 75 percent threshold established in the statute; and therefore, classification of pediatric or youth wheelchairs (HCPCS codes E1232–E1238) as capped rental items is required by the regulations. The data from July 1986 through June 1987 also indicates that only 30 percent of all manual wheelchairs were purchased for Medicare beneficiaries during this time. As Medicare claims data from July 1986 through June 1987 does not exist for adult tilt in space wheelchairs (HCPCS code E1161), the data required by the regulation to classify these items as routinely purchased equipment does not exist and these items will therefore be classified as capped rental items in accordance with this rule. We agree that some items may have a higher cost because they are not mass produced; however, such costs are accounted for in the fee schedule amounts that have been set based on supplier charges or price lists. We note that the fee schedule amounts for the pediatric and adult tilt in space manual wheelchairs are more than double, and in some cases triple, the fee schedule amounts established for other manual wheelchairs. We recognize that commenters have expressed concerns with these changes to payment policy for some durable medical equipment which persons with disabilities rely upon, including specialized wheelchairs. Although we do not anticipate disruptions resulting from the transition from purchase to a capped rental, we understand the important role that this equipment plays in maximizing the independence of persons with disabilities and their ability to direct their own care. Accordingly, CMS is committed to carefully monitoring beneficiary access using real-time claims data to ensure that there isn't an adverse impact.

Comment: One commenter raised concern that suppliers spend multiple hours on supplies, labor and parts to customize a wheelchair; therefore, if patients become temporarily institutionalized, regress and need new customized parts, or pass away so that the wheelchair is returned to the supplier, the supplier would have a need to readjust and customize the chair to fit the needs of the next patient.

Response: This rule has no impact on items that meet the definition of customized items at 42 CFR 414.224. For items that are affected by this rule, we agree that some items may have a higher cost because they are not mass produced; however, such costs are accounted for in the fee schedule amounts that have been set based on supplier charges or price lists. We appreciate hearing about the concerns with these changes to payment policy for some durable medical equipment which persons with disabilities rely upon, including specialized wheelchairs. Although we do not anticipate disruptions resulting from the transition from purchase to a capped rental, we understand the important role that this technology plays in maximizing the independence of persons with disabilities and their ability to direct their own care. Accordingly, CMS is committed to carefully monitoring beneficiary access using real-time claims data to ensure that there isn't an adverse impact.

Comment: There were concerns raised by many commenters regarding reclassification of wheelchair options and accessories added to individually

configure wheelchairs to meet long-term mobility needs.

Response: In this final rule, an exception is established so that wheelchair options and accessories furnished for use with purchased complex rehabilitative power wheelchairs can be paid under a routinely purchased basis consistent with 42 CFR 414.229(a)(5). Other expensive wheelchair options and accessories that are paid separate from the rental payments for the wheelchair base and were not routinely purchased from July 1986 through June 1987 fall under the payment category for capped rental items. Payment will therefore be made on a capped rental basis for the options and accessories furnished for use with the rented wheelchair base. As a result, when payment for less than 13 months of continuous use is made for the wheelchair and associated options and accessories, the supplier can furnish the equipment to other patients and receive additional payment for the equipment. If payment is made for 13 months of continuous use of the wheelchair, then title to the wheelchair and all options and accessories will transfer to the beneficiary.

Comment: One commenter recommended CMS should establish that all manual wheelchairs should remain in the routinely purchased category and that options and accessories provided with/for a ''routinely purchased'' wheelchair base should be considered ''routinely purchased'' as well.

Response: With the exception of ultralightweight manual wheelchairs, manual wheelchairs were not routinely purchased under the Medicare program from July 1986 through June 1987. The data from July 1986 through June 1987 indicates that only 30 percent of manual wheelchairs and 55 percent of power wheelchairs were purchased for Medicare beneficiaries during this time. These percentages are well below the 75 percent threshold established in the statute. As discussed above. an exception is established so that wheelchair options and accessories furnished for use with purchased complex rehabilitative power wheelchairs can be paid under a routinely purchased basis consistent with 42 CFR 414.229(a)(5). Wheelchair options and accessories falling under the payment category for capped rental items will be paid for on a rental basis when they are furnished with other wheelchair bases, with title to the equipment transferring to the beneficiary after 13 months of continuous use.

Comment: Many commenters complained that a capped rental payment method will result in a significant financial burden for suppliers who may face challenges securing capital/lines of credit in the current economic environment.

Response: We do not agree with this comment. The capped rental payment method allows suppliers to reclaim capital equipment that is not needed for 13 months of continuous use. While Medicare payments may total 105 percent of the historic purchase price over 13 months of continuous use by a single beneficiary, the item could be rented for significantly more than 13 monthly payments and significantly more than 105 percent of the historic purchase price if it is used by multiple beneficiaries who do not need the item for the full 13 months.

Comment: Commenters stated that the proposed change in payment rules will be adopted by payers other than Medicare and therefore should not be adopted.

Response: Speculation about how other payers will pay for items that are also paid for by Medicare is beyond the scope of this rule and we have not taken such things into consideration when finalizing our policies. We must comply with the requirements of section 1834(a)(2) through (7) of the Act regarding how we classify and pay for DME items.

Comment: Various commenters argued that since the ultralightweight wheelchair (HCPCS code K0005) is classified as routinely purchased equipment, other complex rehabilitative manual wheelchairs (HCPCS codes E1161 and E1232 through E1238) should similarly be classified as routinely purchased equipment.

Response: The ultralightweight wheelchair was classified as routinely purchased equipment based on the regulatory standard (that is, it was acquired for purchase on a national basis at least 75 percent of the time from July 1986 through June 1987). Other manual wheelchairs have not been routinely purchased under the Medicare program. Claims for ''youth'' or ''pediatric'' wheelchairs were submitted using HCPCS code E1091 (Youth Wheelchair, Any Type) from July 1986 through June 1987, and this equipment was paid on a purchase basis 25 percent of the time during this time. This is well below the 75 percent threshold established in the statute; and therefore, classification of pediatric or youth wheelchairs (HCPCS codes E1232—E1238) as capped rental items is required by the regulations. The data from July 1986 through June 1987 also indicates that only 30 percent of all manual wheelchairs were purchased for Medicare beneficiaries during this time. As Medicare claims data from July 1986 through June 1987 does not exist for adult tilt in space wheelchairs (HCPCS code E1161), these items will be classified as capped rental items in accordance with this rule, and this is consistent with the classification of youth or pediatric wheelchairs and for manual wheelchairs in general based on Medicare claims data from July 1986 through June 1987.

Comment: One commenter concurred with our proposal by indicating it is a waste for patients at end stage of life to purchase complex wheelchairs which they then would not use for more than 1–2 years, due to various life ending diseases or due to regression in function, or at an older terminal age. The commenter noted it is advisable to have a system of rental and return, so that the same equipment can be modified, then rented to someone else. This will greatly reduce waste in this area of assistive technology/wheelchair supply and demand.

Response: We appreciate this comment.

Comment: Several commenters supported our proposal permitting a supplier to give the beneficiary the option of purchasing a wheelchair accessory classified as a capped rental item and furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be used as part of the complex rehabilitative power wheelchair) at the time the accessory is furnished. These wheelchair accessory items would be considered as part of the complex rehabilitative power wheelchair and associated purchase option set forth at § 414.229(a)(5).

Response: We appreciate this comment.

Comment: Several commenters urged CMS to extend our proposal to permit a supplier to give the beneficiary the option of purchasing a wheelchair accessory classified as a capped rental item and furnished for use with a complex rehabilitative power wheelchair (that is, furnished to be used as part of the complex rehabilitative power wheelchair) to accessories furnished for use with standard power wheelchairs.

Response: We disagree with this comment. The statute does not provide a purchase option for standard power wheelchairs. Section 1834(a)(7)(A)(iii) provides the purchase agreement option only for complex, rehabilitative, power-driven wheelchairs.

Comment: Some commenters were concerned that Part B coverage and payment for rented DME is no longer allowed when a beneficiary enters a hospital, so the beneficiary will be billed for equipment during the time the beneficiary is in the hospital because the provider would not be able to remove a tilt mechanism from their wheelchair without rendering their chair non-functional.

Response: The Part B benefit for DME and the payment rules at section 1834(a) of the Act do not extend to DME items furnished for use in hospitals. Classification of items under the payment classes established in sections 1834(a)(2) through (7) is not affected by whether or not the item will later be available for use in a hospital. Medicare benefit payments for items used in hospitals may be available under other parts of the program other than the Part B benefit for DME. In addition, suppliers are responsible for submitting claims for payment under the Medicare Part B DMEPOS fee schedule in compliance with our regulations and program instructions, such as those in the Medicare Claims Processing Manual (Pub 100.04), chapter 20, section 30.5.4 which address such temporary interruptions

Comment: Several commenters argued that the estimated program savings are not accurate primarily because the 8 month average use assumed for the items moved from routinely purchased to capped rental is in error because the 8 month average use was established for existing capped rental items, not routinely purchased.

Response: We believe that Medicare data on the average number of monthly rental claims paid for items currently classified as capped rental items is a reasonable proxy for the average number of monthly rental claims that will be paid for items reclassified as a result of this rule and provides an accurate estimate of the impact of this rulemaking on Medicare part B expenditures for DME. Most of the items being reclassified are either wheelchairs or wheelchair accessories. In reviewing the data used to determine that an average of 8 monthly rental payments are made for items currently classified as capped rental items, the average number of paid monthly rental claims per beneficiary drops to 7 when only wheelchairs and wheelchair accessories currently classified as capped rental item are considered. Our goal is to create a reasonable model by which to estimate the fiscal impact of the policy. The method used to calculate the savings is as follows:

- Sum the 2011 allowed charges for the HCPCS that are affected
- Increase the allowed charges by Medicare Advantage add-on
- Apply the annual increases for fee-for-service Medicare Part B population and for fee update to the total expenditures through the year 2023
- Based on claims data, the average duration of use of capped rental equipment is approximately 8 months, which is 2/3 of purchase price.
- So it is assumed that moving an item from routinely purchased to capped rental will on average save 33 percent of the purchased price, which is the factor applied to allowed charges to generate the savings indicated in the proposed rule.

Comment: Several commenters argued that the estimated savings in the rule does not consider the cost of possible increased institutional care.

Response: We do not believe the policy described in this final rule would increase the use of institutional care. We are not reducing the number of items that would be covered or reducing payment for certain DME items such that more institutional care may be needed.

Comment: Some commenters recommended classifying equipment as routinely purchased equipment if any of the following conditions are met: 1) the item is routinely needed for a period exceeding 13 months; 2) the item is intended for use by people with permanent disabilities; 3) the item is designed, manufactured, or assembled for a single individual (not intended to be used by multiple individuals); 4) the item was previously classified as routinely purchased equipment; and 5) other payers routinely pay for the item on a purchase basis.

Response: We disagree with this suggestion. We have interpreted the statutory definition of routinely purchased equipment, as set forth in the regulations, as ''equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.'' The statute does not contemplate use of additional factors in making determinations regarding whether equipment is routinely purchased, such as the ones raised by the commenters,. Also, we see no reason to revise the longstanding definition of routinely purchased equipment, but we may reconsider the issue in the future if necessary.

Comment: One commenter noted the United States Supreme Court held in Olmstead v. L.C. (527 US 581 (1991)) that unjustified segregation of persons with disabilities constitutes discrimination in violation of title II of the Americans with Disabilities Act. As noted by the commenter, the Court held that public entities must provide community-based services to persons with disabilities to support them to live independently in the community. The commenter asserts a change in the terms of usage of assistive devices jeopardizes the spirit of the decision made in the Olmstead case. A person can be in a position of not having these devices at time of need.

Response: We do not concur that changing the payment classification of certain codes from routinely purchased DME to capped rental DME jeopardizes the spirit of the decision made in the Olmstead case. Our proposal is not designed to undermine payment of the items; rather it is clarifying the definition of routinely purchased equipment set forth at section § 414.220(a)(2) and reclassifying some codes that are not presently classified consistent with the regulatory definition. In addition, the proposal is not designed to have any impact on coverage of items and services under the Medicare Part B benefit for DME. Such items and services would continue to be available consistent with the statute and regulations. This rule is designed to clarify the payment provisions applicable to accessories used in conjunction with items paid for under section 1834(a) of the Act.

Comment: Some commenters stated that speech generating devices (SGDs) (HCPCS codes E2500–E2510) should not be covered as DME but instead as prosthetic devices.

Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage/benefit category for an item is not addressed in this rule. Information on the process can be found at the Web site *http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html*

Comment: Several commenters stated that certain patients may benefit from renting SGDs. One commenter wrote once an individual has the initial assessment, there is often a trial period with one or more devices. The average time for trials is 90 days. One commenter stated a rental may be appropriate for short-term use such as a temporary loss of natural speech due to a surgical procedure or when waiting to purchase one. Another commenter indicated patients may benefit from renting a device for up to 1 year. Furthermore, one commenter supported implementation of a rental payment basis for certain DME to prevent abuse

of the purchase basis system and to help keep co-insurance costs lower when extended over the number of rental months.

Response: We thank the commenters for their helpful comments and agree about the potential benefits of our capped rental policy. We are aware that some manufacturers make their SGC products available on a rental basis so that patients can try out the products to figure out which one best meets their needs. Under the capped rental payment system, the patient will have the ability to obtain a new physician order and change equipment during the rental period to equipment that better meets their medical needs while Medicare rental payments continue up to the point where title to the equipment transfers to the beneficiary after 13 months of continuous use.

Comment: Numerous commenters opposed reclassification of SGDs, indicating that these devices are individually programmed based on each patient's need and access method (that is, eye-gaze, touch screen, switch) and language skills. The commenters stated that these devices are not similar to wheelchairs which are primarily generic in their design and can be used by a wide variety of individuals without significant modifications. Also, the commenters reviewed that patients' caregivers may be accustomed to specific devices used by their patients. One commenter suggested that a SGD is more appropriately analyzed as a complex rehabilitation tool, and as part of that analysis, the importance of integration and customization with the other rehab tools and medical needs of the patient must be considered. Other commenters reiterated that SGDs assist with communication that is essential for an individual's independence and functional living. Another commenter described an analysis of the diagnoses of the patients using SGDs, which shows that an estimate of eight months for a rental is unrealistic given that many SGD patients have a long term need for the device.

Response: We recognize that patients may use long term DME such as SGDs because of chronic conditions or permanent disabilities; however, we believe assigning the appropriate payment category in accordance with the statute and regulations ensures appropriate payment, supplier responsibilities, and beneficiary safeguards. Our final policy is not designed to interfere with patient care or a practitioner's efforts to program SGDs.

Comment: Many commenters claimed that reclassifying SGDs from routinely purchased DME to capped rental DME would cause suppliers to limit the amount of time and attention given to furnishing quality SGDs. Several commenters are concerned suppliers will require patients to switch devices and the devices would be taken away from patients who need them when the patient has reached maximum rental fees. Another commenter raised concerns that suppliers will not furnish SGDs that adequately serves patients who move from one location to another.

Response: The HCPCS codes for SGDs and other DME describe different categories of items. The supplier must furnish the item ordered by the physician to meet the patient's medical needs as required by 42 CFR 424.57(c)(4). Suppliers that are found not in compliance with the DMEPOS supplier standards are not allowed to possess a supplier number and receive Medicare payment for DME in accordance with section 1834(j) of the Act. These standards and requirements are not affected by the methodology used to pay for the item. In addition, regulations at 42 CFR 414.229(g) require that suppliers furnishing capped rental items continue to furnish the item for the full 13-month capped rental period with very limited exceptions and are prohibited from switching the patient's equipment unless the physician orders different equipment, the beneficiary chooses to obtain a newer technology item or an upgraded item, or the equipment is replaced because of loss, theft, or irreparable damage or wear. If the device is used for 13 continuous months, then the supplier is required to transfer title to the equipment to the beneficiary. Regarding patients who relocate near the end of the capped rental period and need to find a new supplier, CMS has been able to work with suppliers of capped rental items in the past to ensure beneficiary access in these situations.

Comment: Numerous comments were concerned that a rental payment method would impact access to SGDs in certain settings such as a hospital or nursing facility. As a result, commenters were concerned because the patient should not need to worry that the device will be taken away when circumstances require the patient to communicate to practitioners in the facilities. Commenters explained the patient may be forced to accept an inappropriate device because the right one for them is not available while in a facility resulting in practitioners and caregivers having difficulty in understanding the patient.

Response: In accordance with the statute, we do not establish payment rules for DME based on how the item is furnished in institutional settings, especially in light of the definition of DME in section 1861(n) of the Act, which defines DME as equipment used in a patient's home.

Comment: One commenter expressed concern that our proposal did not include codes for Accessory for Speech Generating Device, Not Otherwise Classified (HCPCS code E2599) and Accessory for Speech Generating Device, Mounting System (HCPCS code E2512).

Response: We appreciate this comment, but we are not including codes E2599 and E2512 in our list of codes for reclassification at this time because fee schedule amounts for these codes have not been established. When fee schedules are developed, we will review the data for these accessory codes to ensure compliance with the Medicare definition of routinely purchased equipment set forth at 42 CFR § 414.220(a). If a change in payment category is required in the future, CMS expects to provide notice via program instructions.

Comment: Some commenters recommended that the low volume of services for SGDs should exempt these codes from our proposal for reclassification from routinely purchased to capped rental. One commenter stated the proposal from CMS reports $20,170,612 in payments for SGDs in 2012 at an average cost of $7,356 for 2,742 services. The commenter also stated this represents .000008 of the United States population utilizing data from the census bureau.

Response: The payment rules at section 1834(a) of the Act do not classify items under the payment classes based on volume of services. As discussed above, the Medicare definition of routinely purchased equipment is set forth at 42 CFR § 414.220(a)(2) and specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. As a result of clarifying and reaffirming this definition, equipment for which claims data did not exist during the 1986/87 period cannot be classified as routinely purchased equipment. This results in such codes being reclassified as capped rental items if they do not fall under any of the other DME payment classes.

Comment: One commenter stated that the pneumatic compression trunk appliance (HCPCS code E0656) and the pneumatic compression chest appliance (HCPCS code E0657), both used in conjunction with pneumatic compression pumps for treatment of lymphedema, are considered routinely

purchased because the common diagnosis that allows reimbursement is lymphedema. The commenter states lymphedema is not curable and can only be managed. When a person has been diagnosed with lymphedema and a pneumatic compression pump has been prescribed, it is never for short term use. Thus, the items should not be reclassified from routinely purchased to capped rental payment method.

Response: The payment rules at section 1834(a) of the Act do not classify items under the payment classes based on diagnosis and intended use. As discussed above, the Medicare definition of routinely purchased equipment is set forth at 42 CFR § 414.220(a)(2) and specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. In this final rule, we are reclassifying DME that was not acquired during the period July 1986 through June 1987 or was not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987, and therefore cannot be classified as routinely purchased DME under 42 CFR 414.220(a). This results in certain codes receiving reclassification to capped rental DME if the codes do not fall under any of the other DME payment classes. We do note that only some of the codes in use during July 1986 through June 1987 that describe pneumatic compression appliances for the arm and leg met the definition of routinely purchased equipment. However, the appliances that were not routinely purchased met the definition of inexpensive equipment under § 414.220(a)(1). The codes for pneumatic compression appliances for the trunk and chest are considerable more expensive than the pneumatic compression appliances for the arm and leg and were not acquired on a purchase basis at least 75 percent of the time during July 1986 through June 1987. Payment will therefore made on a capped rental basis for pneumatic compression appliances for the trunk and chest furnished for use with pneumatic compression pumps. Thus, under the capped rental category whether the pneumatic compression chest appliance device is used short term or long term, payment is made in alignment with the number of months for which the equipment was in use, until the beneficiary no longer needs the device or the rental period has ended.

Comment: One commenter requested reclassification of code K0730 controlled dose inhalation drug delivery system from the routinely purchased to the frequently serviced payment category. The commenter also requested CMS reclassify code E0574, which also describes a nebulizer item, to the frequently serviced payment category.

Response: We are not adopting this suggestion to reclassify codes K0730 and E0574 to the frequently serviced payment category. Section 13543 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) removed nebulizers from the statutory list of items classified under the frequent and substantial servicing payment class effective with respect to items furnished on or after January 1, 1994. In accordance with these provisions, we continue to believe that these devices should not be classified as items under the payment category for items requiring frequent and substantial servicing under § 1834(a)(3)(A) of the Act. As such, we are implementing our proposal to reclassify these codes to the capped rental payment category.

Comment: One commenter opposed reclassification of code E0762 transcutaneous electrical joint stimulation system from the routinely purchased to the capped rental payment category because while significant relief is provided by the system within a short period of time, more significant results are achieved with increased use of the device.

Response: We continue to believe it is appropriate to reclassify code E0762 from the routinely purchased to the capped rental payment category. As discussed above, the Medicare definition of routinely purchased equipment is set forth 42 CFR § 414.220(a)(2) and specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Therefore, DME, including code E0762, for which claims data did not exist during the 1986/87 period cannot be classified as routinely purchased equipment. This results in such codes being reclassified as capped rental items if they do not fall under any of the other DME payment classes. Furthermore, under the capped rental payment method, the supplier owns the equipment during the rental period and title to the equipment transfers to the beneficiary at the end of a 13th month rental period. Thus, whether the device is used short term or long term, payment is made in alignment with the number of months until the beneficiary no longer needs the device or the rental period has ended.

Comment: One commenter stated jaw motion rehabilitation system from Dynasplint (HCPCS code E1700) should not remain routinely purchased because it was previously billed under a capped rental miscellaneous code and it was assigned by the Medicare Pricing, Data Analysis and Coding (PDAC) contractor to code E1700 which contains other less expensive items.

Response: Since HCPCS code assignment is outside the scope of the proposed rule which only concerns the reclassification of code E1700 from the routinely purchased payment category to the capped rental payment category, and we are not addressing this comment in this final rule.

Comment: Some commenters stated that code E0760 for Osteogenesis Ultrasound Stimulator is not DME but is a therapeutic intervention similar to a drug treatment.

Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage/benefit category for an item is not addressed in this rule. Information on the process can be found at the Web site *http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html*

Comment: Many commenters raised concerns that code E0760 for Osteogenesis Ultrasound Stimulator remains comparable to electric bone growth stimulators (codes E0747 and E0748) that also treat established nonunion of fractures of long bones and as adjunctive therapy to spinal fusion to improve fusion success rates, which are assigned to the routinely purchased category in accordance with the existing regulatory definition of routinely purchased items. Commenters pointed out the code used to describe osteogenesis stimulators in 1986 through 1987 did not specify the type of stimulator Medicare purchased. Also, commenters noted that code E0760 was initially classified as capped rental DME and reclassified by Medicare to routinely purchased DME based on data from other payers and claims submitted to Medicare.

Response: We recognize the commenters' concerns and in this final rule, we will revise the list of codes by removing code E0760 from the final list of codes for reclassification to the capped rental DME. We agree that HCPCS codes used to routinely pay for the purchase of osteogenesis stimulators in 1986 and 1987 did not differentiate between types of osteogenesis stimulators and therefore, believe that the general category of osteogenesis stimulator are correctly classified as routinely purchase equipment in

accordance with current regulations § 414.220(a)(2).

Comment: Commenters noted that the proposed list of HCPCS codes that would be reclassified as capped rental items includes HCPCS codes that describe products cleared by the FDA for single patient use. Commenters stated that reclassifying these devices as capped rental items goes against their labeling as single patient use devices by the FDA and that some of these devices cannot be cleaned or refurbished for another patient's use. A commenter noted that a change in payment category could affect various levels of market availability including FDA clearance, product marketing or the company's business model. Commenters stated a significant investment of resources and time is required to seek a new FDA label to allow these items to be rented to multiple patients. One commenter objected that reclassification would essentially force devices currently labeled for single patient use to be used off-label as rental equipment. Additionally, one commenter recommended that we amend our regulation to provide that all devices cleared by the FDA as class III devices under the Federal Food, Drug, and Cosmetic Act are classified as routinely purchased equipment.

Response: The payment rules under section 1834(a) of the Act do not classify items under the payment classes based on how they are cleared by the FDA. As discussed above, the Medicare definition of routinely purchased equipment under § 414.220(a)(2) specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. As a result of our clarification of this definition, equipment that was not acquired at all during the period July 1986 through June 1987, was not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987, and therefore, cannot be classified as routinely purchased equipment. This results in such codes being reclassified as capped rental items if they do not fall under any of the other DME payment classes. We agree that manufacturers and suppliers of products should be in compliance with FDA requirements, but we do not believe that FDA requirements dictate how items should be classified under sections 1834(a)(2) through (7) of the Act.

After consideration of comments received on the proposed rule and for the reasons we discussed above and in the proposed rule, we are finalizing our proposals and reclassifying certain items identified in this final rule with the exception of code E0760 which will remain classified as routinely purchased equipment. We did not receive comments regarding the effective dates for the reclassifications of these items from the routinely purchased DME category to capped rental DME. For the reasons discussed in the proposed rule (78 FR 40875), we are finalizing the effective dates for the changes of this section in compliance with the required regulatory process as follows:

- April 1, 2014, for items furnished in all areas of the country if the item is not included in Round 2 or Round 1 Recompete CBP;
- July 1, 2016, for items furnished in all areas of the country if the item is included in a Round 2 CBP and not a Round 1 Recompete CBP and for items included in a Round 1 Recompete CBP but furnished in an area other than one of the 9 Round 1 Recompete areas; and
- January 1, 2017, for items included in a Round 1 Recompete CBP and furnished in one of the nine Round 1 Recompete areas.

The April 1, 2014, effective date was selected in order to ensure that these changes do not occur sooner than 60 days after publication of the final rule for claims processing purposes.

V. Clarification of the 3-Year Minimum Lifetime Requirement (MLR) for DME

DME is covered by Medicare based, in part, upon section 1832(a) of the Act, which describes the scope of benefits under the supplementary medical insurance program (Medicare Part B), to include ''medical and other health services,'' which is further defined under section 1861(s)(6) of the Act to include DME. In addition, section 1861(m)(5) of the Act specifically includes DME in the definition of the term ''home health services.'' In accordance with section 1861(n) of the Act, the term ''durable medical equipment'' includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home whether furnished on a rental basis or purchased. The patient's home includes an institution used as his or her home other than an institution that meets the requirements of section 1861(e)(1) or section 1819(a)(1) of the Act. Besides being subject to this provision, the coverage of DME must meet the requirements of section 1862(a)(1)(A) of the Act, which in general excludes from payment any items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and section 1862(a)(6) of the Act, which (except for certain specified exceptions) precludes payment for personal comfort items.

Section 414.202 defines DME as equipment furnished by a supplier or a home health agency that meets the following conditions: (1) Can withstand repeated use; (2) effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) is primarily and customarily used to serve a medical purpose; (4) generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home. Prior to 2012, the definition for DME did not contain a 3-year minimum lifetime requirement (MLR) although Section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (CMS-Pub. 100–02) provided further guidance with regard to the definition of DME and durability of an item that is when an item is considered durable.

A. Current Issues

On November 10, 2011, CMS issued a final rule in which it revised the definition of DME at § 414.200 by adding a 3-year MLR effective January 1, 2012, that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME (76 FR 70228 (November 10, 2011)). Specifically, an additional condition under § 414.200 is that DME must be equipment furnished by a supplier or a home health agency that, effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years. The change to the regulation was designed to further clarify the meaning of the term ''durable'' and provide an interpretation of the statute generally consistent with the DME payment and coverage provisions, including, Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (Pub. 100–03) which specifies that an item can withstand repeated use means that the item could normally be rented and used by successive patients. The 3-year MLR is intended to specify that durable equipment is equipment that can withstand repeated use over an extended period of time. Since the vast majority of items covered under the DME benefit over the years last for 3 or more years, the MLR is intended to clarify the scope of the DME benefit primarily for new items coming on the market or in the process of being developed. The standard set forth in regulations gives manufacturers and the public a clear understanding of how long an item would need to withstand

repeated use in order the meet the durability requirement for DME. The rule also provides clear guidance to CMS and other stakeholders for making consistent informal benefit category determinations (BCDs) and national coverage determinations (NCDs) for DME.

The 3-year MLR is designed to represent a minimum threshold for a determination of durability for a piece of equipment. The 3-year MLR is not an indication of the typical or average lifespan of DME, which in many cases is far longer than 3 years. The 3-year MLR does not apply to disposable supplies or accessories covered for use with DME such as masks, tubing, and blood glucose test strips. The 3-year MLR is prospective only and does not apply to equipment classified as DME before the regulation was effective, that is, January 1, 2012.

We also determined that the 3-year MLR should not apply to equipment classified as DME before the effective date to allow for continued coverage of such equipment that healthcare industry and beneficiaries have come to rely on, regardless of whether those items met the 3-year MLR set forth at 42 CFR 414.202 (76 FR70288). Given that reliance, we indicated we did not intend to reopen those prior decisions and reclassify the equipment in light of the 3-year standard. We believe that continuing Medicare coverage for items that qualified as DME prior to the effective date helps avoid disrupting the continuity of care for the beneficiaries that received such items for medical treatment prior to January 1, 2012.

Beneficiaries have been relying on these items for their treatment to the extent that the items have been covered as DME under Medicare. Furthermore, we believed that a vast majority of the categories of items that were classified as DME before January 1, 2012, did function for 3 or more years. We also noted that the 3-year durability rule would only apply to new products, and, to the extent that a modified product is not a new product, the 3-year MLR would not be applicable.

In response to the public comments that requested further clarification on the application of the grandfathering provision for the 3-year MLR, we noted that we would consider issuing additional guidance to provide further clarification, if necessary (76 FR 70290). For purposes of providing additional guidance on the scope of the grandfathered items under the provision, we invited public comments on this issue.

B. Scope of the 3-Year MLR for DME

Under § 414.202, effective with respect to items classified as DME after January 1, 2012, an item is not considered durable unless it has an expected life of at least 3 years. Therefore, the 3-year MLR applies to new items after January 1, 2012, and does not apply to items covered under the DME benefit on or prior to January 1, 2012. Items classified as DME on or before January 1, 2012, are considered ''grandfathered items'' for the purpose of this requirement, regardless of whether they meet the 3-year rule.

For the purpose of providing further guidance on the scope of the 3-year MLR, in the proposed rule (78 FR 40877), we provided clarification about how we would regard grandfathered items covered as DME prior to the effective date and we requested comments on that clarification. We proposed that if the product is modified (upgraded, refined, reengineered, etc.) after January 1, 2012, the item would still be classified as DME as a grandfathered item unless the modified product now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012. In this case, we would consider the item, as modified, to be a new item that is subject to the 3-year MLR. For example, equipment covered prior to January 1, 2012, and described by code X has a life of at least 2 years. If, after January 1, 2012, that item is modified such that it is less durable, such that it no longer lasts for the 2 year period, that modification would render the item ''new'' and it would be subject to the 3-year MLR. Therefore, since the new (modified) product does not last 3 years, it would not meet the definition of DME under the regulation and could not be covered or be billed using the code that described the item before it was modified.

We sought comments on this proposed clarification.

C. Response to Comments on the 3-Year MLR for DME

We received approximately 13 comments on the proposed regulation (78FR 40876–40877) regarding clarification of the grandfathering provision of the 3-year MLR for DME. Commenters included medical device manufacturers, suppliers, advocacy groups and coalitions.

Comment: Most commenters acknowledged and appreciated that CMS proposed the clarification of the grandfathering provision of the 3-year MLR for DME.

Response: We thank the commenters for their input and support. We note that the clarification regarding grandfathered items that are modified relates to the durability of the item under the definition, and in particular, whether the modified item has a shorter useful life than the expected lifetime for the items covered prior to January 1, 2012.

Comment: Two commenters supported our clarification in the proposed rule of the grandfathering provision of the 3-year MLR for DME. The commenters believed that the proposed clarification to continue to cover grandfathered items if modified as long as the modification did not shorten its useful life was reasonable and encouraged CMS to adopt it.

Response: We thank the commenters for their support. However, we wish to clarify that the proposed rule addressed how we would regard grandfathered items covered as DME prior to the effective date. We proposed that if a grandfathered product is modified (upgraded, refined, reengineered, etc.), the item would still be classified as a grandfathered item unless the product has been modified to be less durable, such that it now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012. In this case, we would consider the item, as modified, to lose its grandfathered status and thus it would be treated as a new item that is subject to the 3-year MLR.

Comment: Several commenters indicated that the proposed rule still leaves great uncertainty regarding which modifications will result in products that continue to be, or are no longer, grandfathered. Without specific vignettes or parameters that illustrate how CMS will address these matters when certain new products come onto the market, the guidance in the proposed rule will not resolve the questions that remain. Specifically,

1. If application of new technology renders a product more effective but reduces its minimum lifetime; will the 3-year requirement be applied?

2. It does not provide further details regarding the extent of changes that could be made to an existing DME product such that it would still be subject to grandfathering provision.

3. Must a modified item fall within the same HCPCS code and/or DME product category as a grandfathered item in order for it to also fall within the grandfathering provision and not be considered a new item?

4. If a modification of an existing product results in the designation of another HCPCS code; will this trigger the 3-year requirement?

Response: We thank the commenters for their input. As noted in the final rule (76 FR 70289, 70290 (November 10, 2011)), the 3-year MLR for DME is applied on a prospective basis. That is, the 3-year MLR only applies to new items, meaning items that were not covered as DME on or prior to January 1, 2012. We clarified in the proposed rule (78 FR 40877) that items paid for as DME on or before January 1, 2012, are considered ''grandfathered items'' for the purpose of the 3-year MLR for DME, regardless of whether they meet the 3-year rule. If a grandfathered item is modified (upgraded, refined, reengineered, etc.) after January 1, 2012, the item would still be considered a grandfathered item unless the item has been modified to be less durable, such that it now has an expected life that is shorter than the lifetime for the grandfathered item, which was covered as DME on or prior to January 1, 2012. Therefore, if application of new technology renders a product more effective but reduces its durability; then the product would lose its grandfathered status and the 3-year requirement would apply.

The change we made to the regulation to establish a 3-year MLR for DME was designed to further clarify the meaning of the term ''durable.'' Based on our experience with the Medicare program, the vast majority of items covered as DME last for 3 years or longer; however, the purpose of the grandfathering provision is to ensure continued coverage for the items that were paid as DME before the effective date of the MLR requirement and, to avoid disruption of the continuity of care for the beneficiaries using such equipment. . . . In response to the specific concerns of the commenters, the parameters of the grandfathering provision are:

1. An item paid for as DME on or before January 1, 2012, is considered a grandfathered item for the purpose of the 3-year MLR for DME, regardless of whether they meet the 3-year rule; and

2. A grandfathered item that is modified (upgraded, refined, reengineered, etc.), is still considered a grandfathered item rather than a new item unless the item is less durable, such that it now has an expected life that is shorter than the expected lifetime for the item covered as DME on or prior to January 1, 2012.

Making individual determinations about whether a modified version of an item that was paid as DME on or prior to January 1, 2012, lasts as long as the item that was paid as DME on or prior to January 1, 2012, involves a case-by-case review of the relevant facts. Therefore, specific vignettes or parameters that illustrate how CMS will make these individual determinations could be misleading since it is not possible to illustrate every possible scenario addressing various items paid for as DME in the past and how they could be modified in the future. With regard to comments regarding HCPCS codes, there are a variety of coding changes. A code could be added for a completely new category of items that have never been paid for by Medicare and therefore these items would be subject to the 3-year MLR. Alternatively, a new code could be the result of a coding action whereby existing codes are revised to form a new code or codes. In these cases, the determination regarding whether an item is a grandfathered item not subject to the 3-year MLR will depend on whether the item was paid for as DME on or prior to January 1, 2012, under codes in effect on or prior to January 1, 2012.

Comment: Some commenters stated that the proposed rule does not provide clarity on what is a completely ''new product'' that would never be subject to the grandfathering provision.

Response: A new product is a product that was not paid for as DME on or prior to January 1, 2012, or a grandfathered item that loses its grandfathered status.

Comment: Some commenters indicated that it is unclear what would be considered a modified product that would be subject to the grandfathering provision provided that the modifications do not result in a reduced minimum lifetime of the product. Would a premarket approval product approved after January 1, 2012, that is similar in structure and function to grandfathered products be considered a modified version of the grandfathered products? Is newly cleared 510(k) product considered to be a modified version of the predicate device? It is unclear whether a new product cleared by the FDA through the Premarket Approval (PMA) process as opposed to a PMA supplement approved after January 1, 2012, can be considered to be a modification of a grandfathered product or whether a new product cleared by the FDA through the 510(k) process as substantially equivalent to other, previously cleared, predicate products is considered to be a modification of a predicate device.

Response: A grandfathered product is a specific product (make, manufacturer, model, model number, etc.) that was covered and paid for as DME on or prior to January 1, 2012. Any product that is not a grandfathered product or a grandfathered product that is modified so that it is less durable, such that it now has an expected lifetime that is shorter than the expected lifetime of the product covered as DME on or prior to January 1, 2012, is subject to the 3-year MLR. CMS will continue to consider these issues and provide additional guidance if necessary.

Comment: Several commenters voiced concerns that the final rule will serve as a major deterrent to future investments in new technologies. There may be desirable innovations made to a grandfathered product that would reduce the minimum lifetime of the product. If changes to a product that result in a different HCPCS code assignment or DME product category by definition do not fall within the grandfathering provision then manufacturers do not have the incentive to research and develop a grandfathered product's safety and effectiveness in treating. By eliminating reimbursement under Medicare DME benefit for modified grandfathered products containing innovations that are clinically beneficial to the patients but may reduce the minimum lifetime of those products, the proposed clarification discourages innovation of existing technologies.

Response: We believe that the 3-year MLR to clarify the term durable and the grandfathering provision are reasonable given the 5 year reasonable lifetime requirement, general DME payment rules and industry standards which support the fact that DME items should be able to withstand repeated use. We do not believe the rule is a deterrent. The rule is designed to clarify the grandfathering provision and ensure that such products are not modified to be less durable.

Based upon our experience with the Medicare program, the vast majority of items covered as DME last for 3 years or longer. The purpose of the grandfathering provision is to continue the Medicare coverage for the items that were paid as DME on or prior to the effective date, in order to avoid disruption of the continuity of care for the beneficiaries that had received items for medical treatment on or prior to January 1, 2012.

Comment: A few commenters suggested that instead of using the MLR to determine whether modified DME is a ''new'' device, CMS should focus on whether the modified device has the same clinical application as the grandfathered DME. This criterion would be a better measure of whether the device is ''new'' than whether it meets what a few commenters characterized as an arbitrary MLR rule. CMS should instead establish reasonable parameters under which products should be considered

comparable to existing DME products in order to be subject to the grandfathering provision-any modification, upgrade, redesign, improvement or new indication of an existing DME product that maintains the product's core clinical technology or mechanism of action should be eligible for reimbursement under the DME benefit category.

Response: We thank the commenters for their input. However, our proposal regarding the 3-year MLR with regard to the definition of DME was to clarify the issue of durability as it relates to grandfathering status. Our proposal centered on the lifetime of the product as a result modification (upgraded, refined, reengineered, etc.). We do not believe that issues such as core clinical technology or clinical application to determine whether a modified grandfathered item is a new DME as suggested by the commenters, speaks to the issue of durability with regard to our interpretation of the statutory DME provisions.

Comment: A few commenters expressed concerns that the proposed rule will require manufacturers to undertake expensive testing to demonstrate that their equipment continues to qualify under the grandfathering provision. They questioned whether there is a benchmark for deciding whether the modified device has an MLR that is shorter than the grandfathered device (e.g., is it an MLR that is a year shorter, 90 days shorter, or a day shorter than that of the grandfathered DME?). Commenters believe that, instead of providing clarity, CMS has injected even more subjectivity and ambiguity into the Medicare coverage and coding process and provides virtually no guidance when the minimum lifetime of a modified device does not conclusively meet the 3-year threshold. Commenters stated that, in the past, CMS has stated that it will base these decisions on a review of existing data, but the outcome in these cases ultimately will hinge on subjective interpretation of the data. The commenters note that this type of analysis will be useless in assessing new technologies, which typically are not included in independent comparative studies of the type CMS has said it plans to consult.

Response: We thank the commenters for their input but do not believe that the proposed regulation injects subjectivity and ambiguity into the Medicare coverage and coding process. We are not proposing a new process to determine whether a modified device has an expected life that is shorter than the original grandfathered device; therefore, no new types of tests are needed to make determinations regarding the expected lifetime of products. As discussed previously, we will continue to follow the current BCD process to determine on an individual consideration basis if a modified grandfathered item falls within the grandfathering provision. We will review information and evidence, which a supplier/manufacturer may submit, consistent with the current BCD process to determine the expected life of the equipment. As discussed previously, the BCD process typically involves reviewing information from various sources including but not limited to information related to FDA pre-market clearance, product manuals, operating guides, warranty documents, and standardized test results. The NCD process is available at *http://www.cms.gov/DeterminationProcess/Downloads/FR09262003.pdf*. See also, 68 FR 55638 (September 23, 2003). Additionally, we routinely collect information regarding durability of new products as part of the HCPCS editorial process in order to identify categories of new DME subject to the procedures established in accordance with the mandate of section 531(b) of the Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act of 2000 (BIPA 2000), Public Law 106–554. Based on our experience with the program, this information has been readily available from the manufacturers of these items and other entities submitting requests for changes to the HCPCS. Information on the HCPCS Level II coding process is available at: *http://www.cms.gov/MedHCPCSGenInfo/Downloads/2013_HCPCS_Application.pdf* and *http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage*.

Comment: Some commenters argued that in this case, CMS' original concern about disrupting patient care continues to hold true. Commenters claim that the proposal to modify the grandfathering provision of § 414.202 will disrupt the care of beneficiaries using the grandfathered DME. Beneficiaries who have been using the grandfathered DME will no longer have Medicare coverage for the medically necessary device they depend on. Physicians and other practitioners will be unable to order devices that have been proven therapeutically effective for the patients they treat. For these beneficiaries and providers, it will almost certainly be true that they will be left without an equally effective alternative for continuing their care.

Response: We thank the commenters for their input, but we do not agree with the above comment. We note that the proposed rule was designed to clarify the grandfathering provision. The proposed clarification of the grandfathering provision is designed to address how grandfathered products could be modified without losing their grandfathered status. The commenters concerns that beneficiaries who have been using the grandfathered DME will no longer have Medicare coverage for the medically necessary device they depend on or that physicians will be unable to order devices that have been proven therapeutically effective for the patients are inaccurate. On the contrary, the purpose of the grandfathering provision for the 3-year MLR was to continue Medicare coverage for items that were classified as DME on or prior to the effective date, in order to avoid disruption of the continuity of care for the beneficiaries that had already received these items for medical treatment. For the reasons stated above, we do not believe that the clarification of the grandfathering provision will disrupt the continuing care for beneficiaries that are using the grandfathered DME.

Comment: Some commenters urged CMS to convene a study panel to allow stakeholders to collaborate with the agency to examine a few central questions such as whether a modified item must fall within the same HCPCS code and/or DME product category as a grandfathered item in order for it to also fall within the grandfathering provision. Commenters asked CMS to consider convening a stakeholder meeting to solicit views from patients, healthcare providers, DME manufacturers and other health policy experts.

Response: We appreciate the comment. We established the 3-year MLR effective with respect to items classified as DME on or after January 1, 2012, via notice and comment rulemaking. We are clarifying the grandfathering provision for the 3-year MLR via notice and comment rulemaking. In addition, we will continue to follow the current processes including BCD, NCD, Local Coverage Determinations (LCD), and HCPCS codes to implement the 3-year MLR and the grandfathering provision. These processes include meetings with manufacturers in addition to the public where we seek input from the stakeholders. We will continue to receive input from stakeholders consistent with the BCD and NCD process when applying the 3-year MLR and the grandfathering provision. See 68 FR 55634 (September 26, 2003); and *http://www.Cms.gov/DeterminationProcess/Downloads/*

FR09262003.pdf. See also, information on the HCPCS Level II coding process at: *http://www.cms.gov/MedHCPCSGenInfo/Downloads/2013_HCPCS_Application.pdf. http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage*.

Comment: Some commenters stated that as other payers follow Medicare guidelines, it is important to revise ill-conceived Medicare policy now before regulations that harm people with disabilities and chronic conditions are replicated at the State level.

Response: This comment is outside the scope of the proposed rule.

Comment: One commenter stated that CMS proposes to clarify the scope and application of the MLR ''grandfathering'' provision by stipulating that products will lose the grandfather status if the modified product will have an expected life that is shorter than three years. In other words, the commenter believes the proposed rule would result in non-coverage of any grandfathered item that is modified.

Response: We thank the commenter for the input. However, the statement in the above comment that a modified product that has an expected life that is shorter than three years will no longer be grandfathered and therefore, lose coverage status is inaccurate. We proposed that a product covered as DME prior to 2012 that is modified would still be grandfathered as long as the expected lifetime of the product is equal to or greater than the lifetime of the product covered prior to 2012. Under this proposal, if the product lost grandfathered status (because the modification reduced the expected lifetime of the product covered prior to 2012), the product would be subject to the 3-year MLR. The application of 3-year MLR would determine whether product would be otherwise covered under the definition. For grandfathered items that have a lifetime shorter than 3-years, modifications that reduce such lifetime generally would result in the product no longer meeting the definition given the application of the 3-year MLR (because the grandfathered status was lost). However, for grandfathered products that have a lifetime greater than 3 years, modifications that shorten such lifetime may or may not result in non-coverage under the definition when the 3-year MLR is applied. For example, if a grandfathered product covered as DME prior to 2012 with a lifetime of four years is modified, resulting in a product with a lifetime of two and a half years (and thereby losing grandfathering status), the product would no longer meet the definition of DME, because the 3-year MLR is not met given that the lifetime of the modified product is less than three years. In the same example, if the modification resulted in a reduced lifetime of the product to 3.5 years, the product, even though it lost grandfathering status, would satisfy the 3-year rule, and continue meet the definition of DME.

After consideration of comments received on the proposed rule, we are finalizing the clarification of the grandfathering provision of the 3-year MLR for DME. The 3-year MLR applies, effective January 1, 2012, but does not apply to items covered under the DME benefit on or prior to January 1, 2012 (''grandfathered items''). However, effective April 1, 2014, if the grandfathered item is modified (upgraded, refined, reengineered, etc.), and the modified item now has an expected life that is shorter than the expected lifetime for the item covered as DME prior to January 1, 2012, the modified item will lose grandfathered status. In this case, we would consider the item, as modified, to be a new item that is subject to the 3-year MLR.

VI. Implementation of Budget-Neutral Fee Schedules for Splints, Casts and Intraocular Lenses (IOLs)

A. Background

1. Payment Under Reasonable Charges

Payment for most items and services furnished under Part B of the Medicare program is made through contractors known as Medicare Administrative Contractors (MACs). These contractors were previously referred to as carriers. Prior to 1988, in accordance with section 1842(b) of the Act, payment for most of these items and services was made on a reasonable charge basis by these contractors, with the criteria for determining reasonable charges set forth at 42 CFR part 405, subpart E of our regulations.

Under this general methodology, several factors or ''charge screens'' were developed for determining the reasonable charge for an item or service. In accordance with § 405.503, each supplier's ''customary charge'' for an item or service, or the 50th percentile of charges for an item or service over a 12-month period, was one factor used in determining the reasonable charge. In accordance with § 405.504, the ''prevailing charge'' in a local area, or the 75th percentile of suppliers' customary charges for the item in the locality, was also used in determining the reasonable charge. For the purpose of calculating prevailing charges, a ''locality'' is defined at § 405.505 of our regulations and ''may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States.'' The regulation further specifies that the locality ''should include a cross section of the population with respect to economic and other characteristics.'' In accordance with § 405.506, for certain items, such as parenteral and enteral nutrients, supplies, and equipment, an additional factor referred to as the ''lowest charge level'' was used in determining the reasonable charge for an item or service. In accordance with section 5025 of the Medicare Carriers Manual (HCFA Pub. 14–3) and § 405.509 of our regulations, effective for items furnished on or after October 1, 1985, an additional factor, the ''inflation-indexed charge (IIC),'' was added to the factors taken into consideration in determining the reasonable charge for certain items and services. The IIC is defined in § 405.509(a) as the lowest of the fee screens used to determine reasonable charges for items and services, including supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services) that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor. The inflation adjustment factor is based on the current percentage increase in the consumer price index for all urban consumers (United States city average) (CPI–U) for the 12-month period ending June 30. The reasonable charge is generally set based on the lowest of the actual charge for the item or service or the factors described above.

2. Payment Under Fee Schedules

Specific provisions have been added to the Act mandating replacement of the reasonable charge payment methodology with fee schedules for most items and services furnished under Part B of the Medicare program. The phase in of fee schedules to replace reasonable charges for Medicare payment purposes began with the fee schedule for clinical diagnostic laboratory tests in 1988. As of 1997, very few items and services were still paid on a reasonable charge basis, which is a very time consuming and laborious process. Contractors must collect new charge data each year, perform the various calculations, and maintain pricing files and claims processing edits for the various charge screens. For each item that is paid on a reasonable charge basis, administrative funding must be provided to contractors for the purpose of performing these

calculations and maintaining these pricing files. Therefore, replacing reasonable charge payments with fee schedules eliminates the need to fund these efforts and saves money that can be used to implement other parts of the program. Section 4315 of the Balanced Budget Act of 1997 (BBA) amended the Act at section 1842 by adding a new subsection (s). Section 1842(s) of the Act provides authority for implementing statewide or other area wide fee schedules to be used for payment of the following services that were previously on a reasonable charge basis:

- Medical supplies.
- Home dialysis supplies and equipment (as defined in section 1881(b)(8) of the Act).
- Therapeutic shoes.
- Parenteral and enteral nutrients, equipment, and supplies (PEN).
- Electromyogram devices.
- Salivation devices.
- Blood products.
- Transfusion medicine.

For Medicare payment purposes, we interpret the category ''medical supplies'' under section 1842(s) of the Act to include all other items paid on a reasonable charge basis as of 1997 that do not fall under any of the other categories listed in section 1842(s) of the Act. We believe that section 1842(s) of the Act is intended to provide authority for establishing fee schedules for all of the remaining, and relatively small number of items and services still paid for on a reasonable charge basis at the time of enactment in 1997. In light of this provision, we generally consider ''intraocular lenses'' to be paid as ''medical supplies.'' Therefore, in addition to including splints and casts under this category, we also proposed to include intraocular lenses inserted in a physician's office for the purpose of implementing this specific section. Although we recognize the terms ''intraocular lenses'' and ''medical supplies'' are separately identified under § 414.202, we note that such terms are listed for purposes of defining what constitutes orthotic and prosthetic devices (that is, these terms are excluded from such definition), and not intended to suggest these are mutually exclusive things. Accordingly, we do not believe we are precluded from establishing fee schedules for IOLs under the category of medical supplies under section 1842(s) of the Act.

Section 1842(s)(1) of the Act provides that the fee schedules for the services listed above are to be updated on an annual basis by the percentage increase in the CPI–U (United States city average) for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Total payments for the initial year of the fee schedules must be budget-neutral, or approximately equal to the estimated total payments that would have been made under the reasonable charge payment methodology. As explained below, we used this authority to establish fee schedules for parental and enteral nutrition (PEN) items and services for use in paying claims with dates of service on or after January 1, 2002.

On July 27, 1999, we published a notice of proposed rulemaking (64 FR 40534) to establish fee schedules for PEN items and services, splints and casts, intraocular lenses (IOLs) inserted in a physician's office, and various other items and services for which section 1842(s) of the Act provided authority for replacing the reasonable charge payment methodology with fee schedules. After reviewing public comments on the proposed rule, we decided to move ahead with a final rule establishing fee schedules for the Parenteral and Enteral Nutrition (PEN) items and services, but not the other items and services, primarily related to concerns regarding data used for calculating fee schedule amounts for items and service that are no longer paid on a reasonable charge basis. The final rule for implementing the fee schedules for PEN items and services was published on August 28, 2001 (66 FR 45173). For splints and casts, national reasonable charge amounts, updated on an annual basis by the IIC, have been used to pay for the splint and cast materials. Converting these amounts to national fee schedule amounts that are updated by the same index factor used in updating the reasonable charge amounts would result in no change in payment, or 100 percent budget-neutrality. Currently, very few IOLs are inserted in a physician's office nationally. In 2011, total allowed charges for 437 IOLs furnished to 287 beneficiaries equaled $75,914. Since IOLs are considerably low volume items furnished by very few suppliers nationally, there are some states where none of these items are furnished; therefore, charge data for use in calculating prevailing charges, even at the state level, are not available and budget-neutrality is not an issue. If the national average allowed amount for these items were used as the fee schedule amount for the few IOLs that are still inserted in a physician's office, we did not believe that total allowed charges in the first year of the fee schedule would be significantly different than what would otherwise be paid nationally under the current reasonable charge payment methodology. For 2011, the national average allowed charge for covered claims for the 287 beneficiaries receiving IOLs inserted in a physician's office was $174 ($75,914 ÷ 437). In some cases, the allowed charge for specific claims in 2011 was less than $174 and in other cases the allowed charge was more than $174. However, given the low volume of items furnished nationally, the budget impact of paying all of the approximately 437 claims based on the national average allowed amount would be negligible. We believe establishing budget-neutral fee schedule amounts for splints and casts, and IOLs inserted in a physician's office would save government resources in calculating the reasonable charge payment for the low volume items. Therefore, in the proposed rule (78 FR 40878 through 40879), we proposed to establish fee schedules for these items effective for paying claims with dates of service on or after January 1, 2014.

B. Summary of the Proposed Provisions and Responses to Comments on the Implementation of Budget Neutral Fee Schedules for Splints, Casts and IOLs

For the reasons we articulated above, we proposed (78 FR 40879), under section 1842(s) of the Act, to implement fee schedules for splints and casts, and IOLs inserted in a physician's office falling under the category of medical supplies. In addendum C of the proposed rule (78 FR 40879), which can be found on *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/CMS-1526-P-Addendum-C.pdf,* we inserted the current 2013 reasonable charge amounts for splints, casts and IOLs inserted in a physician's office. The 2013 reasonable charge amounts for splints and casts are gap-filled reasonable charges updated by the CPI-U factor ending with June of the preceding year, in this case June 2012. The 2013 reasonable charge amounts for IOLs inserted in a physician's office that are described by HCPCS code V2632 are estimates of the 2012 average allowed charges for these items and services. With regard to other HCPCS codes for IOLs inserted in a physician's office, Medicare payment was made for one claim for code V2631 over the past ten years and ten claims for code V2630 over the past 6 years. We indicated in Appendix C of the proposed rule that we would gap-fill the fee schedule amounts for HCPCS codes V2630 and V2631. In the case of fee schedule amounts for other prosthetic devices

paid for in accordance with the rules at section 1834(h) of the Act, the fee schedule amounts are gap-filled using fee schedule amounts for comparable items or supplier price lists in accordance with program instructions related to gap-filling fee schedule amounts for DMEPOS items and services located at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. 100–04). We would not have the entire calendar year estimates for 2013 average allowed charge for IOLs inserted in a physician's office in order to implement the fee schedule amounts for these items effective for paying claims with dates of service on or after January 1, 2014; therefore, we stated we would use the estimate of the 2012 average allowed charge including the percentage increase in the CPI–U for the 24-month period ending with June of 2012, which is 1.7 percent, and June of 2013, which is 1.8 percent, to update the fee-schedule amounts for splints and casts (78 FR 40879). Specifically, we proposed to amend 42 CFR § 414.106 and § 414.100 to include the general rule for updating the fee schedules for splints, casts and IOLs inserted in a physician's office. We also proposed to add § 414.106 and § 414.108 to set forth the fee schedule methodology and updates as explained above for splints, casts, and IOLs inserted in a physician's office. Subject to coinsurance and deductible rules, Medicare payment for these services is to be equal to the lower of the actual charge for the item or the amount determined under the applicable fee schedule payment methodology.

For splints and casts, we proposed national fee schedule amounts for items furnished from January 1, 2014, thru December 31, 2014, based on 2013 reasonable charges updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June 2013 (78 FR 40879). For subsequent years, we proposed that the fee schedule amounts would be updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act (78 FR 40879).

For IOLs inserted in a physician's office, we proposed national fee schedule amounts for items furnished from January 1, 2014, thru December 31, 2014, based on the national average allowed charge for the item from January 1, 2012 through December 31, 2012, updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 24-month period ending with June 2013. For subsequent years, the fee schedule amounts would be updated by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act.

We received one comment on the proposal to implement budget-neutral fee schedules for splints, casts and IOLs inserted in a physician's office from an advocacy group representing doctors of optometry. The issues raised in the comment were specifically in regard to IOLs. We received no comments on the topic of splints and casts.

Comment: The commenter indicated that the statute does not provide specific authority for implementing fee schedules for IOLs as part of the authority for implementing fee schedules for the general category of ''medical supplies'' listed under section 1842(s) of the Act. The commenter indicates that under 42 CFR 414.202, the list of items not considered prosthetics or orthotics separately identifies ''medical supplies'' and ''intraocular lenses,'' and that if intraocular lenses were considered ''medical supplies,'' they would not need to be separately listed in § 414.202.

Response: We disagree with this comment. The terms ''medical supplies'' and ''intraocular lenses'' are listed in 42 CFR 414.202 for the purpose of implementing section 1834(h)(4)(C) of the Act. The regulation clearly states that the definitions in 42 CFR 414.202 are for the purposes of Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices. The term ''medical supplies'' referred to in section 1834(h)(4)(C) of the Act include catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are specifically furnished by a home health agency. As a result, we implemented § 414.202 consistent with the payment rules under section 1834(h) of the Act, which identifies a different group of items of ''medical supplies'' than those addressed under section 1842(s) of the Act. As we stated in the proposed rule (78 FR 40878), although the terms ''intraocular lenses'' and ''medical supplies'' are separately identified under § 414.202 for purposes of defining what constitutes orthotic and prosthetic devices, the regulation is not intended to suggest these are mutually exclusive items. Indeed, under the Medicare statute and regulations, items and services are identified specifically and generally, as part of larger categories.

We believe our interpretation of this statutory authority is reasonable and that we have been consistent in our interpretation of section 1842(s) of the Act in the past. As we noted above, we proposed to adopt fee schedules for IOLs under this authority in 1999, though we declined to finalize this proposal (64 FR 40534 (July 27, 1999). We continue to interpret the category ''medical supplies'' to include IOLs, splints and casts, and other items paid for on a reasonable charge basis that are not specifically listed as separate categories under section 1842(s). We believe that the intent of section 1842(s) is to provide authority for phasing out reasonable charge payments for those few items and services still paid in accordance with these old payment rules, and therefore, we generally consider ''intraocular lenses'' to be paid as ''medical supplies.'' Accordingly, we do not believe we are precluded from establishing fee schedules for IOLs under the category of medical supplies under section 1842(s) of the Act.

Comment: The commenter also suggested that if we continue with converting the IOLs to fee schedule amounts, then we should delay implementation of the fee schedule amounts so that suppliers of IOLs have more time to learn about and prepare for the change in payment.

Response: We disagree that extra time is needed to prepare for implementation of fee schedule amounts that the statute specifies must be initially budget neutral. Our review of CY 2012 submitted charge data indicates that there is little variation in the charges submitted for the items that have enough claims data information to implement the fee schedule amounts.

Comment: The commenter agreed with us that fee schedule amounts should be a national amount rather than local because several states have no suppliers of IOLs.

Response: We appreciate this comment and have made the fee schedules of IOLs a national fee schedule amount.

After careful review of the comment received and for the reasons we discussed previously, we are finalizing the implementation of budget-neutral fee schedules for splints, casts and IOLs inserted in a physician's office. Part 414, Subpart C of the regulations at 42 CFR are being revised to indicate that the fee schedule amounts for payment for splints and casts furnished in 2014, effective April 1, 2014, is the reasonable

charge amount for 2013, updated by the percentage increase in the CPI–U for the 12-month period ending with June of 2013. We will start paying the national fee schedule amounts specified in Table 11 below for these items on April 1, 2014. Part 414, Subpart C of the regulations at 42 CFR are being revised to indicate that the fee schedule amounts for payment for splints and casts furnished on April 1, 2014, is the reasonable charge amount for 2013, updated by the percentage increase in the CPI–U for the 12-month period ending with June of 2013, and that the fee schedule amounts for payment for IOL inserted in a physician's office on April 1, 2014, is the national average allowed charge for the IOL furnished in calendar year 2012, updated by the percentage increase in the CPI–U for the 24-month period ending with June of 2013. For each year subsequent to 2014 for splints and casts, and IOLs inserted in a physician's office, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

TABLE 11—FINAL FEE SCHEDULE AMOUNTS EFFECTIVE APRIL 1, 2014

2014 Fee Schedule Amounts for Splints and Casts							
A4565	$8.41	Q4013	$15.40	Q4026	$115.34	Q4039	$8.05
Q4001	47.85	Q4014	25.97	Q4027	18.48	Q4040	20.13
Q4002	180.82	Q4015	7.71	Q4028	57.69	Q4041	19.55
Q4003	34.36	Q4016	12.98	Q4029	28.25	Q4042	33.37
Q4004	118.96	Q4017	8.91	Q4030	74.36	Q4043	9.78
Q4005	12.67	Q4018	14.19	Q4031	14.12	Q4044	16.69
Q4006	28.55	Q4019	4.46	Q4032	37.18	Q4045	11.35
Q4007	6.34	Q4020	7.11	Q4033	26.35	Q4046	18.25
Q4008	14.27	Q4021	6.59	Q4034	65.54	Q4047	5.66
Q4009	8.46	Q4022	11.89	Q4035	13.17	Q4048	9.13
Q4010	19.04	Q4023	3.31	Q4036	32.78	Q4049	2.07
Q4011	4.22	Q4024	5.95	Q4037	16.07		
Q4012	9.53	Q4025	36.94	Q4038	40.27		
2014 Fee Schedule Amounts for Intraocular Lenses Implanted in a Physician's Office							
V2630	***	V2631	***	V2632	111.81		

*** No claims submitted in 2012
Note: These fee schedule amounts are effective April 1, 2014.

VII. DMEPOS Technical Amendments and a Correction

A. Background

Medicare pays for various DMEPOS items and services based on payment rules that are set forth in section 1834 of the Act and 42 CFR Part 414, Subpart D. We proposed to make three minor, conforming technical amendments to the existing DMEPOS payment regulations (the title of Subpart D and 42 CFR § 414.200 and § 414.226) (78 FR 40879 through 40880).

B. Summary of the Proposed Provisions and Responses to Comments on the Proposed Technical Amendments and a Correction

We proposed to make three minor, conforming technical amendments and a correction to the existing DMEPOS payment regulations as follows (78 FR 40879 through 40880):

- We proposed to modify the title of ''Subpart D—Payment for Durable Medical Equipment, Prosthetic and Orthotic Devices'' to read ''Subpart D—Payment for Durable Medical Equipment, Prosthetic and Orthotic Devices, and Surgical Dressings'' to reflect that payment for surgical dressings is addressed under this subpart at § 414.220(g).
- In subpart § 414.200, we proposed to modify the phrase ''This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.'' as follows: ''This subpart implements sections 1834 (a), (h), and (i) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment, prosthetic and orthotic devices, and surgical dressings for Medicare beneficiaries.'' The Omnibus Budget Reconciliation Act of 1993 amended section 1834 of the Act by adding subsection (i), mandating payment on a fee schedule basis for surgical dressings. Although § 414.220(g) addresses this requirement, the regulation at § 414.200 was not updated to indicate that this subpart implements section 1834(i) in addition to sections 1834(a) and (h) of the Act.
- Section 1834(a)(9)(D) of the Act provides authority for creating separate classes of oxygen and oxygen equipment. Section 1834(a)(9)(D)(ii) of the Act prohibits CMS from creating separate classes of oxygen and oxygen equipment that result in expenditures for any year that are more or less than expenditures which would have been made if the separate classes had not been created. In other words, the new classes and payment amounts for oxygen and oxygen equipment must be established so that creating the new classes is annually budget-neutral. In November 2006, we published a final rule (CMS–1304–F) establishing separate classes for oxygen and oxygen equipment and included a methodology for meeting the requirements of section 1834(a)(9)(D)(ii) of the Act by applying annual reductions to the monthly fee schedule amounts for the stationary oxygen equipment class at § 414.226(c)(1)(i) in order to establish budget neutrality for total oxygen and oxygen expenditures for all oxygen classes. Increases in expenditures for oxygen and oxygen equipment that are attributed to higher payment amounts established for new classes of oxygen and oxygen equipment are offset by reducing the monthly payment amount for stationary oxygen equipment. Due to a drafting error in the regulation text portion of the November 2006 final rule, CMS–1304–F (71 FR 65933), 42 CFR § 414.226(c)(6) needs to be corrected. The regulation text at § 414.226(c)(6) mistakenly states that budget neutrality should be achieved by adjusting all

oxygen class rates. Section 414.226(c)(6) should read that only the stationary oxygen equipment rate should be adjusted to achieve budget neutrality. Therefore, we proposed to revise § 414.226(c)(6) to read as follows: ''Beginning in 2008, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.''

• We also proposed a technical correction to existing 42 CFR § 414.102(c) to conform the regulation governing parenteral and enteral (PEN) nutrients, equipment and supplies covered item fee schedule update with the statute. Although section 1842(s)(1)(B)(ii) of the Act is self-implementing, the PEN nutrients, equipment and supplies payment regulations at 42 CFR 414 Subpart C were not updated to reflect the application of the multifactor productivity adjustment to the CPI–U update factor for 2011 and subsequent calendar years. Therefore, we are revising § 414.102(c) of our regulations to specify that for years 2003 through 2010, the PEN items and services fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year. For each year subsequent to 2010, the PEN items and services fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment describe in section 1886(b)(3)(B)(xi)(II) of the Act.

We received no public comments on the DMEPOS proposals for technical amendments and a correction. Therefore, for the reasons we previously explained, we are finalizing our proposed modifications to the above regulations.

VIII. Waiver of Delayed Effective Date

In the absence of an appropriation for FY 2014 or a Continuing Resolution, the federal government funding lapsed on October 1, 2013. During the funding lapse, which lasted from October 1, 2013 through October 16, 2013, only excepted operations continued, which largely excluded work on this final rule. Accordingly, most of the work on this final rule was not completed in accordance with our usual schedule for final CY payment rules, which aims for an issuance date of November 1 followed by an effective date of January 1 to ensure that the policies are effective at the start of the calendar year to which they apply.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. We believe it would be contrary to the public interest to delay the effective date of the ESRD PPS and ESRD QIP portions of this final rule. The ESRD PPS is a calendar-year payment system, and we typically issue the final rule by November 1 of each year to ensure that the payment policies for the system are effective on January 1, the first day of the calendar year to which the policies are intended to apply. CMS also includes in the ESRD PPS final rule its policies for the ESRD QIP because the performance of dialysis facilities under the ESRD QIP has a direct effect on that facility's payment under the ESRD PPS. A dialysis facility's ESRD PPS payment in 2016 will be based, in part, on the policies finalized in this final rule, including the requirement that the facility report certain quality measures beginning January 1, 2014. If the effective date of this final rule is delayed by 60 days, the ESRD PPS and the ESRD QIP policies adopted in this final rule will not be effective until after January 1, 2014. This would be contrary to the public's interest in ensuring that dialysis facilities receive appropriate payments in a timely manner, and that their payments in 2016 properly and completely reflect their performance on quality measures in 2014. In addition, in the case of the ESRD PPS, section 1881(b)(14)(I) of the Act, as added by section 632(a) of the ATRA, requires that, for services furnished on or after January 1, 2014, the Secretary shall make reductions to the single payment for renal dialysis services to reflect the Secretary's estimate of the change in utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs) by comparing per patient utilization data from 2007 with such data from 2012. We are finalizing the drug utilization adjustment in this final rule, and in order to adhere to the statutory requirement that the adjustment apply to services furnished on or after January 1, 2014, this final rule must be effective on that date. We note that our waiver of the delayed effective date only applies to the ESRD PPS and ESRD QIP policies that are adopted in this final rule. The delayed effective date for the DMEPOS policies is not waived and these policies will be effective on April 1, 2014, for provisions that clarify the grandfathering provision related to the 3-year MLR for DME, the clarification of the definition of routinely purchased DME, fee schedules for splints and casts, and IOLs inserted in a physician's office, and technical amendments and corrections to existing regulations related to payment for DMEPOS items and services. For the items that we identified that will be reclassified as capped rental items and paid for in accordance with the rules set forth in 42 CFR 414.229, such reclassifications will be effective in three phases beginning on or after April 1, 2014. Items will be reclassified as capped rental items effective April 1, 2014, in all areas of the country if the item is not included in a Round 2 or Round 1 Recompete DMEPOS CBP. Items will be reclassified as capped rental items effective July 1, 2016, in all areas of the country if the item is included in a Round 2 CBP and not a Round 1 Recompete CBP. Items will be classified as capped rental items effective July 1, 2016, when it is furnished in any area of the country that is not in one of the 9 Round 1 Recompete areas if the item is included in a Round 1 Recompete CBP. Finally, items will be classified as capped rental items effective January 1, 2017, when it is furnished in one of the 9 Round 1 Recompete areas if the item is included in a Round 1 Recompete CBP.

IX. 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 requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

In section II.D. of this final rule, we changed the regulatory text for the ESRD PPS in CY 2014. However, the changes that are being made do not impose any new information collection requirements.

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.

1. ESRD QIP

a. Expanded ICH CAHPS Reporting Measure for PY 2016 and Future Payment Years of the ESRD QIP

As stated above in section III.C.2.a of this final rule, we proposed to include in the PY 2016 ESRD QIP an expanded ICH CAHPS reporting measure, which assesses facility usage of the ICH CAHPS survey. Unlike the ICH CAHPS reporting measure finalized in the CY 2013 ESRD PPS final rule (77 FR 67480 through 67481), the proposed expanded ICH CAHPS reporting measure would require facilities to report (via a CMS-approved vendor) survey data to CMS once for PY 2016, and, for PY 2017 and beyond, to administer (via a CMS-approved vendor) a second ICH CAHPS survey and report the second set of survey data to CMS. Therefore, for PY 2016, we estimated the burden associated with this requirement to be the time and effort necessary for facilities to submit (via a CMS-approved vendor) survey results to CMS. For PY 2017 and future payment years, we estimated the burden associated with this requirement is the time and effort necessary for facilities to administer (via a CMS-approved vendor) a second ICH CAHPS survey and submit (via a CMS-approved vendor) the survey results to CMS.

We estimated that approximately 5,506 facilities will treat adult, in-center hemodialysis patients in PY 2016 and, therefore, will be eligible to receive a score on this measure. We further estimated that all 5,506 facilities will report (via a CMS-approved vendor) survey results to CMS, and that it will take each vendor approximately 5 minutes to do so. Therefore, the estimated total annual burden associated with meeting the measure requirements in PY 2016 is 459 hours [(5/60) hours x 5,506 facilities). According to the Bureau of Labor Statistics, the mean hourly wage of a registered nurse is $32.66/hour. Since we anticipate nurses (or administrative staff who would be paid at a lower hourly wage) will submit this data to CMS, we estimated that the aggregate cost of this requirement for PY 2016 will be $14,991 (459 hours x $32.66/hour).

We estimated that approximately 5,693 facilities will treat adult, in-center hemodialysis patients in PY 2017 and, therefore, will be eligible to receive a score on this measure. We estimated that all 5,693 facilities will administer the ICH CAHPS survey through a third-party vendor and arrange for the vendor to submit the data to CMS. We estimated that it would take each patient 30 minutes to complete the survey (to account for variability in education levels) and that approximately 103 surveys per year would be taken per facility. Interviewers from each vendor would therefore spend a total of approximately 52 hours per year with patients completing these surveys (0.5 hours * 103 surveys) or $1,698 (52 hours × $32.66) for an estimated annual burden of $9,666,714 ($1,698 per facility × 5,693 facilities). We previously estimated that the aggregate cost of submitting survey data to CMS is $14,991. Therefore, we estimated that the total annual burden for ESRD facilities to comply with the collection of information requirements associated with the proposed expanded ICH CAHPS measure for PY 2017 and future payment years would be approximately $9,681,705 ($9,666,714 + $14,991) across all ESRD facilities.

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

Comment: One commenter asked CMS to take a global look at the burden placed on dialysis facilities for all aspects of the ESRD QIP.

Response: We appreciate the commenter's suggestion and we clarify that we take an overarching view of provider burden each year during the rulemaking process when we conduct analyses associated with the Collection of Information Requirements.

Comment: One commenter stated that the aggregate costs associated with the collection of information requirements are accurate, but that the costs are too high for facilities and amount to an unfunded mandate.

Response: Although we recognize that the ESRD QIP imposes significant costs to providers, we disagree that those costs are too high or amount to an unfunded mandate. We continue to believe that the ESRD QIP drives improvements in the quality of care for patients with ESRD. We also believe that the benefits for patients far outweigh the costs for providers, and that the ESRD QIP does not amount to an unfunded mandate because it is tied to the reimbursements providers receive through the ESRD Prospective Payment System.

Comment: A few commenters did not agree with the cost estimates in the collection of information requirements because it does not account for the burdens associated with entering data into CROWNWeb, as CROWNWeb is not fully functional.

Response: We understand that members of the ESRD community have reported difficulties accessing and using the CROWNWeb system. As stated above, we are working to address known defects in CROWNWeb, and we look forward to continuing to work with facilities to minimize the burden of entering data into CROWNWeb. We note that entering data in CROWNWeb is a Condition for Coverage for dialysis facilities (§ 494.180(h)), and that CROWNWeb supports the 1995 Paperwork Reduction Act. We will take the commenters' suggestions under advisement in the future when estimating burdens associated with collection of information requirements

Comment: Several commenters did not agree with the cost estimates for the collection of information requirements for the ICH CAHPS measure. These commenters stated that the cost estimates do not accurately capture the cost of using a third party vendor, and that these costs can vary significantly.

Response: We agree that the cost estimates for the ICH CAHPS measure did not include the costs associated with contracting a third-party vendor to conduct the survey. As noted above (see Section III.C.2.a), the costs of these contracts vary significantly. Therefore, we assumed that third party vendors would employ registered nurses to administer the survey. We recognize the estimation method may not be entirely accurate, but we believe it is the most reliable way to generate a single cost estimate.

b. Data Validation Requirements for the PY 2016 ESRD QIP

Section III.C.13 of the proposed rule outlines our data validation proposals. We proposed to randomly sample records from 300 facilities; each

sampled facility would be required to produce up to 10 records; and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with this validation requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with these requirements. If 300 facilities are tasked with providing the required documentation, the estimated annual burden for these facilities across all facilities would be 750 hours (300 facilities × 2.5 hours) at a total of $24,495 (750 hours × $32.66/hour) or $81.65 ($24,495/300 facilities) per facility in the sample.

We requested comments on this proposal. We did not receive any comments on this proposal.

2. The clarification of the definition of routinely purchased DME does not contain any new information collection requirements.

3. The clarification of the 3-year MLR for DME does not contain any new information collection requirements.

4. The implementation of Budget-Neutral Fee Schedules for Splints, Casts and IOLs does not contain any new information collection requirements.

X. 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. Even though this rule has been designated non-economically significant under section 3(f)(1) of Executive Order 12866, it 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 services in CY 2014, implements the fourth year of the ESRD PPS transition, and makes several policy changes to the ESRD PPS. These include updates and changes to the ESRD PPS base rate, the wage index values, the wage index budget-neutrality adjustment factor, the home dialysis training add-on payment, and the outlier payment policy. This rule will also implement section 1881(b)(14)(I), which requires the Secretary, by comparing per patient utilization from 2007 with such data from 2012, to reduce the single payment amount to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2014.

This rule finalizes to implement the ESRD QIP for PY 2016 and beyond by finalizing proposals to adopt measures, scoring, and payment reductions to incentivize improvements in dialysis care as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2016 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2015.

In addition, this final rule clarifies the grandfathering provision related to the 3-year MLR for DME, provides clarification of the definition of routinely purchased DME and reclassifies certain items of DMEPOS, and implements budget-neutral fee schedules for splints and casts, and IOLs inserted in a physician's office. Finally, this final rule makes a few technical amendments and corrections to existing regulations related to payment for DMEPOS items and services.

3. Overall Impact

We estimate that the revisions to the ESRD PPS will result in no increase in payments to ESRD facilities in CY 2014. This includes the amount associated with the increase in the ESRDB market basket reduced by the productivity adjustment, updates to outlier threshold amounts, the inclusion of the Pacific Rim ESRD facilities, updates to the wage index, the change from payments based on 25 percent composite rate system and 75 percent ESRD PPS to 100 percent ESRD PPS for those facilities that opted to be paid under the blend, and the drug utilization adjustment required by section 1881(b)(14)(I), as added by section 632(a) of ATRA.

For PY 2016, we estimate that the requirements related to the ESRD QIP will cost approximately $39,486 ($14,991 for ICH CAHPS measure reporting + $24,495 data validation requirements) and the predicted payment reductions will equal about $15.1 million to result in a total impact from the ESRD QIP requirements of approximately $15.2 million. For PY 2017 and future payment years, we expect the costs associated with the collection of information requirements for the expanded ICH CAHPS measure in the proposed ESRD QIP to be approximately $9.7 million.

We estimate that the changes for implementing the fee schedule amounts from reasonable charge payments will be budget neutral and will have no impact to DMEPOS providers of splints, casts and IOLs inserted in a physician's office.

We estimate that our clarification of the definition of routinely purchased DME and re-classification of certain items as cap rental items would impact certain DMEPOS providers. The estimated overall impact on payments to suppliers is furnished in table 17 below. In addition, suppliers will incur additional expenses in submitting monthly claims for payment on a rental basis versus a single claim for payment on a purchase basis. Suppliers will be positively impacted by this change because they will not have to replace equipment in their inventory as often since they retain title to rented items that are not used on a continuous basis for 13 months by Medicare beneficiaries. We estimate that the clarification of the 3-year MLR for DME would have no impact on DMEPOS suppliers.

B. Detailed Economic Analysis

1. CY 2014 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2013 to estimated payments in CY 2014. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2013 and CY 2014 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 2013 update of CY 2012 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2012 claims to 2013 and 2014 using various

updates. The updates to the ESRD PPS base rate are described in section II.C of this final rule. For those providers that opted to be paid a blended payment amount during the transition, we used the price growth between the established 2013 and 2012 composite rate, drug add-on and part D add-on amounts. In addition we used the CY 2010 amounts as the CY 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 is not increased. Since some ESRD facilities received blended payments during the transition and received payment for ESRD drugs and biologicals based on their average sales price plus 6 percent (ASP+6), we used price growth for the top twelve drugs and biologicals based on ASP+6 percent 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. We updated payments for laboratory tests paid through the laboratory fee schedule to 2013 using the statutory required update. Table 12 shows the impact of the estimated CY 2014 ESRD payments compared to estimated payments to ESRD facilities in CY 2013.

TABLE 12—IMPACT OF CHANGES IN PAYMENTS TO ESRD FACILITIES FOR THE CY 2014 ESRD PPS FINAL RULE

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

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2014 changes in outlier policy [4] (percent)	Effect of 2014 changes in wage Indexes (percent)	Effect of 2014 changes in blend of payments (percent)	Effect of 2014 changes in market basket minus productivity update (percent)	Effect of 2014 changes in base rate due to drug utilzation [5] (percent)	Effect of total 2014 changes (percent)
	A	B	C	D	E	F	G	H
All Facilities	5,873	42.7	0.4	0.0	0.2	2.8	−3.3	0.0
Type:								
Freestanding	5,362	39.6	0.4	0.0	0.1	2.8	−3.3	0.0
Hospital based	511	3.1	0.3	0.1	0.9	2.8	−3.2	0.8
Ownership Type:								
Large dialysis organization	4,023	29.7	0.5	0.0	0.0	2.8	−3.3	−0.1
Regional chain	813	6.2	0.4	0.1	0.4	2.8	−3.3	0.2
Independent	601	4.2	0.2	0.1	0.7	2.8	−3.3	0.4
Hospital based [1]	424	2.6	0.3	0.1	0.9	2.8	−3.2	0.7
Unknown	12	0.1	0.4	−0.1	0.2	2.8	−3.3	−0.1
Geographic Location:								
Rural	1,283	7.0	0.4	−0.1	0.2	2.8	−3.3	−0.1
Urban	4,590	35.7	0.4	0.0	0.2	2.8	−3.3	0.0
Census Region:								
East North Central	962	6.4	0.5	−0.1	0.2	2.8	−3.3	−0.1
East South Central	487	3.2	0.5	−0.2	0.0	2.8	−3.3	−0.2
Middle Atlantic	651	5.1	0.4	0.4	0.3	2.8	−3.3	0.6
Mountain	346	2.0	0.3	−0.1	0.2	2.8	−3.3	−0.1
New England	172	1.4	0.4	0.1	0.1	2.8	−3.3	0.0
Pacific [2]	692	5.9	0.2	0.6	0.1	2.8	−3.3	0.3
Puerto Rico and Virgin Islands	43	0.3	0.4	−2.3	0.4	2.8	−3.3	−2.1
South Atlantic	1,307	9.9	0.5	−0.3	0.2	2.8	−3.3	−0.2
West North Central	426	2.2	0.4	−0.2	0.4	2.8	−3.3	0.0
West South Central	787	6.2	0.5	−0.2	0.2	2.8	−3.3	−0.2
Facility Size:								
Less than 4,000 treatments [3]	1,090	3.1	0.4	−0.1	0.3	2.8	−3.3	0.1
4,000 to 9,999 treatments	2,167	11.1	0.4	−0.1	0.2	2.8	−3.3	−0.1
10,000 or more treatments	2,431	27.5	0.4	0.0	0.2	2.8	−3.3	0.0
Unknown	185	1.0	0.6	−0.2	0.3	2.8	−3.3	0.0
Percentage of Pediatric Patients:								
Less than 2%	5,759	42.3	0.4	0.0	0.2	2.8	−3.3	0.0
Between 2% and 19%	47	0.4	0.3	0.1	0.5	2.8	−3.3	0.4
Between 20% and 49%	7	0.0	0.1	−0.2	0.3	2.8	−3.3	−0.4
More than 50%	60	0.1	0.1	0.0	0.0	2.8	−3.3	−0.5

1. Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
2. Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.
3. Of the 1,088 ESRD facilities with less than 4,000 treatments, only 362 qualify for the low-volume payment adjustment. The low-volume payment adjustment is mandated by Congress, and is not applied to pediatric dialysis treatments. The impact to these low-volume ESRD facilities is a 0.4% increase in payments.
4. Includes the effect of including the Pacific Rim ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands into the ESRD PPS.
5. Includes the effect of adjusting the training add-on payment to $50.16, and the effect of an $8.16 decrease in the base rate due to the drop in drug utilization.
Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

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 changes to the outlier payment policy described in section II.B.6. of this final rule is shown in column C. For CY 2014, 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 0.1 percent to a 0.6 percent increase. All ESRD facility types are anticipated to experience a positive effect in their estimated CY 2014 payments as a result of the outlier policy changes.

Column D shows the effect of the wage index on ESRD facilities and reflects the CY 2014 wage index values for the ESRD PPS payments. ESRD facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 2.3 percent decrease in estimated payments in CY 2014. 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 2014). The other categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.3 percent decrease to a 0.6 percent increase due to the update of the wage index.

Column E shows the effect of the change in the blended payment percentage from 25 percent of payments based on the composite rate system and 75 percent based on the ESRD PPS in CY 2013, to 100 percent based on the ESRD PPS in CY 2014, for those facilities that choose to be paid under the transition. The impact on all facilities would be a 0.2 percent increase in estimated payments. The estimated impacts of the change in the blend ranges from a 0.0 percent to 0.9 percent increase.

Column F shows the effect of the ESRDB market basket increase minus productivity adjustment. The impact on all facilities would be a 2.8 percent increase.

Column G shows the effect of the drug utilization adjustment required by section 1881(b)(14)(I) of the Act. For CY 2014, the impact on all facilities as a result of the $8.16 decrease to the base rate, as described in section II.B.2.a, would be a 3.3 percent decrease in estimated payments. The estimated impact ranges from 3.2 percent to 3.3 percent decrease.

Column H reflects the overall impact (that is, the effects of the outlier policy changes, the wage index, the effect of the blended payment percentage change, the effect of the ESRDB market basket increase minus productivity adjustment, and the effect of the drug utilization adjustment required by section 1881(b)(14)(I)). We expect that overall ESRD facilities will experience a 0.0 percent increase in estimated payments in 2014. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 2.1 percent decrease in their estimated payments in CY 2014. This larger decrease is primarily due to the negative impact of the wage index. The other categories of types of facilities in the impact table show impacts ranging from a decrease of 0.5 percent to an increase 0.8 percent in their 2014 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 2014, the fourth year of the ESRD PPS, we estimate that the ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2014 will be approximately $8.8 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 3.1 percent in CY 2014.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0.0 percent overall increase in the final ESRD PPS payment amounts in CY 2014, we estimate that there will be an increase in beneficiary co-insurance payments of 0.0 percent in CY 2014, which translates to approximately $0 million.

e. Alternatives Considered

For this final rule, we considered implementing the full drug utilization adjustment amount in CY 2014. In particular, we could have implemented a one-time reduction of $29.93 to the CY 2014 ESRD PPS base rate. We also considered several transition options. For example, we considered equal reductions over a 3 or 4 year period. We chose to implement the drug utilization adjustment by offsetting the payment update, that is the ESRDB market basket minus productivity increase factor, and other impacts (such as, changes to the outlier thresholds) by a portion of the drug utilization adjustment amount necessary to create an overall impact of zero percent for ESRD facilities from the previous year's payments for CY 2014 and CY 2015. We believe that this approach will minimize disruption in the delivery of critical ESRD services.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2016 ESRD QIP

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS by implementing a ESRD QIP that reduces ESRD PPS payments by up to 2 percent for dialysis facilities that fail to meet or exceed a TPS with respect to performance standards established by the Secretary with respect to certain specified measures. The methodology that we proposed to determine a facility's TPS is described in section III.D.9 of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2016 ESRD QIP would begin with services furnished on January 1, 2016.

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 TPS), approximately 24 percent or 1,390 of the facilities would likely receive a payment reduction in PY 2016. Facilities that do not receive a TPS are not eligible for a payment reduction.

The ESRD QIP impact assessment assumes an initial count of 5,771 dialysis facilities paid through the PPS. Table 13 shows the overall estimated distribution of payment reductions resulting from the PY 2016 ESRD QIP.

TABLE 13—ESTIMATED DISTRIBUTION OF PY 2016 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities (percent)
0.0%	4,483	76.3
0.5%	957	16.3
1.0%	305	5.2
1.5%	70	1.2
2.0%	58	1.0

Note: This table excludes 285 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 on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 14.

TABLE 14—DATA USED TO ESTIMATE PY 2016 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 2012–Dec 2012	Jan 2013–Aug 2013.
Vascular Access Type:		
% Fistula	Jan 2012–Dec 2012	Jan 2013–Aug 2013.
% Catheter	Jan 2012–Dec 2012	Jan 2013–Aug 2013.
Kt/V:		
Adult HD	Jan 2012–Dec 2012	Jan 2013–Aug 2013.
Adult PD	Jan 2012–Dec 2012	Jan 2013–Aug 2013.
Pediatric HD	Jan 2012–Dec 2012	Jan 2013–Aug 2013.
Hypercalcemia	July 2012–Dec 2011	Jan 2013–June 2013.

Clinical measures with less than 11 cases for a facility were not included in that facility's TPS. Each facility's TPS was compared to the estimated minimum TPS and the payment reduction table found in section III.C.11 of this proposed rule. Facilities were required to have a score on at least one clinical measure to receive a TPS. For these simulations, the NHSN Bloodstream Infection in Hemodialysis Outpatients and the reporting measures were not included due to lack of data availability. Therefore, the simulated facility TPSs were calculated using only some of the clinical measure scores. Additionally, since data for the reporting measures were not available, facilities were scored at the median, or 5, for each of the three reporting measures.

To estimate the total payment reductions in PY 2016 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the one year period between January 2012 and December 2012 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 2012 through December 2012 times the estimated payment reduction percentage). For PY 2016 the total payment reduction for all of the 1,390 facilities expected to receive a reduction is approximately $15.1 million ($15,137,161). Further, we estimate that the total costs associated with the collection of information requirements for PY 2016 described in section IX.C.1 of this final rule would be approximately $39.5 thousand for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of $15.2 million ($39,486 + $15,137,161 = $15,176,647) in PY 2016, as a result of the PY 2016 ESRD QIP.

Table 15 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2016. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we propose to use for the PY 2016 ESRD QIP, the actual impact of the PY 2016 ESRD QIP may vary significantly from the values provided here.

TABLE 15—IMPACT OF FINALIZED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2016

	Number of facilities	*Number of treatments 2012 (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	5,873	42.7	5,645	1,390	−0.17
Facility Type:					
Freestanding	5,362	39.6	5,248	1,259	−0.16
Hospital-based	511	3.1	397	131	−0.32
Ownership Type:					
Large Dialysis	4,023	29.7	3,963	966	−0.16
Regional Chain	813	6.2	789	149	−0.13
Independent	601	4.2	563	161	−0.23
Hospital-based (non-chain)	424	2.6	323	112	−0.34
Unknown	12	0.1	7	2	−0.28
Facility Size:					
Large Entities	4,836	35.9	4,752	1,115	−0.15
Small Entities[1]	1,025	6.7	886	273	−0.27
Unknown	12	0.1	7	2	−0.28
Rural Status:					
(1) Yes	1,283	7.0	1,233	288	−0.16
(2) No	4,590	35.7	4,412	1,102	−0.18
Census Region:					
Northeast	806	6.5	772	201	−0.20
Midwest	1,359	8.6	1,286	391	−0.21
South	2,544	19.2	2,490	570	−0.15
West	1,020	7.9	992	186	−0.14

TABLE 15—IMPACT OF FINALIZED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2016—Continued

	Number of facilities	Number of treatments 2012 (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)
U.S. Territories[2]	144	0.5	105	42	−0.33
Census Division:					
East North Central	962	6.4	904	310	−0.24
East South Central	487	3.2	476	102	−0.13
Middle Atlantic	651	5.1	615	165	−0.20
Mountain	346	2.0	331	65	−0.16
New England	172	1.4	164	39	−0.20
Pacific	692	5.9	674	126	−0.13
South Atlantic	1,307	9.9	1,269	321	−0.17
West North Central	426	2.2	402	85	−0.15
West South Central	787	6.2	769	152	−0.13
U.S. Territories[2]	43	0.3	41	25	−0.50
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,090	3.1	938	277	−0.26
4,000–9,999 treatments	2,167	11.1	2,147	440	−0.13
Over 10,000 treatments	2,431	27.5	2,422	629	−0.17
Unknown	185	1.0	138	44	−0.24

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] Based on claims data through December 2012.

b. Alternatives Considered for the PY 2016 ESRD QIP

In the proposed PY 2016 ESRD QIP, we selected measures that we believe are important indicators of patient outcomes and quality of care as discussed in section III.C of this final rule. Poor management of anemia, for example, can lead to avoidable hospitalizations, decreased quality of life, and death. In order to provide strong incentives to improve patient outcomes in this clinically important area, we considered proposing a clinical measure for Pediatric Iron Therapy. However, upon further review we recognized that we lacked the necessary baseline data to establish achievement thresholds, performance standards, and benchmarks. We, therefore, proposed a reporting measure in order to gather the data we will need to introduce a clinical measure in the future. In the case of the NHSN Bloodstream Event in Hemodialysis Outpatient measure, we considered proposing a reporting measure instead of a clinical measure, because we lacked the necessary baseline data to establish achievement thresholds, performance standards, and benchmarks. However, we decided not to do so. Due to the great impact hospital acquired infections have upon patients and the industry, we believe it is important to begin assessing facilities on the number of these events rather than on merely whether they report these events as soon as possible. Similarly, in the case of the Patient Informed Consent for Anemia Treatment measure, we considered proposing a reporting measure instead of a clinical measure, because we lacked the necessary baseline data to establish achievement thresholds, performance standards, and benchmarks. We decided not to do because we believe that providing counseling on the risks and benefits of anemia treatment, and seeking informed consent for such treatment, is already a standard of clinical care in the ESRD provider community. We also considered proposing the Standardized Hospitalization Ratio Admissions (SHR) measure and the Standardized Mortality Ratio (SMR) measure as reporting measures for the PY 2016 ESRD QIP. We decided not to do so due to outstanding concerns about the measures' validity and reliability. As an alternative, we proposed the Comorbidity reporting measure to provide a reliable source of data that we can use to properly risk-adjust SHR and SMR clinical measures (should we propose to adopt such measures in the future), and to improve our understanding of the risk factors that contribute to morbidity and mortality in the ESRD patient population.

In developing the proposed scoring methodology for the PY 2016 ESRD QIP, we considered several alternatives. For example, we considered weighting the clinical measures at 80 percent and the reporting measures at 20 percent of the TPS. We ultimately decided to propose the weighting methodology used in the PY 2015 ESRD QIP because the ratio of clinical to reporting measures did not change significantly, and also because we wanted to retain a strong incentive for facilities to meet the requirements for the reporting measures. We also considered a number of ways to establish achievement thresholds and benchmarks for the NHSN clinical measure. For example, we considered using baseline data from CYs 2012 through 2013 to set achievement thresholds and benchmarks. However, we ultimately decided to propose to use data from CY 2014 when establishing baseline data for scoring purposes, because facilities were not required to submit twelve full months of NHSN data during CY 2012–2013, and rates of healthcare-acquired infections are susceptible to seasonal variability. In light of the importance of monitoring and preventing infections in the ESRD population, we decided that it would be preferable to propose a clinical measure with equivalent baseline and performance periods, rather than a reporting measure that would have less of a direct impact on clinical practice. We also considered a number of ways to score the Patient Informed Consent for Anemia Treatment clinical measure. In this case, we lacked baseline data that could be used to establish achievement thresholds and benchmarks, so we considered proposing a reporting measure in place of the clinical measure. In light of the importance of the measure, however, we ultimately decided to propose a clinical measure in order to provide a stronger incentive for

facilities to obtain informed consent from patients receiving anemia treatment. In considering possible scoring methodologies for the measure, we specifically considered setting the achievement threshold at 100 percent because we believe that facilities should always obtain informed consent from patients receiving ESA. However, we recognized that unexpected events in the clinical setting might preclude the possibility of obtaining informed consent in every instance, so we ultimately decided to propose to set the achievement threshold for the measure at 92 percent. We selected 92 percent because this would allow facilities with 26 patients to meet the achievement threshold if they failed to obtain informed consent from 2 patients (see section III.C.8 for more details).

3. DMEPOS Provisions

a. Effects of the Implementation of Fee Schedules for Splints, Casts and IOLs

The implementation of fee schedules for use in paying claims for splints, casts, and IOLs inserted in a physician's office would result in administrative savings associated with determining and implementing the Medicare allowed payment amounts for these items. As a result, the agency would save approximately $94,000 in annual administrative expenses for calculating reasonable charge payment amounts and maintaining multiple pricing files necessary for making payment on a reasonable charge basis.

b. Clarification of the 3-Year MLR for DME

We expect no significant impact regarding application of the 3-year MLR for DME. As we noted in the final rule implementing the 3-year MLR, we believe that a vast majority of the categories of items that were classified as DME before January 1, 2012, did function for 3 or more years (76 FR 70289). The 3-year MLR is designed to represent a minimum threshold for determination of durability for equipment that is consistent with the statutory DME payment provisions and applies on a prospective basis, effective January 1, 2012. CMS recognizes that the healthcare industry and beneficiaries have come to rely on items that have qualified as DME prior to January 1, 2012, regardless of whether those items met the 3-year MLR set forth at § 414.202. We note that given that reliance and consistent with the regulation at § 414.202, CMS would not reopen those prior decisions and reclassify the equipment in light of the new 3-year standard. We believe that continuing the Medicare coverage for all the items that qualified as DME on or prior to January 1, 2012, would avoid disrupting the continuity of care for the beneficiaries that received these items for medical treatment prior to January 1, 2012. As noted in the final rule for the 3-year MLR (76 FR 70301, 70311) it is difficult to predict how many different types of new devices will be introduced in the market in the future that may or may not meet the 3-year MLR. However, even absent the 3-year MLR, it is likely that new products which do not meet the 3-year MLR will not qualify as DME based upon our current interpretation of the criteria for DME. It is possible that with the clarification of the 3-year MLR, we would limit what can be covered as DME compared to what we would have covered as DME absent this regulatory clarification. In general, we expect that the 3-year MLR we finalized effective January 1, 2012 (76 FR 70311) and clarification we are now providing of the 3-year MLR would have a minimal, if any, savings impact on the expenditures under program.

c. Definition of Routinely Purchased DME

As discussed in section IV of this final rule, this final rule clarifies the definition of routinely purchased equipment set forth at section § 414.220(a) and re-classifies an expensive item of DME or accessory (over $150) as a capped rental item for which Medicare claims data from July 1986 through June 1987 does not exist or for which Medicare claims data indicates that the item was not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Because concerns were brought to our attention on the application of the definition of routinely purchased DME, we performed a review of the approximately 250 HCPCS codes assigned to the routinely purchased category of DME in excess of $150. Based on our review, and given the definition of routinely purchased equipment set forth at section § 414.220, we would classify such items in the capped rental category if the items were not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

This final rule identified the HCPCS codes requiring reclassification from routinely purchased DME to capped rental DME in section IV. The majority of codes relate to manual wheelchairs and wheelchair accessories. Also, accessories of complex rehabilitative power wheelchairs that will be classified as capped rental items and for which suppliers must also offer to the beneficiary on a lump sum purchase basis in accordance with § 414.229(h)(3) of the regulations are noted. Below are shown approximately 14 codes which will be reclassified in two stages effective July 1, 2016, for all items included in competitive bidding programs other than those furnished in the Round 1 Recompete programs and areas; and on January 1, 2017, for those items furnished as part of the Round I Recompete competitive bidding programs.

TABLE 16—ITEMS RECLASSIFIED TO CAPPED RENTAL DME CATEGORY EFFECTIVE JULY 1, 2016 *

HCPCS category	HCPCS
Support Surfaces	E0197.
Walkers	E0140 E0149.
Wheelchairs	E0985 E1020 E1028 E2228 E2368 E2369.
Options/Accessories	E2370 E2375 K0015 K0070.
Wheelchair Seating	E0955.

* Items furnished in accordance with Round 1 Recompete contracts would be reclassified effective January 1, 2017

In Table 17 below, we show estimated savings associated with making payment on a capped rental basis rather than a lump sum purchase basis for items that will be reclassified.

TABLE 17—IMPACT OF ITEMS RECLASSIFIED TO CAPPED RENTAL DME CATEGORY

FY	Impact to the federal government) (in $ millions)
2014	−10
2015	−20
2016	−20
2017	−30
2018	−40

The decrease in expenditures is expected because the changes would eliminate the lump sum purchase method for the certain items, and instead payment would be made under the monthly rental method resulting in lower aggregate payments because many beneficiaries do not rent items for as long as 13 months. In order to prepare our impact on the Medicare program, we reviewed claims data and utilization for all items currently classified as capped rental items from 2009 through 2011 and determined that the weighted average number of allowed monthly rental services for beneficiaries

receiving capped rental items during that period was 8 months. We therefore used 8 months as the estimated number of months beneficiaries would rent items in Table 11 of section IV of the preamble of this final rule that would not have a purchase option. All anticipated savings include the price growth for the covered item fee schedule update factors for DME mandated by section 1834(a)(14) of the Act. In addition, our estimate takes into account projected changes in DME beneficiary enrollment. Furthermore, we reflected the savings for these items that are currently included under any existing competitive bidding program and which will be reclassified from routinely purchased to capped rental effective July 1, 2016.

Approximately $100 million in allowed charges in 2011 are for items that would no longer be eligible for purchase. Under the capped rental payment rules, these items would be rented for up to 13-continuous months, following which title to the equipment would transfer from the supplier to the beneficiary.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 18 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 18—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS for CY 2014	
Annualized Monetized Transfers	$0 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments	$0 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2016	
Category	Transfers
Annualized Monetized Transfers	−$15.1 million.*
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$39.5 thousand.**

DME Definition of Routinely Purchased DME

Category	Transfers			
Annualized Monetized Transfer Payments	−$23.1 million −$23.6 million	2013 2013	7% 3%	2014–2018 2014–2018
From Whom to Whom	Federal government to Medicare providers.			

* It is the reduced payment to the ESRD facilities, which fall below the quality standards as stated in section III.C.11 of this final rule.
** It is the cost associated with the collection of information requirements for all ESRD facilities.

XI. 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 17 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 $35.5 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/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $35.5 million).

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 17 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 12. Using the definitions in this ownership category, we consider the 601 facilities that are independent and the 424 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 $35.5 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 0.4 percent increase in payments for CY 2014. An independent facility (as defined by ownership type) is estimated to receive a 0.7 percent increase in payments for CY 2014.

We solicited comment on the RFA analysis provided. The comments received and our responses are as follows.

Comment: A few commenters requested that CMS improve the impact analysis for small entities. One association requested that we improve transparency for ESRD facilities and that we update our description of small entities. The association provided a study that identified all the ESRD facilities that have $35.5 million in revenues, consistent with the RFA definition of a small entity. The Small Business Administration, Office of Advocacy commented that the rule's transparency would be improved if CMS: 1) improved its description of small entities likely to be impacted by the rule; 2) provided further details on the rule's impacts on affected small ESRD facilities; and 3) entertained reasonable alternatives to the provisions of the proposed rule pursuant to RFA section 603(c). Such alternatives might include adoption of a transition or phase-in period on which CMS solicited comments in the proposed rule. The commenter suggested that CMS provide an impact table tailored to the size standards utilized in the RFA to enable small entities to better anticipate and comment on the impacts of this rule and that we include a margin analysis in the RFA.

Response: We thank the commenters for their suggestions to enhance the RFA analysis. We will take these suggestions into consideration for future rulemaking. We note that CMS publishes a provider level impact table each year. The CY 2014 Final ESRD PPS Facility Level Impact File may be viewed at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html*. We believe that this file for allows adequate transparency and identification for all ESRD facilities. For example, Medicare certified ESRD facilities are identified by provider number, Medicare payments, number of furnished treatments, as well as, rural or urban status.

In section II.C.2.a.v. of this final rule we discuss the implementation of the drug utilization adjustment. Specifically, for CYs 2014 and 2015, we are implementing a transition of the drug utilization adjustment by offsetting the payment update, that is the ESRDB market basket minus productivity increase factor and other impacts (such as, changes to the outlier thresholds), by a portion of the reduction amount necessary to create an overall impact of zero percent for ESRD facilities from the previous year's payments. For CY 2016, we will evaluate how to apply the balance of the reduction when we conduct an analysis of the case-mix adjustments as required by section 632(c) of ATRA and implement the inclusion of oral-only ESRD-related drugs and biologicals as permitted by section 632(b) of ATRA. Following this evaluation, we will determine whether we should apply the balance of the reduction in CY 2016 or provide one additional transition year so that the full amount of the drug utilization adjustment will have been applied to the base rate over a 4-year transition period ending in CY 2017.

Based on the finalized QIP payment reduction impacts to ESRD facilities for PY 2016, we estimate that of the 1,390 ESRD facilities expected to receive a payment reduction, 273 ESRD small entity facilities would experience a payment reduction (ranging from 0.5 percent up to 2.0 of total payments), as presented in Table 13 (''Estimated Distribution of PY 2016 ESRD QIP Payment Reductions'') and Table 15 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2016'') above. We anticipate the payment reductions to average approximately $10,890 per facility among the 1,390 facilities receiving a payment reduction, with an average of $12,011 per small entity facilities receiving a payment reduction. Using our projections of facility performance, we then estimated the impact of anticipated payment reductions on ESRD small entities, by comparing the total payment reductions for the 273 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 1,025 small entity facilities. For this entire group of 1,025 ESRD small entity facilities, a decrease of 0.27 percent in aggregate ESRD payments is observed.

Splints and casts, and IOLs affected by this rule are generally furnished by physicians. Approximately 95 percent of physicians are considered to be small entities for the purposes of the RFA. Individuals and states are not included in the definition of a small entity. The reasonable charge payment amounts for splints and casts are based on national reasonable charge amounts increased each year by the 12-month percentage change in the CPI–U ending June of the previous year. These national inflation-indexed charges can easily be converted to fee schedule amounts with no impact on the national Medicare payment amounts for these items. Therefore, the fee schedule amounts that will take effect on April 1, 2014, for splints and casts would be the same as the reasonable charge amounts that will take effect on April 1, 2014, for these items. This final rule will have no impact on small businesses that furnish these items. Given that Medicare pays for very few IOLs inserted in a physician's office, these entities do not rely on Medicare payment for these items to support their businesses. Because the fee schedule amounts that would take effect on April 1, 2014, for IOLs inserted in a physician's office would be based on the national average allowed charge for the item, the payment amounts these entities would receive under the fee schedule will be, on average, the same amounts they are currently paid for these items when considering the small national volume of claims as a whole. For example, in 2011, the average allowed charge for an IOL inserted in a physician's office was $174 for just 287 cases nationwide. If a particular physician office is a small business that charges less than $174 per IOL, a national fee schedule amount of $174 could increase payment for this small business for this item. Alternatively, if a particular physician office is a small business that charges more than $174 per IOL, a national fee schedule amount of $174 could decrease payment for this small business for this item. However, with only 287 cases nationwide, implementing a national fee of $174 would not have a significant impact on any physician office that is a small business because the volume of claims indicates that the small businesses are not relying on payment for these items to fund their businesses (physician practices) as a whole. Therefore, we expect that the overall impact of this rule on small businesses that are physician offices that insert IOLs covered by Medicare would be minimal. Approximately 85 percent of suppliers of DMEPOS in general are considered to be small entities for the purposes of the RFA.

We expect that the impact of moving certain expensive DME items from the routinely purchased payment class to the capped rental payment class on small business will be minimal since the suppliers would still receive 105 percent of the purchase fee for items that are rented for the full 13-month capped rental period. In addition, the supplier would retain ownership of

equipment that is not used for 13 months and can furnish the equipment to another beneficiary, beginning a new, separate 13-month capped rental period for the same item.

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 162 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 162 rural hospital-based dialysis facilities will experience an estimated 0.2 percent increase in payments. As a result, this final rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

XII. 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 2013, that threshold is approximately $141 million. This final rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $141 million.

XIII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this 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.

XIV. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XV. 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 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, 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), sec. 3201 of Pub.L. 112–96 (126 Stat. 156), and sec. 632 of Pub. L. 112–240 (126 Stat. 2354)

§ 413.174 [Amended]

■ 2. Section 413.174 (f)(6) (as added on August 12, 2010 at 75 FR 49198, and effective on January 1, 2014) is amended by removing ''January 1, 2014'' and by adding in its place ''January 1, 2016''.

§ 413.237 [Amended]

■ 3. Section 413.237 (a)(1)(iv) is amended by removing ''excluding'' and by adding in its place ''including''; and by removing ''January 1, 2014'' and adding in its place ''January 1, 2016''.

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

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

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

■ 5. The heading for subpart C is revised to read as follows:

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies, Splints, Casts, and Certain Intraocular Lenses (IOLs)

* * * * *

■ 6. Section 414.100 is revised to read as follows:

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services, splints and casts, and IOLs inserted in a physician's office as authorized by section 1842(s) of the Act.

■ 7. Section 414.102 is amended by revising paragraphs (a) introductory text, (a)(2), (b)(1), and (c) to read as follows:

§ 414.102 General payment rules.

(a) *General rule.* For PEN items and services furnished on or after January 1, 2002, and for splints and casts and IOLs inserted in a physician's office on or after April 1, 2014, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—-

* * * * *

(2) The fee schedule amount for the item or service, as determined in accordance with §§ 414.104 thru 414.108.

(b) * * *

(1) CMS or the carrier determines fee schedules for parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, splints and casts, and IOLs inserted in a physician's office, as specified in §§ 414.104 thru 414.108.

* * * * *

(c) *Updating the fee schedule amounts.* For the years 2003 through 2010 for PEN items and services, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year. For each year subsequent to 2010 for PEN items and services and for each year subsequent to 2014 for splints and casts, and IOLs inserted in a physician's office, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

■ 8. Section 414.106 is added to read as follows:

§ 414.106 Splints and casts.

(a) *Payment rules.* Payment is made in a lump sum for splints and casts.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2014 is the reasonable charge amount for 2013, updated by the percentage increase in the CPI–U for the 12-month period ending with June of 2013.

■ 9. Section 414.108 is added to read as follows:

§ 414.108 IOLs inserted in a physician's office.

(a) *Payment rules.* Payment is made in a lump sum for IOLs inserted in a physician's office.

(b) *Fee schedule amount.* The fee schedule amount for payment for an IOL furnished in 2014 is the national average allowed charge for the IOL furnished from in calendar year 2012, updated by the percentage increase in the CPI–U for the 24-month period ending with June of 2013.

■ 10. Revise the heading to Subpart D to read as follows:

Subpart D—Payment for Durable Medical Equipment, Prosthetic and Orthotic Devices, and Surgical Dressings

* * * * *

■ 11. Section § 414.200 is revised to read as follows:

§ 414.200 Purpose

This subpart implements sections 1834(a), (h) and (i) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment, prosthetic and orthotic devices, and surgical dressings for Medicare beneficiaries.

■ 12. Section 414.226 is amended by revising paragraph (c)(6) to read as follows:

§ 414.226 Oxygen and oxygen equipment

* * * * *

(c) * * *

(6) Beginning in 2008, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

* * * * *

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

Dated: November 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 21, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–28451 Filed 11–22–13; 4:15 pm]

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