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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1526-P]

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: Proposed rule.

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

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. E.S.T on **August 30, 2013**.

ADDRESSES: In commenting, please refer to file code CMS-1526-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1526-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1526-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

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Washington, DC 20201

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b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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

FOR FURTHER INFORMATION CONTACT:

Michelle Cruse, (410) 786-7540, for issues related to the ESRD PPS.

Stephanie Frilling, (410) 786-4507, for issues related to the ESRD PPS wage index, home dialysis training, and the delay in payment for oral-only drugs under the ESRD PPS.

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

Anita Segar, (410) 786-4614, for issues related to the ESRD QIP.

Sandhya Gilkerson, (410) 786-4085, for issues related to the clarification of the grandfathering provision related to the 3-year MLR for DME.

Anita Greenberg (410) 786-4601, for issues related to the clarification of the definition of routinely purchased DME.

Christopher Molling (410) 786-6399, for issues related to DMEPOS technical amendments and corrections.

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:

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To

schedule an appointment to view public comments, phone 1-800-743-3951.

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

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

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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
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

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)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted bundled prospective payment system for renal dialysis services furnished by ESRD facilities. Effective January 1, 2014, the transition to the ESRD PPS will conclude and all Medicare ESRD facilities will be paid 100 percent under the ESRD PPS. This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2014. In accordance with section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (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 (ACA) (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 rule also proposes to set 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 rule would clarify 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 rule proposes to implement budget neutral fee schedules for splints and casts as well as intraocular lenses (IOLs) inserted in a physician's office. Finally, this rule would make 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, we propose an ESRD PPS base rate of $216.95. This amount reflects the application of the proposed ESRD bundled (ESRDB) market basket reduced by the productivity adjustment, or 2.5 percent, the wage index budget-neutrality adjustment factor of 1.000411, and the drug

utilization adjustment to the CY 2013 ESRD PPS base rate of $240.36. The proposed CY 2014 ESRDB market basket increase factor is 2.9 percent. The current forecast of the proposed CY 2014 productivity adjustment is 0.4 percent. The proposed drug utilization adjustment factor to account for changes in utilization as required by section 1881(b)(14)(I) is -12 percent.

- Updates to the wage index and wage index floor: We adjust wage indices on an annual basis using the most current hospital wage data to account for differing wage levels in areas in which ESRD facilities are located. In CY 2014, we are not proposing any changes to the application of the wage index budget-neutrality adjustment factor and will continue to apply the budget-neutrality adjustment to the base rate for the ESRD PPS. We have been gradually decreasing the wage index floor by .05 in an effort to gradually phase out the floor. For CY 2014 and CY 2015 we are proposing to continue our policy for the gradual phase out of the wage index floor and to reduce the wage index floor values to 0.45 and 0.40, respectively.

- Update to 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 $54.23 and the MAP amount would remain $38.65 as compared to CY 2013 values. For adult beneficiaries, the fixed-dollar loss amount would decrease from $110.22 to $94.26 and the MAP amount would decrease from $61.38 to $52.45. 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 percentage.

- 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 propose that all ICD-10-CM codes to which ICD-9-CM codes that are eligible for the comorbidity payment adjustment crosswalk will be eligible for the comorbidity payment adjustment with two exceptions.

2. ESRD QIP

This proposed rule proposes to implement requirements for the ESRD QIP. With respect to the PY 2016 ESRD QIP, we propose to continue some of the previous ESRD QIP measures, add new measures, and expand the scope of some of the existing measures to cover the measure topics as follows:

- To evaluate anemia management:
  - Hemoglobin Greater Than 12 g/dL, a clinical measure
  - Patient Informed Consent for Anemia Treatment, a clinical measure*
  - Anemia Management, a reporting measure†
  - Pediatric Iron Therapy, 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‡
- To gather data regarding comorbidities:
  - Comorbidity, a 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.

It also proposes to 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 rule would clarify the definition of routinely purchased DME set forth at section §414.220(a), as well as address 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 rule would provide further clarification about how we would applythe 3-year minimum lifetime requirement (MLR) set forth at § 414.202, which must be satisfied for an item or device to be considered durable medical equipment.

- Implementation of budget neutral fee schedules for splints and casts, and IOLs inserted in a physician's office: For CY 2014, we are proposing to implement budget neutral fee schedule amounts for splints, 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 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 intraocular lenses inserted in a physician's office were $76 thousand.

C. Summary of Costs and Benefits

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

1. Impacts of the Proposed ESRD PPS

The impact chart in section X.B.1. of this proposed 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 be a 9.4 percent decrease in payments. Hospital-based ESRD facilities have an estimated 9.3 percent decrease in payments compared

with freestanding facilities with an estimated 9.4 percent decrease.

We estimate that the aggregate ESRD PPS expenditures would decrease by approximately $780 million from CY 2013 to CY 2014. This reflects a $210 million increase from the payment rate update, a $30 million increase due to the updates to the outlier threshold amounts, and a $1.02 billion decrease in expenditures specifically related to the -12 percent drug utilization adjustment required by section 1881(b)(14)(I). The estimated 9.4 percent overall payment decrease would result in a $190 million savings to beneficiaries.

2. Impacts for ESRD QIP

The overall economic impact of the proposed ESRD QIP is an estimated $26.4 million in PY 2016. In PY 2016, we expect the total payment reductions to be approximately $26.4 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 the DMEPOS proposal to implement fee schedules for splints and casts and IOLs inserted in a physician's office is insignificant. The reasonable charge amounts that we propose to convert to fee schedule amounts would be budget neutral the first year and would 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 will 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, could 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 expect that the overall impact of reaffirming the definition of routinely purchased DME and our proposal for classifying certain expensive items as cap rental would 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 would 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 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. In that rule, we finalized the following:

- An ESRD PPS base rate of $240.36 per treatment for renal dialysis services. The ESRD PPS base rate applies to the ESRD PPS portion of the blended payments during the

transition and to the ESRD PPS payments. This amount reflected the CY 2013 ESRD bundled (ESRDB) market basket update of 2.9 percent minus a multifactor productivity adjustment of 0.6 percent, that is, a 2.3 percent increase. This amount also reflected the application of the wage index budget-neutrality adjustment of 1.000613.

- A composite base rate of $145.20 per treatment for renal dialysis services that is used in the composite rate portion of the ESRD PPS payment for ESRD facilities receiving blended payments during the transition. This amount reflected the application of the ESRDB market basket reduced by the multifactor productivity adjustment, or a 2.3 percent increase.
- A zero update to the drug add-on adjustment and maintaining the $20.33 per treatment drug add-on amount for the composite rate portion of the ESRD PPS blended payment. This resulted in a 14.0 percent drug add-on adjustment to the composite rate portion of the ESRD PPS blended payment.
- A 0.1 percent transition budget-neutrality adjustment factor.
- A 1.001141 wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment, which is applied to the wage index values.
- A 1.000613 wage index budget-neutrality adjustment factor for the ESRD PPS portion of the blended payment and for the ESRD PPS, which is applied to the ESRD PPS base rate.
- A 0.05 reduction to the wage index floor which resulted in a wage index floor of 0.500 under the ESRD PPS.
- A 0.501 wage index floor under the composite rate portion of the blended payment (1.500 x 1.001141 = 0.501).

- Revisions to the outlier policy. Specifically, for pediatric beneficiaries, a fixed-dollar loss amount of $47.32 and a Medicare Allowable Payment (MAP) amount of $41.39. For adult beneficiaries, a fixed-dollar loss amount of $110.22 and a MAP amount of $59.42.
- Eliminating the restriction on daptomycin to allow ESRD facilities to receive separate payment by appending the AY modifier on the claim for daptomycin when the diagnosis reported on the claim indicates the drug was used to treat a non-ESRD related condition.
- Excluding alteplase and other thrombolytics from separate payment for the composite rate portion of blended payments during the remainder of the transition.
- Use of the Average Sales Price (ASP) methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute outlier MAP amounts, the drug add-on, and any other policy that requires the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS and for the composite rate portion of the blended payment during the transition.

Finally, in the CY 2013 ESRD PPS final rule, we reiterated policies regarding the following billing practices because we believed that ESRD facilities may be billing renal dialysis services for separate payment:

- Any item or service included in the composite rate should not be identified on ESRD claims.
- An AY modifier can be appended to claims for drugs and laboratory tests that are not ESRD-related to allow for separate payment. The AY modifier should not be used for renal dialysis services and we have monitoring efforts in place to analyze billing trends.

B. Routine Updates and Proposed 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. We are proposing to implement 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 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). 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 proposed 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.B.3., 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, for this proposed rule, we applied the 2.5 percent increase to the CY 2013 ESRD PPS base rate of $240.36, which results in a proposed CY 2014 ESRD PPS base rate of $246.37 ($240.36 x 1.025 = $246.37).

In addition, as discussed in section II.B.4.d. of this proposed rule, for CY 2014 we are applying the wage index budget-neutrality adjustment factor of 1.000411 to the CY 2014 ESRD PPS base rate (that is, $246.37), yielding a proposed CY 2014 ESRD PPS wage-index budget-neutrality adjusted base rate of $246.47 ($246.37 X 1.000411 = $246.47).

a. Proposed Adjustment to the ESRD PPS Base Rate to Reflect 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 American Taxpayer Relief Act of 2012 (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). Consistent with these requirements, we propose 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

We are proposing an adjustment that would reduce the ESRD PPS base rate. Because the ESRD PPS base rate is a per treatment base rate, the adjustment would be calculated on a per treatment basis. We propose 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 note the CY 2014 ESRD PPS base rate is reflective of 2007 utilization because the base rate is based on CY 2007 data. We believe 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, we believe that because we are proposing to make the reduction in CY 2014, we should price the ESRD-related drugs and biologicals for the year in which the adjustment applies. 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 for ESRD. We would take the estimated amount of the per treatment difference between the estimated spending of drugs and biologicals in CY 2007 and CY 2012 and reduce 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 propose to reduce the CY 2014 ESRD PPS base rate by the resulting amount.

ii. Determining Utilization of ESRD-Related Drugs and Biologicals

Section 1881(b)(14)(I) 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 1811(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 propose 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 based on 2007 claims data. We explain 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 propose to use the latest available claims data based on the 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). For the CY 2014 ESRD PPS final rule, we will 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. We solicit comments on the proposed use of 2007 and 2012 claims data to capture the utilization of ESRD-related drugs and biologicals in those years.

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 believe that this 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 propose 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 this proposed rule, we did not readily have access to the 2007 utilization data for the ESRD facilities located in these areas; however, we plan to include these data in our calculation for the final rule. Because there are very few ESRD facilities in this region, we do not believe that the inclusion of utilization of drugs and biologicals furnished in CY 2007 at these facilities will have a significant impact on the amount of the adjustment. We solicit 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.

iii. Pricing of ESRD-Related Drugs and Biologicals

As we stated above, we are proposing to price 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.

During the development of the 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. For setting the CY 2011 ESRD PPS base rate, for Part B separately billable drugs, we used the first two quarters of ASP+6 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 propose 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 are 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 is 2.5 percent. The wage index budget neutrality adjustment factors for the same years are 1.001520, 1.000613, and a proposed factor of 1.000411. Therefore, we propose 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 solicit comments on the use

of the ESRDB market basket percentage increase factor to inflate prices for drugs and biologicals to CY 2014 levels.

iv. Calculation of the Amount of the Per Treatment Reduction.

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 these 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. While most of these drugs had minimal utilization, we note that 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 x .9407 x .99 x .98 = $29.52). We would apply 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 would then reduce 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 results in a 12 percent reduction in Medicare payments. We solicit 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.

While we propose to implement the full reduction in CY 2014, we note that we are also concerned that this one-time reduction to the ESRD PPS base rate could be a significant reduction to ESRD facilities for the year and potentially impact beneficiary access to care. Therefore, we are soliciting comments on a potential transition or phase-in period of the 12 percent reduction and the number of years for such transition or phase-in period.

v. Comparison of ASP versus PPI

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 believe 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. We performed 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 website 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 are minimally different (a difference of $29.40 versus

$29.52), and we believe that the ESRDB market basket approach is a more appropriate measure of how Medicare pays for these drugs under the ESRD PPS

We are soliciting 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.

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. Proposed 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.

For this proposed rule, we propose to use the same methodology and 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 is 2.9 percent.

For the CY 2014 ESRD payment update, we propose 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).

c. Proposed Productivity Adjustment

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 is 0.4 percent.

d. Calculation of the 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 are proposing 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).

Thus, in accordance with section 1881(b)(14)(F)(i) of the Act, the proposed ESRDB market basket percentage increase factor for CY 2014 is based on the 1st quarter 2013 forecast of the CY 2008-based ESRDB market basket, which is estimated to be 2.9 percent. This market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2014) of 0.4 percent, which is based on IGI's 1st quarter 2013 forecast. The resulting proposed MFP-adjusted ESRDB market basket update for CY 2014 is equal to 2.5

percent, or 2.9 percent less 0.4 percentage point. If more recent data is subsequently available (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.

4. The Proposed CY 2014 Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a 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) 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, is available online at http://www.whitehouse,gov/omb/bulletins.

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 corresponds with the IPPS hospital wage index. For FY 2014, we use the FY 2013 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 and, thus, the FY 2014 ESRD PPS wage index will not reflect the OMB changes. As stated in the FY 2014 IPPS/LTCH PPS proposed rule, CMS intends to propose changes to the hospital wage index based on this OMB Bulletin in the FY 2015 IPPS/LTCH PPS proposed rule (78 FR 27486 (May 10, 2013)). 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 from the prior year, we anticipate that the OMB Bulletin changes would be reflected 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 propose to adjust wage indices for CY 2014 to account for annually updated wage levels in areas in which ESRD facilities are located. We propose to use the most recent, FY 2014 inpatient prospective payment system (IPPS) pre-floor, pre-reclassified hospital wage index. 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 proposed CY 2014 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed 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 are not proposing any changes to the labor-related share of 41.737. Because all providers that elected to participate in the transition are entering their 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 note 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.B.3.b. of this proposed rule.

a. Payment under the ESRD PPS for Facilities Located in Guam, American Samoa, and the Northern Mariana Islands and Proposed Wage Index Value for Guam

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 (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, ESRD facilities located in the Pacific Rim must be paid under the ESRD PPS and will be paid under this system beginning for services furnished on or after January 1, 2014. In order

to pay these facilities under the ESRD PPS, we must identify an appropriate wage index value for these areas as required under §413.231 of the regulations. We propose to use the current value calculated under the existing methodology, that is, the pre-floor, pre-reclassification, 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). In addition, the most recent proposed 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 propose below to apply the wage index value for Guam to facilities located in American Samoa and the Northern Mariana Islands.

b. Proposed Policies for Areas with No Wage Data

In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values for the ESRD PPS. In that final rule (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. 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.

In the case of 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. In addition, the Northern Mariana Islands and American Samoa are rural areas with no hospital data. Therefore, we will use our established

methodology to compute an appropriate wage index using the average wage index values from contiguous CBSAs, to represent a reasonable proxy. While we appreciate that the islands of the Pacific Rim are not actually contiguous, we believe that same principle applies here, and that Guam is a reasonable proxy for American Samoa and the Northern Marianas. We note that if hospital data becomes available for any of the islands of the Pacific Rim we will use that data for the appropriate CBSA's instead of the proxy. As discussed previously, the current wage index value using the existing methodology for Guam is 0.9611. Therefore, for CY 2014, we propose to apply this wage index value of 0.9611 to ESRD facilities located in America Samoa and the Northern Mariana Islands, which we are including 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 (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. For CY 2014 the wage index value for CBSA #11 (Georgia) is 0.7482 and this is included in Addendum A. Accordingly, we propose to apply the statewide urban average wage index value of 0.7582 to Hinesville-Fort Stewart, GA.

c. Proposed 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. We further specified in the CY 2012 ESRD PPS (76 FR 70241) that 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.

Our intention has been to provide a wage index floor only through the 4-year transition to 100 percent implementation of the ERSD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241). 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. 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), however, 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 of a gradual and systematic elimination of the wage index floor. Therefore, for CY 2014 and for CY 2015, we propose 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 or beyond we believe they should have the benefit of a gradual reduction in the floor as well. We will continue to review wage index values and the appropriateness of a wage index floor in the future.

For CY 2014 and CY 2015, we also propose to continue our policy of gradually reducing the wage index floor by 0.05 per year. Specifically, we propose a wage index floor value of 0.45 for CY 2014 and a wage index floor value of 0.40 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.

d. Proposed 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 are not proposing any changes to the methodology, but we note that we will no longer compute a 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 December 31, 2012), 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 Website 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 Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/WIFN/list.asp. The wage index data are located in the section entitled, "FY 2014 Proposed 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 proposed 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 are proposing 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.

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 adjustment recognizes the increased costs associated with comorbidities and provides additional payment for certain conditions that occur concurrently with the need for dialysis.

To develop the comorbidity payment adjustment, 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 the 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 adjustment 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 co-morbidity either by altering dialysis care, changing diagnostic testing patterns, or liberalizing the diagnostic criteria.

We finalized six comorbidity categories eligible for the 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 the 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 the comorbidity payment adjustment are subject to the annual ICD-9-CM coding updates that occur in the hospital inpatient PPS 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 the 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 the comorbidity payment adjustment in accordance with the annual ICD-9-CM update effective October 1, 2011. This CR can be found on the CMS website 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 the 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 the comorbidity payment adjustment.

We crosswalked the ICD-9-CM codes that are eligible for the 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 could crosswalk to one ICD-10-CM code; one ICD-9-CM code crosswalked to multiple ICD-10-CM codes; or multiple ICD-9-CM 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 propose that ICD-10-CM codes will be eligible for the comorbidity payment adjustment where they crosswalk from ICD-9-CM codes that are eligible for the 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 propose to exclude these codes from eligibility for the 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 propose that all of those ICD-10-CM codes will be subject to the 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 propose 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 propose that all of the other ICD-10-CM codes listed in the Table 1 below will be eligible for the 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
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 propose that all the crosswalked ICD-10-CM codes will be subject to the 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 erythropoiesis stimulating agent (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 propose that D89.2

Hypergammaglobulinemia, unspecified will not be eligible for the comorbidity payment adjustment. We propose that all of the other ICD-10-CM codes listed in Table 2 below will 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	I30.1	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
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 will be eligible for the 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**

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 propose that both D89.2 Hypergammaglobulinemia, unspecified and K52.81 Eosinophilic gastritis or gastroenteritis would not be eligible for the comorbidity payment adjustment. We propose that all other ICD-10-CM codes to which eligible ICD-9-CM codes crosswalk that are listed in the Tables above will be eligible for the

comorbidity payment adjustment effective October 1, 2014. We are soliciting comments on the ICD-10-CM codes that we propose to exclude and those we propose will be eligible for the comorbidity payment adjustment.

6. Proposed Revisions to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Our regulations at 42 CFR §413.237(a)(1) 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, if necessary.

Our regulations at 42 CFR §413.237(a)(2) through (a)(6), (b), and (c) 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 patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments. The average outlier services MAP amount per treatment for CY 2011 was based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. For CY 2012, the outlier services MAP amounts and fixed dollar loss amounts were based on 2010 data (76 FR 70250). 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 epoetin 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 Proposed Changes to the Outlier Policy

For CY 2014, we are not proposing any changes to the methodology used to compute the

MAP or fixed dollar loss amounts. Rather, in this proposed rule, we are updating the outlier services MAP amounts and fixed dollar loss amounts to reflect the utilization of outlier services reported on the 2012 claims using the December 2012 claims file. Accordingly, for CY 2014, the MAP and fixed dollar loss amounts are based on the ESRD PPS claims and utilization. The impact of this update is shown in Table 4, 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 this proposed rule. The estimates for the proposed outlier 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** **Proposed 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	$38.65	$52.45
Adjustments Standardization for outlier services[2]	1.0927	0.9878	1.0960	0.9893
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount[3]	$41.39	$59.42	$41.51	$50.85
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold[4]	$47.32	$110.22	$54.23	$94.26
Patient months qualifying for outlier payment	7.6%	5.1%	6.2%	5.1%

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect updated prices for outlier services (t
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 servic
amounts are based on 2012 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in pl
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 patient groups.
[3]This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP patient.
[4]The fixed dollar loss amounts were calculated using 2012 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

As seen 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 epoetin 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 ($52.45, which is based on 2012 data).

For pediatric patients, there was no change in the overall average outlier service MAP amount between 2011 and 2012 ($38.65 per treatment in both Columns I and II). 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 (6.2 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 therefore 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.

We propose to update 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 $94.26 for adult patients and from $47.32 to $54.23 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 5.1 percent and 6.2 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 epoetin 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. Based on the 2012 claims, 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 outlier services. Use of 2012 data to recalibrate the thresholds, which reflect lower utilization of EPO and other outlier services, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2014. We believe the proposed update to the outlier MAP and fixed dollar loss amounts for CY 2014 will increase payments for ESRD beneficiaries requiring higher resource utilization and come closer to meeting our 1 percent outlier policy.

We note that recalibration of the fixed dollar loss amounts in this proposed rule 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 would also increase for renal dialysis services eligible for outlier payments.

C. Discussion of Self-Dialysis and Home Dialysis Training Add-On Adjustment and Request for Public Comments

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). 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 facility must furnish to ESRD patients as a condition of coverage is 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. For additional information on the requirements for ESRD facilities in furnishing dialysis training, see 42 CFR Part 494, and additional information regarding home dialysis training certification, see the State Operations Manual, which may be viewed on the Medicare website at the following link: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html.

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(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 hemodialysis, even if this 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, parenteral items used in dialysis, 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 method of training. This includes compliance with patient assessments as described in 42 CFR 494.80(a)(9) "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 patients 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 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 adjustment, to be added on to the ESRD PPS base rate, 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 above. 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.

The add-on payment adjustment is also 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 modality change. 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.

We discuss our policy for retraining sessions in the Medicare Benefit Policy Manual, Publication 100-02, Chapter 11. 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 on 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.

For 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 base rate payment when

a training treatment is furnished by the ESRD facility. In addition, we noted that because the training add-on adjustment 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 indexes, please see section II.B.4. of this proposed rule.) When home dialysis training sessions are furnished to a Medicare beneficiary by a Medicare-certified 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 our CY 2013 ESRD final rule (77FR 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 this proposed rule we are seeking comments on the costs associated with furnishing self or home dialysis training. We request 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 are also seeking 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, we are seeking comments on the length of time necessary for a successful transition to a home dialysis modality and the percentage of the payment that should be held back.

D. 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) 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 (other than ESAs, which are included under clause (ii)) used for the treatment of ESRD, but also all non-injectable drugs 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, Congress enacted the American Taxpayer Relief Act of 2012 (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 propose to pay for oral-only drugsconsistent 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 section 42 CFR 413.174(f)(6) from January 1, 2014 to January 1, 2016.

Because we propose that oral-only drugs will be included in the ESRD PPS starting in CY 2016, we also propose to change the reference to January 1, 2014 in section 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 propose to clarify our regulation at 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).

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 proposed rule discusses each of these elements and our proposals 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. 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 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, 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 are proposing 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. The following measures seek to evaluate facilities on the clinical quality of care:

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

- 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 measure is new to the ESRD QIP.

**Indicates that the measure is newly expanded or converted to a clinical measure in the ESRD QIP.

At this time, we are not proposing to adopt measures that address care coordination, efficiency, population and community health, or cost of care. However, we are soliciting comments in this proposed rule on potential measures that would cover these areas. We welcome further comments on these and other potential measures for future program years.

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 under section 1890(a) of the Act (currently the NQF) to convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures for use in certain programs. Section 1890A(a)(2) of the Act requires the Secretary 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)

- Measures Application Partnership #2774: 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 the measures section below, we further discuss these considerations, describe our proposals for the PY 2016 ESRD QIP, and provide rationale for why we believe it is appropriate to propose the measures at this time.

C. Proposed 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 are proposing 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 are also proposing 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.

NQF #	Measure Title and Description
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 phosphorous 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.

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 Proposals for scoring 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:

1. (i) The Hemoglobin Greater than 12 g/dL measure.

The Dialysis Adequacy measure topic, which is comprised of

2. (a) Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose (NQF# 0249),

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

4. (c) Minimum spKt/V for Pediatric Hemodialysis Patients (NQF #1423); and

The Vascular Access Type measure topic, which is comprised of

5. (a) Vascular Access Type: Arterial Venous (AV) Fistula (NQF #0257); and

6. (b) Vascular Access Type: Catheter >= 90 days (NQF #0256).

The technical specifications for these measures can be found at:

http://www.dialysisreports.org/ESRDMeasures.aspx

2. Proposal to Expand One PY 2015 Measure and Revise 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 are proposing to expand and revise the measures discussed below that we finalized in the CY 2013 ESRD PPS final rule. For all measures except for ICH CAHPS reporting measure, these proposed and revised 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. Proposed 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 #0285: CAHPS In-Center Hemodialysis Survey, which is based on how facilities perform on the 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 are proposing 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 website (https://ichcahps.org). Facilities will need to register on the https://ichcahps.org website in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each facility must then administer (via its vendor) the survey once during the proposed performance period and, by 11:59 ET on January 28, 2015, report the survey data to CMS using the specifications on the ICH CAHPS website.

For PY 2017 and subsequent payment years, we are proposing 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 website.

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, 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 measure without unduly burdening facilities. We request comment on

this proposal. The technical specifications for this measure are located at http://www.dialysisreports.org/pdf/esrd/public-measures/ICHCAHPS-2016NPRM.pdf.

b. Proposed Revised Mineral Metabolism Reporting Measure

Adequate management of bone mineral metabolism and disease in ESRD patients 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 are proposing 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 patients from the measure specifications. For PY 2016 and future payment years, we are now proposing to include home peritoneal patients in the Mineral Metabolism reporting measure. Therefore, we are proposing 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 are proposing to change the specifications for the mineral metabolism measure such that it no longer requires facilities to report serum calcium levels. We welcome 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 we do not finalize the proposed hypercalcemia measure.

As described in more detail below (Proposed Minimum Data for Scoring Measures), we are also proposing to eliminate the 11-case minimum for this measure, which was finalized in the CY 2013 ESRD PPS final rule at 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 are proposing 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 are further proposing 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 make 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).

We welcome comments on this proposal. Technical specifications for this proposed measure can be found at: http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Hypercalcemia-2016NPRM.pdf.

c. Proposed 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 (FDA) 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 are now proposing to include home peritoneal patients in the Anemia Management reporting measure. Therefore, we are proposing 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, and therefore, we are proposing 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 are proposing 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 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 make 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).

Technical specifications for this proposed measure can be found at: http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2016NPRM.pdf. We request comment on this proposal to revise the Anemia Management

reporting measure.

3. New Measures Proposed 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 are proposing 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. Proposed 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 are proposing 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 are proposing 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 are proposing 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 would retain the Hgb>12 measure as an independent measure. We welcome comments on this proposal.

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[2] for ESAs and Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Management Guidelines[3] 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 are proposing 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 propose that qualifying 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 will be January 31, 2015 or, if that is not a regular business day, the first business day thereafter. Missing attestation data for a patient will be interpreted as failure to obtain informed consent from that patient.

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

[3] 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.

We welcome comments on this proposed measure. Technical specifications for this proposed measure can be found at: http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-InformedConsent-2016NPRM.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 ESRD patients.

Elevated serum calcium level (or hypercalcemia) has been shown to be significantly associated with increased all-cause mortality in patients with advanced Chronic Kidney Disease (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[4,5] and subsequent risk for cardiovascular deaths. We previously proposed a hypercalcemia clinical measure for the PY 2015 ESRD QIP (77 FR 40973

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[4] 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.

5 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.

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 are proposing 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 demoninator is the total number of eligible patient-months. We are proposing 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 three months of data) for all eligible patients that was greater than 10.2 mg/dL.

Because we are proposing to adopt this measure not only for PY 2016, but also

subsequent payment years, we also propose 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 propose that the 3-month rolling average rate for January would be calculated using the rates from November and December of the previous year as well as January of that year. Likewise, we propose that the rate for February would be calculated using the rates from December, January and February to calculate the 3-month rolling average, and so on.

Technical specifications for this measure can be found at http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Hypercalcemia-2016NPRM.pdf. We welcome comments on this proposal.

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.[6] 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.[7,8] 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

6 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.
7 Warady BA, Zobrist RH, Wu J, Finan E. Sodium ferric gluconate complex therapy in anemic children on hemodialysis. Pediatr Nephrol 20: 1320-7, 2005.
8 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.

dialysis facilities provide to pediatric patients, we are proposing 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 are proposing 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 are proposing 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 are proposing that qualifying cases for this measure would be defined as in-center and home dialysis patients under the age of eighteen.

As described in more detail below, we are proposing 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 are proposing 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 are proposing 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.

The technical specifications for this measure can be found at: http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-PediatricIronTherapyReporting-2016NPRM.pdf. We welcome comment on this proposal.

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 immuno-compromised 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 over the past two 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 are proposing 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 NQF

#1460, in that it evaluates the number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.

We are proposing 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 propose 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 are proposing 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; 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 propose that they would receive a score of zero on the measure. We also propose 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 twelve months of data to encourage them to enroll in and report data in the NHSN system. However, we are proposing 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 are not proposing to require facilities to adopt any of these interventions at this time.

We request comment 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 technical specifications for this measure are located at http://www.dialysisreports.org/ESRDMeasures.aspx.

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 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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.

Technical specifications for this proposed measure can be found at http://www.dialysisreports.org/pdf/esrd/public-measures/ComorbidityReporting-2016NPRM.pdf. We welcome comments on these proposals.

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 request comment on these potential areas of future measurement, and

welcome suggestions on other topics for measure development.

5. Proposed 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 are proposing 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 proposed below.

6. Proposed 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 are proposing to establish CY 2014 as the

performance period for all of the measures. We welcome comments on this proposal.

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

We are proposing 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.

a. Proposed Clinical Measure Performance Standards

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we are proposing 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 are proposing 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 are proposing 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 are also proposing 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 two 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 are proposing 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 believe that facilities should meet the standard 100 percent of the time. However, we recognize that unexpected events might make a 100 percent standard difficult to meet, so we are proposing 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, we are proposing that a small facility adjuster will 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 is 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 believe 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 are proposing 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. Furthermore, we propose to calculate the proposed performance standard using the average of the benchmark and achievement threshold, which is 94 percent. We seek 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 are also proposing that for PY 2016, facilities be scored only on achievement for this measure, and not on the basis of improvement. We recognize that with other measures that lacked baseline data we adopted a reporting measure

to ensure that both an achievement and improvement score could be assessed. However, 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 aready be in place at dialysis facilities, so facilities should already have procedures in place to support the measure. 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 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 are proposing to set the performance standard as the 50th percentile of national performance from May 2012 through November 2012. We seek comment on this proposal.

b. Estimated Performance Standards for Proposed Clinical Measures

At this time, we do not have the necessary data to assign numerical values to the

proposed performance standards for the clinical measures, because we do not yet have all of the data from CY 2012 or the first portion of CY 2013. However, we are able to estimate these numerical values based on the most recent data available. For all of the proposed clinical measures except Hypercalcemia, this data comes from the period of January through November 2012. For the Hypercalcemia clinical measure, the most recent data available comes from the period May through November 2012. In Table 8, we have provided the estimated performance standards for all of the measures except for the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure, which will be based on data from CY 2014. We will publish updated values for all measures except the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure in the CY 2014 ESRD PPS final rule.

Table 8 – Estimated Numerical Values for the Performance Standards for the PY 2016 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Performance Standard
Vascular Access Type	
%Fistula	62.4%
%Catheter	10.5%
Kt/V	
Adult Hemodialysis	93.6%
Adult, Peritoneal Dialysis	85.4%
Pediatric Hemodialysis	92.5%
Anemia Management	
Hemoglobin > 12 g/dL	0%
Patient Informed Consent for Anemia Treatment[1]	94%
Hypercalcemia	2.3%
NHSN Bloodstream Infection in Hemodialysis Outpatients	50th percentile of eligible facilities' performance during the performance period

[1] As noted above, the performance standard for the Patient Informed Consent for Anemia Treatment is based on clinical standards, not data collected through the ESRD QIP.

We believe that the ESRD QIP should not have lower standards than in previous years. In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final numerical values for the PY 2016 performance standards are worse than PY 2015 for a measure, then we are proposing to substitute the PY 2015 performance standard for that measure. We request comments on this proposal.

c. Proposed Performance Standards for Reporting Measures

For the proposed ICH CAHPS reporting measure, we are proposing 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 specifications to CMS as specified at https://ichcahps.org. For PY 2017 and future payment years, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are further proposing 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.

8. Proposed Scoring for the PY 2016 ESRD QIP Proposed 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 purposes of assessing their performance on the clinical measures (76 FR 70272 through 70273). We are proposing to use a similar methodology for purposes of scoring facility performance on each of the clinical measures for the PY 2016 ESRD QIP and future payment years, except that we are proposing 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 are proposing 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 are proposing 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 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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. We request comment on these proposals.

With the exception of the NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent Anemia Treatment clinical measure, we are proposing that facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We are proposing 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 are proposing that facilities will not receive improvement scores for these measures for PY 2016.

Like the performance standards, we do not have the necessary data at this time to assign final numerical values to the proposed achievement thresholds and benchmarks for the clinical measures. However, we are able to estimate them based on the most recent data available. For all of the clinical measures except Hypercalcemia and NHSN Bloodstream Infection in Hemodialysis Outpatients, this data comes from the period between January 2012 and November 2012. For the Hypercalcemia clinical measure, the data comes from the period between May 2012 and November 2012. In Table 9, we have provided the estimated achievement thresholds and benchmarks for each of the measures except for NHSN Bloodstream Infection in

Hemodialysis Outpatients clinical measure (which would be based on data from January 1, 2014 through December 31, 2104) and Patient Informed Consent for Anemia Treatment (for which the achievement threshold and benchmark are proposed to be 92 percent and 96 percent, respectively).

Table 9 – Estimated Proposed Achievement Thresholds and Benchmarks for the Proposed PY 2016 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold	Benchmark
%Fistula	49.8%	77.1%
%Catheter	19.6%	3.0%
Kt/V		
Adult Hemodialysis	85.9%	97.5%
Adult, Peritoneal Dialysis	66.7%	94.8%
Pediatric Hemodialysis	83.3%	98.8%
Anemia Management		
Hemoglobin > 12 g/dL	1.2%	0%
Patient Informed Consent for Anemia Treatment[1]	92%	96%
Hypercalcemia	6.1%	0.2%
NHSN Dialysis Event Reporting and Clinical Bloodstream Infection	15th percentile of eligible facilities' performance during the performance period	90th percentile of eligible facilities' performance during the performance period

[1] As discussed above, the proposed achievement threshold and benchmark for the Patient Informed Consent for Anemia Treatment clinical measure are based on clinical standards, not baseline data.

We believe that the ESRD QIP should not have lower standards than previous years. In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final PY 2016 numerical values for the achievement thresholds and benchmarks are worse than PY 2015 for a given measure, we are proposing to substitute the PY 2015 achievement thresholds and benchmarks for that measure. We request comments on these proposals.

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

Using the same methodology we finalized in the CY 2013 ESRD PPS final rule, we are

proposing to award between 0 and 10 points for each of the proposed clinical measures (77 FR 67504). As noted, we are proposing 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 NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and the Patient Informed Consent for Anemia Treatment clinical measure, which we are proposing to score on achievement alone. For purposes of calculating achievement scores for the clinical measures, we are proposing 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 are proposing 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.

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

Using the same methodology we have previously finalized for the ESRD QIP, we are proposing 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 NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure and 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 are proposing 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 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 request comments on this proposal.

c. Proposals for 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 proposed criteria that 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 are proposing 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):

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

With respect to the proposed Use of Iron Therapy for Pediatric Patients reporting measure, 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 are proposing 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, and therefore scoring based on monthly reporting rates is not feasible.

With respect to the proposed ICH CAHPS reporting measure and Comorbidity reporting measure, we are proposing 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 are proposing to score

these reporting measures differently than the other reporting measures because these require annual or biannual reporting, and therefore scoring based on monthly or quarterly reporting rates is not feasible.

We request comment on the proposed methodology for scoring the PY 2016 ESRD QIP reporting measures.

9. Proposals for 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are also proposing 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 request comment on the proposed method of weighting individual measure scores to derive a measure topic score.

b. Proposal for 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 are proposing to continue weighting clinical measures as 75 percent and reporting measures as 25 percent of the TPS. We request comment 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 are proposing 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 request comment 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 are proposing that the TPSs be rounded to the nearest integer, with half of an integer being rounded up. We request comment on this proposal. For further examples regarding measure and TPS calculations, we refer readers to the figures below.

c. Examples of the Proposed PY 2016 ESRD QIP Scoring Methodology

In this section, we provide examples to illustrate the proposed scoring methodology for PY 2016. Figures 1–3 illustrate the scoring for a clinical measure. Figure 1 shows Facility A's performance on an example clinical measure. Note that for this example clinical measure, the facility 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 46 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

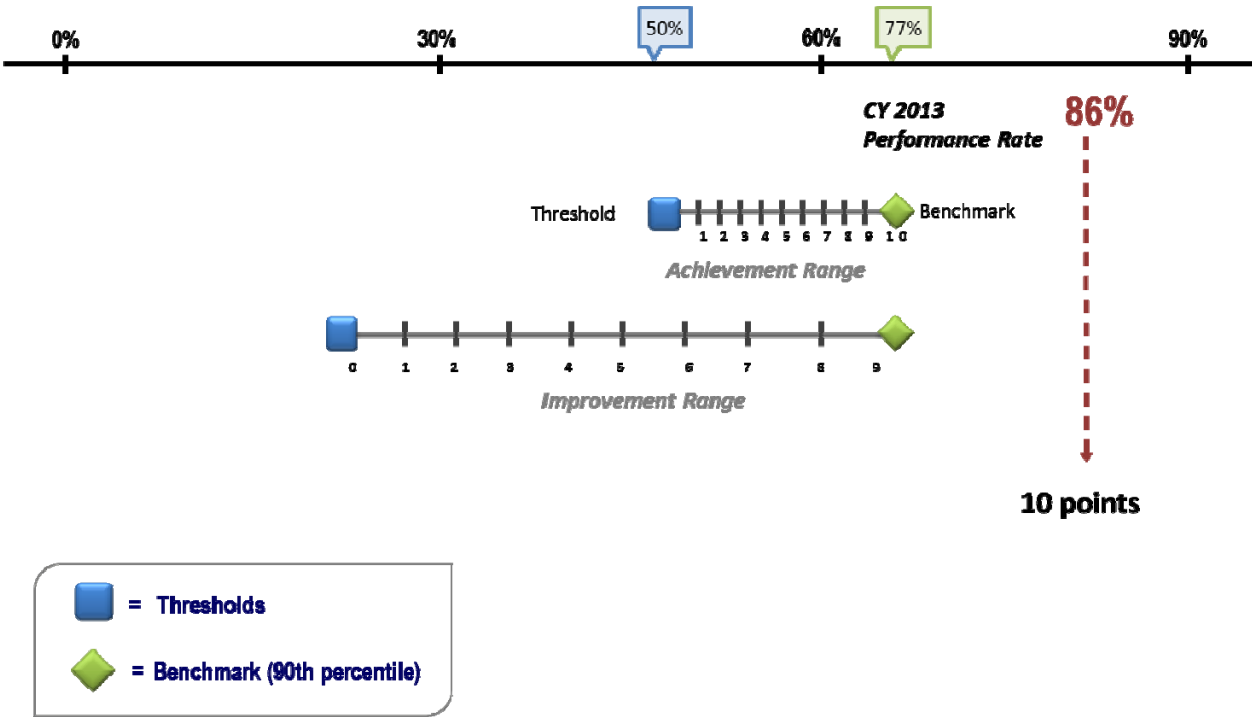


Figure 2 shows an example of scoring for another facility, Facility B. As illustrated below, the facility's performance on the example clinical measure improved from 26 percent in CY 2013 to 54 percent during the performance period. The achievement threshold is 50 percent and the achievement benchmark 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 example clinical measure score.

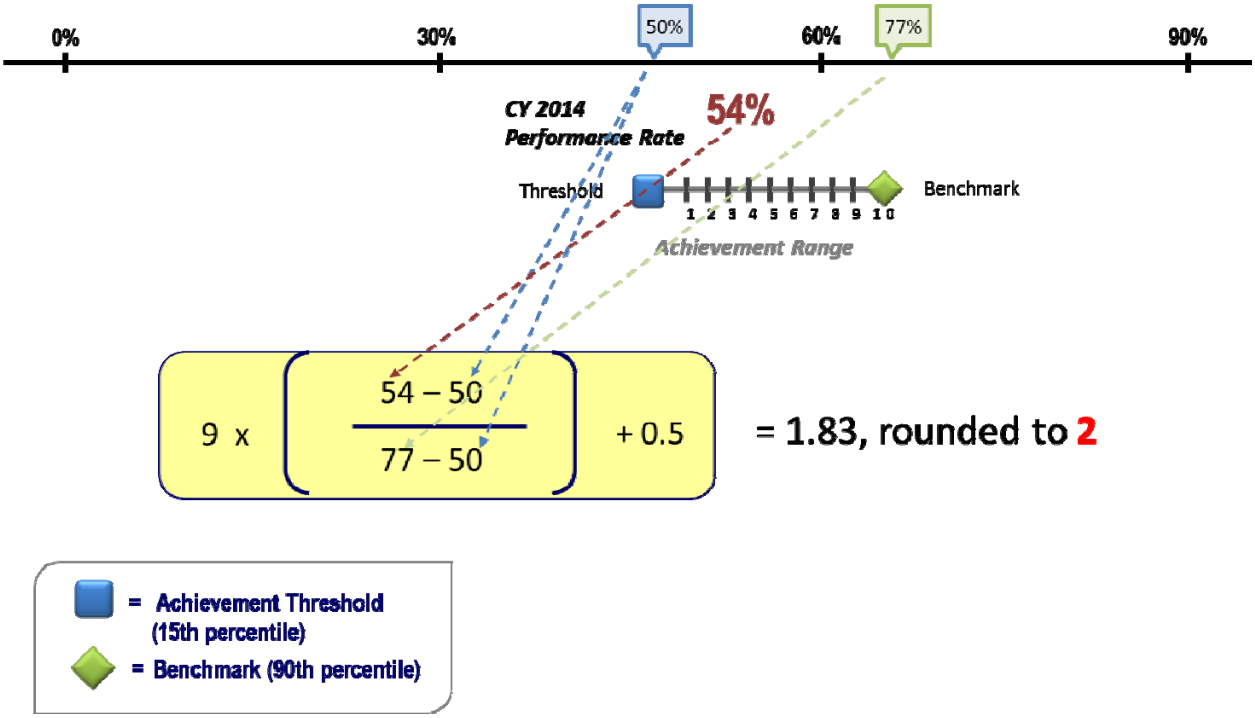
To calculate the achievement score, we would apply the formula discussed above. The result of this formula for this example is [9 * ((54 - 50)/(77 - 50))] + .5, which equals 1.83, and we round to the nearest integer, which is 2.

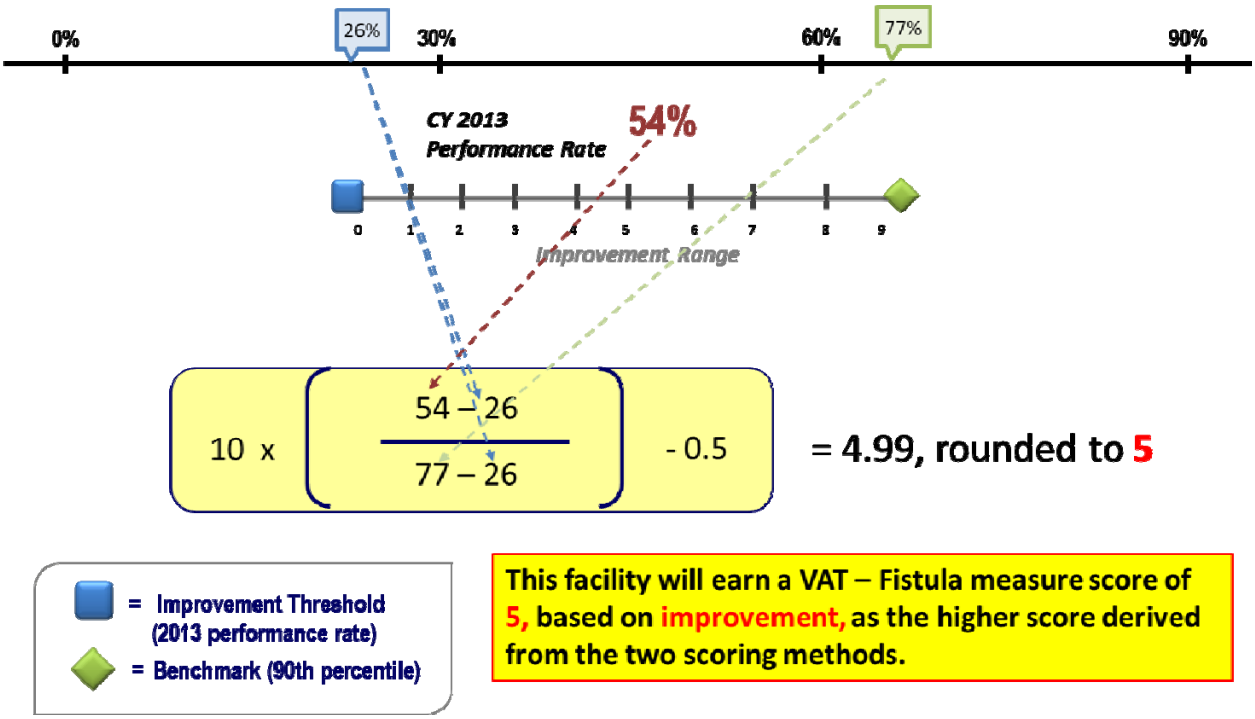
Likewise, to calculate the improvement score, we apply the improvement formula discussed above. The result of this formula for this is example is [10 * ((54 - 26)/(77 - 26))] - .5,

which equals 4.99 and we round to the nearest integer, which is 5.

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

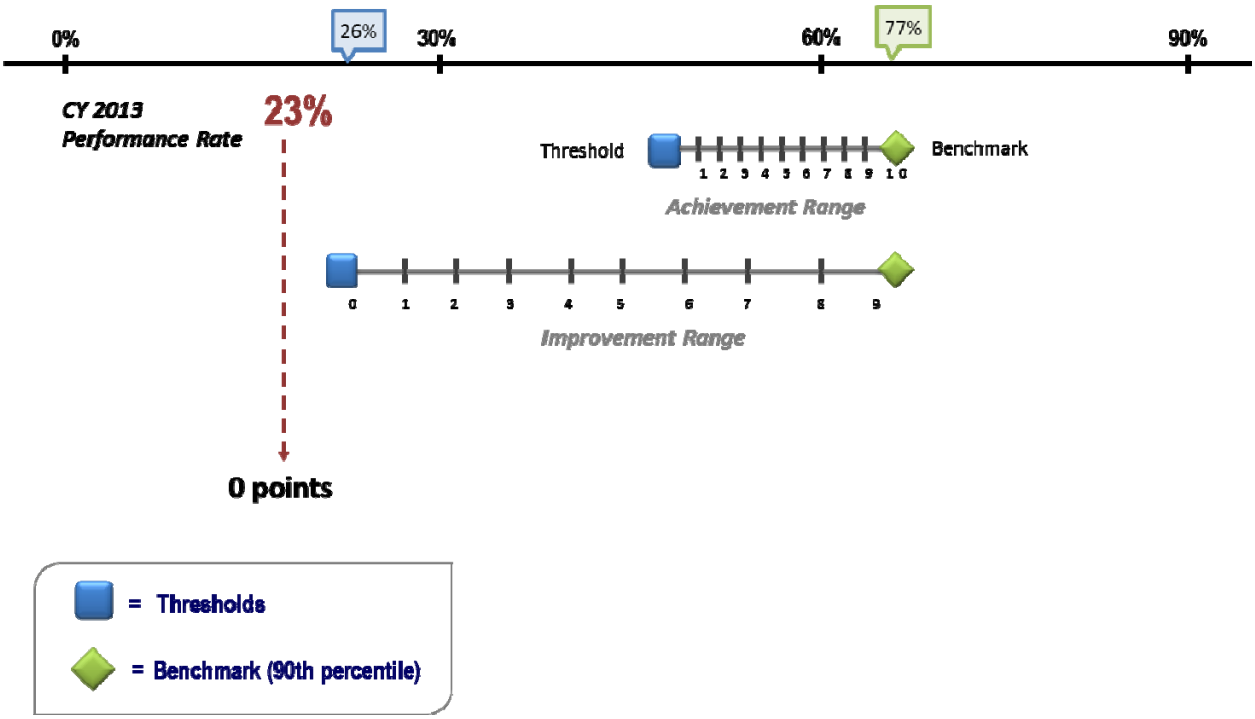
Figure 2





In Figure 3, Facility C's performance on the example clinical 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 example clinical measure.

Figure 3



The method illustrated above would be applied to each clinical measure in order to obtain a score for each measure. Scores for reporting measures are calculated based upon their individual criteria, as 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 = [(.150 * Vascular Access Type Measure Topic) + (.150 * Kt/V Dialysis Adequacy Measure Topic) + (.150 * Anemia Management Clinical Measure Topic) + (.150 * Hypercalcemia Measure) + (.150 * NHSN Bloodstream Infection in Hemodialysis Outpatients) + (.05 * ICH CAHPS Survey Reporting Measure) + (.05 * Mineral Metabolism Reporting Measure) + (.05 * Anemia Management Reporting Measure) + (.05 * Pediatric Iron Therapy Reporting Measure) + (.05 * Comorbidity 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).

However, if, for example, a facility did not receive a score (that is, did not have enough qualifying cases) on the proposed Hypercalcemia 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 * Anemia Management Clinical Measure Topic) + (.188 * NHSN Bloodstream Infection in Hemodialysis Outpatients) + (.05 * ICH CAHPS Survey Reporting Measure) + (.05 * Mineral Metabolism Reporting Measure) + (.05 * Anemia Management Reporting Measure) + (.05 * Pediatric Iron Therapy Reporting Measure) + (.05 * Comorbidity 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).

Finally, for example, 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 = [(.150 * Vascular Access Type Measure Topic) + (.150 * Kt/V Dialysis Adequacy Measure Topic) + (.150 * Anemia Management Cinical Measure Topic) + (.150 * Hypercalcemia Measure) + (.150 * NHSN Bloodstream Infection in Hemodialysis Outpatients) + (.125 * Anemia Management Reporting Measure) + (.125 * Comorbidity 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. Proposed 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 example, if we excluded facilities with 10 or fewer patients from the Pediatric Iron Therapy reporting measure, then very few, if any, facilities would be able to report the measure, and we would be unable to collect meaningful data for future measure development. Similarly, if we excluded facilities with 10 or fewer patients from the comorbidity reporting measure, then we would be unable to use updated comorbidities for patients in these facilities in a risk-adjusment calculation should we propose to adopt an SHR and/or SMR clinical measure in the future. For those reasons, we are proposing that the case minimum for all reporting measures except for ICH CAHPS be one.

For the proposed expanded ICH CAHPS reporting measure, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 seek public comment on these proposals.

For the PY 2016 ESRD QIP and future payment years, we are also proposing 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 are proposing 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 are proposing that only facilities with a CCN open date before January 1 of the performance period to be scored on this measure. Additionally, we are proposing 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 are proposing to collect 12 months of data on this clinical measure because infection rates vary through different seasons of the year.

As discussed above, we are proposing that a facility will not receive a TPS unless it receives a score on at least one clinical and one reporting measure. We note 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 request comment regarding these proposals.

11. Proposed 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 are proposing 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 request 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 are proposing that the payment reduction scale be the same as the PY 2015 ESRD QIP (77 FR 67514 through 67516). We are proposing that, for each 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 request comments on the proposed payment reduction scale.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate the minimum TPS at this time. Based on the estimated performance standards listed above using the most recent data available, we estimate for PY 2016 that a facility must meet or exceed a minimum TPS of 46. For all of the clinical measures except Hypercalcemia, this data comes from the period between January 2012 and November 2012. For the Hypercalcemia clinical measure, the data comes from the period between May 2012 and November 2012. We are proposing that facilities failing to meet the

minimum TPS (as will be published in the Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies final rule in November) will receive payment reductions based on the estimated total performance score ranges indicated in Table 10 below.

Table 10 – Estimated Payment Reduction Scale for PY 2016 based on the Most Recently Available Data

Total Performance Score	Reduction
100–46*	0%
45–36	0.5%
35–26	1.0%
25–16	1.5%
15–0	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 are proposing 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 are proposing 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 QIP reliability while imposing a smaller burden on ESRD QIP-eligible facilities and CMS alike. We are also proposing 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 solicit comments on these proposals.

We are also considering a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module, which may mirror the process used by the Hospital Inpatient Quality Reporting Program (77 FR 53539 through 53553). Although this is still in the early stages of development, we anticipate that this study may mirror the validation sample by targeting "candidate HAI events," much like the methodology used by CMS's Hospital Inpatient Quality Reporting Program. 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.

13. Proposals for 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 (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 proposals are the most operationally efficient and will allow facilities the greatest amount of certainty when they change ownership. We are proposing to continue applying these rules during the PY 2016 ESRD QIP and future years of the program, and we request public comment on this proposal.

14. Proposals for 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 (as 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 are proposing 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 is enough to allow facilites 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 propose that, beginning in PY 2014, facilities must post certificates within fifteen business days of us making these certificates available for download from dialysisreports.org in accordance with section 1881(h)(6)(C) of the Act. We request comments on this proposal.

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 central office issued a program memorandum to the CMS regional offices 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 HCPCS code, 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 indicated that carriers would be provided with a listing of the HCPCS (Health Care Financing Administration Common Procedure Coding System prior to 2003 and Healthcare Common Procedure Coding System beginning in 2003) codes for 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 is under 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." This definition was promulgated via an interim final rule (IFC) on December 7, 1992 (57 FR 57698), 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." 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

Pursuant to 42 CFR §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. Pursuant to 42 CFR §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 a 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, which for Medicare purposes generally require payment on a capped rental basis for any item with a purchase cost of greater than 150 dollars. After reviewing this issue, we do not think the regulation supports the classification of expensive DME as routinely purchased equipment based solely 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 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. We are clarifying the existing definition of routinely purchased equipment at §414.220(a)(2) and providing notice that certain HCPCS codes for DME and DME accessories added to the HCPCS after 1989 that are currently classified as routinely purchased equipment should be reclassified as capped rental items (see Table 11 below). This applies to all expensive items for which Medicare claims data 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, 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 rehabilitiave power wheelchair (that is, furnished to be used as part of the complex rehabilitative powere 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 are soliciting 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. Given that some items (HCPCS codes) may be included in the Round 2 and/or Round 1 Recompete phases of the competitive bidding program, we do not believe we can change the classification for items furnished under these programs until the contracts awarded based on these competitions expire on July 1, 2016, and Janaury 1, 2017, respectively, regardless of whether the item is provided in an area subject to competitive bidding

or not. We propose 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 competitive bidding program (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 propose 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 propose an effective date of January 1, 2017, which would only apply to items furnished in the nine Round 1 Recompete areas. Therefore, we propose to generally base the effect dates on when the competitive bidding programs 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.

With the exception of the items described in the fourth bullet, 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, the effective date for the reclassifications could be January 1, 2014, for all items paid under the fee schedule. In other words, the reclassification would not affect payments for items furnished under the Round 2 or Round 1 Recompete CBPs in the respective CBAs until the contract entered into under these programs expire on July 1, 2016, and January 1, 2017, respectively. However, this alternative would result in an extensive two and a half year period from Janary 2014 through June 2016, where Medicare payment would be on a capped rental basis for the items in half of the country (non-competitive bidding areas) and on a purchase basis in the other half of the country (109 Round 2 and/or Round 1 Recompete competitive bidding areas). We believe that this bifurcation in payment classifications would create confusion and would be difficult to implement, and we are soliciting comments on this alternative implementation strategy.

We have identified approximately 80 HCPCS codes requiring reclassification from the inexpensive or routinely purchased DME payment class to the capped rental DME payment class. The codes are shown in Table 11 below. The impacts of our changes are included in the discussion of impacts in section X of this rule.

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 that are only used with complex rehabilitative power wheelchairs classified as capped rental items, the purchase option for complex rehabilitative power wheelchairs applies to these accessories because they are part of the capped rental wheelchair that the supplier is required to offer to the beneficiary on a lump sum purchase basis. We have displayed in Column B the items that would be associated with the purchase option set forth at section §414.229(a)(5). Wheelchair accessories that are also used with manual wheelchairs or standard power wheelchairs would also be subject to the purchase option if they are furnished for use with a 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
Osteogenesis Stimulator	E0760	Osteogenesis ultrasound stimulator
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
Respiratory Equipment	E0457	Chest shell
Speech Generating Devices	E2500	SGD digitized pre-rec <=8min
	E2502	SGD prerec msg >8min <=20min
	E2504	SGD prerec msg>20min <=40min
	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

Group Category	HCPCS	Descriptor
	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
	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

Group Category	HCPCS	Descriptor
	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

In summary, we are providing notice of certain HCPCS codes that would be reclassified as capped rental items (see Table 11 of codes). We invite comments on this section.

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 undersection 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.

B. 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 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 and national coverage determinations 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 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 these 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 and applying the 3-year MLR to these items could impact the continuity of care for these beneficiaries. 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 invite public comments on this issue.

C. 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, we are providing clarification about how we would regard grandfathered items covered as DME prior to the effective date and we request comments on that clarification. 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 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 no longer lasts 2 years, such 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 seek comments on this proposed clarification.

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 change 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 performaing 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 propose 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. Nevertheless, we are specifically requesting comments on this issue.

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 is used as the fee schedule amount for the few IOLs that are still inserted in a physician's office, we do 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 physicaian'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 will save government resources in calculating the reasonable charge payment for the low volume items. We are proposing to establish fee schedules for these items effective for paying claims with dates of service on or after January 1, 2014.

B. Provisions of the Proposed Regulations

For the reasons we articulated above, we propose, 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 this proposed rule, we have inserted the current 2013 reasonable charge amounts for splints, casts and IOLs inserted in a physican's office. The splints and casts are payment amount limits updated by the CPI-U factor ending with June of the preceding year, in this case June 2012. The IOLs inserted in physician's office estimates the 2012 average allowed charge. 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 are using the estimate of the 2012 average allowed charge. The final fee schedule amount will be specified in the final rule. We currently do not have the percentage change in the CPI-U for the 12-month period ending with June of 2013 to update the fee-schedule amounts for splints and casts. Specifically, we are proposing 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 physican's office. We are also proposing 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 physican'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 propose 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. 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.

For IOLs inserted in a physician's office, we propose 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.

VII. DMEPOS Technical Amendments and Corrections

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 propose 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).

B. Proposed Technical Amendments and Corrections

Below are the proposed technical amendments.

- We propose 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 propose 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 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 off set 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 propose that §414.226(c)(6) be revised 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 are also making 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.

VIII. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection 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 proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2014. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, this proposed rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

a. Proposed 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 proposed 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 estimate 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 estimate 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 estimate 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 estimate 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 estimate that the aggregate cost of this requirement for PY 2016 will be $14,991 (459 hours x $32.66/hour).

We estimate 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 estimate 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 estimate 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 x $32.66) for an estimated annual burden of $9,666,714 ($1,698 per facility x 5,693 facilities).[9] We previously estimated that the aggregate cost of submitting survey data to CMS is $14,991. Therefore, we estimate 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.

b. Proposed 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 x 2.5 hours) at a total of $24,495 (750 hours x $32.66/hour) or $81.65 ($24,495/300 facilities) per facility in the sample.

2. The discussion on clarifying the definition of routinely purchased DME does not contain any new information collection requirements.

[9] We note that this total represents an underestimate of the overall burden because it does not include time costs for patients.

3. The clarification of the the 3-year Minimum Lifetime Requirement for DME does not contain any new information collection requirements.

4. The proposed implementation of Budget-Neutral Fee Schedules for Splints, Casts and Intraocular Lenses does not contain any new information collection requirements.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage

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

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

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

Attention: CMS Desk Officer, **[CMS-1526-P]**

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

IX. Response to Comments

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

X. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We examined the impacts of this proposed rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated economically significant under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rule. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

This rule proposes a number of routine updates for renal dialysis services in CY 2014, proposes to implement the fourth year of the ESRD PPS transition, and proposes to make several policy changes to the ESRD PPS. These include proposed updates and changes to the ESRD PPS base rate, wage index values, the wage index budget-neutrality adjustment factor, 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 proposed rule would result in ESRD

facilities not receiving appropriate payments in CY 2014.

This rule proposes to implement the ESRD QIP for PY 2016 and beyond by proposing to adopt measures, scoring, and payment reductions to incentivize improvements in dialysis care as directed by section 1881(h) of the Act. Failure to propose requirements for the PY 2016 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2015.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in a decrease of approximately $970 million in payments to ESRD facilities in CY 2014, which 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, 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 proposed requirements related to the ESRD QIP will cost approximately $39.5 thousand and the predicted payment reductions will equal about $26.4 million to result in a total impact from the proposed ESRD QIP requirements of $26.4 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 proposed 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 intraocular lenses inserted in a physician's office.

We estimate that our proposed clarification of the definition of routinely purchased DME and re-classification of certain items as cap rental items would impact certain DMEPOS

providers. We estimate that the clarification of the 3-year minimum lifetime requirement 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 proposed rule, we used the December 2012 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.B of this proposed rule. 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 PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2014 PROPOSED RULE

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2014 Changes in Outlier Policy[4] C	Effect of 2014 Changes in Wage Indexes D	Effect of 2014 Changes in Market Basket minus productivity update E	Effect of 2014 Changes in Base Rate due to Drug Utilization F	Effect of Total 2014 changes[5] G
All Facilities	5,771	38.1	0.4%	0.0%	2.5%	-12.0%	-9.4%
Type							

Freestanding	5,270	35.4	0.4%	0.0%	2.5%	-12.0%	-9.4%
Hospital based	501	2.7	0.3%	0.1%	2.5%	-11.9%	-9.3%
Ownership Type							
Large dialysis organization	3,769	25.9	0.4%	0.0%	2.5%	-12.0%	-9.4%
Regional chain	885	6.1	0.4%	0.0%	2.5%	-12.0%	-9.4%
Independent	614	3.9	0.2%	0.1%	2.5%	-12.0%	-9.5%
Hospital based[1]	400	2.1	0.2%	0.1%	2.5%	-11.9%	-9.4%
Unknown	103	0.2	0.3%	-0.2%	2.5%	-12.0%	-9.6%
Geographic Location							
Rural	1,257	6.3	0.4%	-0.1%	2.5%	-12.0%	-9.5%
Urban	4,514	31.8	0.4%	0.0%	2.5%	-12.0%	-9.4%
Census Region							
East North Central	946	5.7	0.4%	-0.2%	2.5%	-11.9%	-9.5%
East South Central	477	2.9	0.5%	-0.2%	2.5%	-11.9%	-9.5%
Middle Atlantic	634	4.6	0.4%	0.5%	2.5%	-12.0%	-9.0%
Mountain	340	1.8	0.3%	0.1%	2.5%	-12.0%	-9.4%
New England	170	1.3	0.4%	0.2%	2.5%	-12.0%	-9.2%
Pacific[2]	684	5.3	0.1%	0.4%	2.5%	-12.0%	-9.3%
Puerto Rico and Virgin Islands	41	0.3	0.4%	-2.3%	2.5%	-11.9%	-11.5%
South Atlantic	1,288	8.8	0.5%	-0.3%	2.5%	-12.0%	-9.6%
West North Central	416	2.0	0.4%	-0.1%	2.5%	-12.0%	-9.5%
West South Central	775	5.5	0.5%	-0.1%	2.5%	-11.9%	-9.5%
Facility Size							
Less than 4,000 treatments[3]	1,044	2.6	0.4%	0.0%	2.5%	-12.0%	-9.4%
4,000 to 9,999 treatments	2,157	10.4	0.4%	-0.1%	2.5%	-12.0%	-9.5%
10,000 or more treatments	2,400	24.7	0.4%	0.0%	2.5%	-12.0%	-9.4%
Unknown	170	0.4	0.4%	-0.1%	2.5%	-12.0%	-9.5%
Percentage of Pediatric Patients							
Less than 2%	5,662	37.7	0.4%	0.0%	2.5%	-12.0%	-9.4%
Between 2% and19%	44	0.3	0.3%	0.0%	2.5%	-11.9%	-9.5%
Between 20% and 49%	6	0.0	0.1%	-0.3%	2.5%	-12.0%	-9.9%
More than 50%	59	0.1	0.0%	0.1%	2.5%	-12.0%	-9.7%

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 1,044 ESRD facilities with less than 4,000 treatments, only 375 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 9.5 percent decrease in payments.

4. Includes the effect of including the Pacific Rim ESRD facilities of Guam, American Samoa, and the Northern Mariana Islands into the PPS.

5. Includes the effect of Market Basket minus productivity increase of 2.5 percent to the ESRD PPS base rate and the effect of the $29.52 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 proposed changes to the outlier payment policy described in section II.B.6. of this proposed 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 0.0 percent to a 0.5 percent increase. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2014 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the wage index on ESRD facilities and reflects the CY 2014 wage index values for the ESRD PPS payments. 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 0.5 percent increase due to the update of the wage index.

Column E shows the effect of the ESRDB market basket increase minus productivity adjustment. The impact on all facilities would be a 2.5 percent increase.

Column F shows the effect of the drug utilization adjustment required by section 1881(b)(14)(I). For CY 2014, the impact on all facilities as a result of the $29.52 decrease to the base rate, as described in section II.B.2.a., would be a 12 percent decrease in estimated payments. The estimated impact ranges from 11.9 percent to 12 percent decrease.

Column G reflects the overall impact (that is, the effects of the proposed outlier policy changes, the proposed wage index, the effect of the ESRDB market basket increase minus productivity adjustment, and the effect of the drug utilization adjustment required by section 1881(b)(14)(I). We expect that overall, ESRD facilities will experience a 9.4 percent decrease in estimated payments in 2014. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive an 11.5 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 negative impacts ranging from a decrease of 9.9 percent to 9.0 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 proposed ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2014 will be approximately $8 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 3.8 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 9.4 percent overall decrease in the proposed ESRD PPS payment amounts in CY 2014, we estimate that there will be a decrease in beneficiary co-insurance payments of 9.4 percent in CY 2014, which translates to approximately $190 million.

e. Alternatives Considered

For this proposed rule, we proposed to implement the full reduction required by section 1881(b)(14)(I) in CY 2014. In particular, we proposed a one-time reduction of $29.52 to the ESRD PPS base rate. We considered proposing to implement the reduction using a transition. For example, we considered transitioning the reduction over a 2 or 3-year period. We chose to implement the full reduction by reducing the ESRD PPS base rate by an adjustment to reflect change in the utilization of ESRD-related drugs and biologicals by comparing utilization data from 2007 with such data from 2012.

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 are proposing to determine a facility's TPS is described in section III.C.11

of this proposed 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 proposed rule, we estimate that, of the total number of dialysis facilities (including those not receiving an ESRD QIP TPS), approximately 36 percent or 2,069 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
0.0%	3,417	62.3%
0.5%	994	18.1%
1.0%	583	10.6%
1.5%	280	5.1%
2.0%	212	3.9%

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 – Jun 2012	July 2012 – Dec 2012
Vascular Access Type		
% Fistula	Jan 2011 – Dec 2011	Jan 2012 – Dec 2012
% Catheter	Jan 2011 – Dec 2011	Jan 2012 – Dec 2012
Kt/V		
Adult HD	Jan 2011 – Dec 2011	Jan 2012 – Dec 2012
Adult PD	Jan 2011 – Dec 2011	Jan 2012 – Dec 2012
Pediatric HD	Jan 2011 – Dec 2011	Jan 2012 – Dec 2012
Hypercalcemia	Jan 2011 – Dec 2011	May 2012 – Dec 2012

Clinical measures with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to the estimated minimum Total Performance Score and the payment reduction table found in section III.C.11 of this proposed rule. Facilities were required to have a score on at least one clinical measure to receive a Total Performance Score. For these simulations, the NHSN Bloodstream Infection in Hemodialysis Outpatients and Patient Informed Consent for Anemia Treatment clinical measures, as well as the reporting measures were not included due to lack of data availability. Therefore, the simulated facility Total Performance Scores were calculated using only some of the clinical measure scores.

To estimate the total payment reductions in PY 2016 for each facility resulting from this proposed 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 2,069

facilities expected to receive a reduction is approximately $26.4 million ($26,355,878). Further, we estimate that the total costs associated with the collection of information requirements for PY 2016 described in section VII.B.2 of this proposed rule would be approximately $15 thousand for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of $26.4 million ($39,486 + $26,355,878= $26,395,364) 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 Proposed QIP Payment Reductions to ESRD Facilities for PY 2016

	Number of Facilities	*Number of Medicare Treatments 2012 (in millions)*[3]	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
All Facilities	5,771	38.1	5,486	2,069	-0.35%
Facility Type:					
Freestanding	5,270	35.4	5,116	1,854	-0.32%
Hospital-based	501	2.7	370	215	-0.67%
Ownership Type:					
Large Dialysis	3,769	25.9	3,710	1,228	-0.29%
Regional Chain	885	6.1	849	355	-0.36%
Independent	614	3.9	572	292	-0.52%

	Number of Facilities	*Number of Medicare Treatments 2012 (in millions)*[3]	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
Hospital-based (non-chain)	400	2.1	289	169	-0.66%
Unknown	103	0.2	66	25	-0.47%
Facility Size:					
Large Entities	4,654	32.0	4,559	1,583	-0.30%
Small Entities[1]	1,014	5.9	861	461	-0.57%
Unknown	103	0.2	66	25	-0.47%
Urban/Rural Status:					
Rural	1,257	6.3	1,191	416	-0.31%
Urban	4,514	31.8	4,295	1,653	-0.35%
Census Region:					
Northeast	786	5.8	741	309	-0.40%
Midwest	1,325	7.7	1,233	478	-0.37%
South	2,501	17.1	2,440	923	-0.34%
West	998	7.0	966	302	-0.27%
US Territories[2]	161	0.5	106	57	-0.66%
Census Division:					
Pacific Rim	7	0.1	7	5	-0.92%
East North Central	946	5.7	868	354	-0.38%
East South Central	477	2.9	465	147	-0.27%
Middle Atlantic	634	4.6	595	254	-0.42%
Mountain	340	1.8	325	82	-0.21%
New England	170	1.3	154	58	-0.28%
Pacific	677	5.2	652	224	-0.30%
South Atlantic	1,288	8.8	1,245	490	-0.37%
West North Central	416	2.0	383	129	-0.34%
West South Central	775	5.5	754	298	-0.34%

	Number of Facilities	*Number of Medicare Treatments 2012 (in millions)*[3]	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
US Territories[2]	41	0.3	38	28	-0.86%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,044	2.6	853	273	-0.36%
4,000-9,999 treatments	2,157	10.4	2,136	730	-0.30%
Over 10,000 treatments	2,400	24.7	2,384	1,027	-0.38%
Unknown	170	0.4	113	39	-0.41%

[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 proposed 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 Total Performance Score. 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 regulation 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 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 will 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 (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 will limit what can be covered as DME compared to what we would have covered as DME absent this regulatory clarification. . Additionally, to the extent the regulatory change is binding to some new products, there may be reduced program cost. The final rule does apply to items that were classified as DME on or before January 1, 2012 which tends to lessen the overall impact to the program. In general, we expect that the final rule (76 FR 70311) and clarification we are now proposing of the 3-year MLR would have a minimal, if any, savings impact on the expenditures under program. This is because the vast majority if items classified as DME in the past have had lifetimes of 3 years or more and so there would be very few instances, if any, where this clarification will have any impact on classification of items as DME.

c. Definition of Routinely Purchased DME

As discussed in section IVof this rule, this rule would clarify the definition of routinely purchased equipment set forth at section §414.220(a) and would classify an expensive item of DME or accessory (over $150) as a capped rental item if it 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.

As shown in Table 11 of section IV of the preamble, our review identified 80 current HCPCS codes requiring reclassification from routinely purchased DME to capped rental DME. The majority of codes relate to manual wheelchairs and wheelchair accessories. We have displayed in Column B accessories of complex rehabilitative power wheelchairs that would 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. In addition, we have displayed in Table 16 below and Column B of Table 11 of section IV of the preamble approximately 14 codes which would be reclassified in two stages effective July 1, 2016, rather than January 1, 2014, 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 Options/Accessories	E0985 E1020 E1028 E2228 E2368 E2369 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 would be reclassified.

Table 17: Impact of Items Reclassified to Capped Rental DME Category

FY	Impact to the federal government) (in $ millions)
2014	-20

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 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.

From table 11 of section IV of the preamble above, entitled Routinely Purchased Items Reclassified to Capped Rental, for items that would be paid on a capped rental basis with no purchase option, the highest volume items in terms of 2012 allowed charges are:

Table 18: Three Highest Volume Routinely Purchased Items Reclassified to Capped Rental

HCPCS	Item	Purchase Fee	Allowed Charges	Code Added
E0760	Ultrasonic Bone Growth Stimulator	$3,514	$21,370,310	1997
E2510	Speech Generating Device	$7,356	$20,170,162	2001
E1161	Tilt In Space Manual Wheelchair	$2,571	$18,666,674	2003

The allowed charges in 2012 for these three items combined were approximately $60 million, which makes up almost half of approximately $130 million in allowed charges 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 19 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

Table 19 Accounting Statement: Classification of Estimated Transfers and Costs/Savings				
ESRD PPS for CY 2014				
Category	**Transfers**			
Annualized Monetized Transfers	$ -780 million			
From Whom to Whom	Federal government to ESRD providers			
Category	**Transfers**			
Increased Beneficiary Co-insurance Payments	$ -190 million			
From Whom to Whom	Beneficiaries to ESRD providers			
ESRD QIP for PY 2016				
Category	**Transfers**			
Annualized Monetized Transfers	-$26.4 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	-$25.3 million	2013	7%	2014 - 2018
	-$25.7 million	2013	3%	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 proposed 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 18 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 18 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 614 facilities that are independent and the 400 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 proposed in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 9.4 percent decrease in payments for CY 2014. An independent facility (as defined by ownership type) is estimated to receive a 9.5 percent decrease in payments for CY 2014.

Based on the proposed QIP payment reduction impacts to ESRD facilities for PY 2016, we estimate that of the 2,069 ESRD facilities expected to receive a payment reduction, 461 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 $12,738 per facility among the 2,069 facilities receiving a payment reduction, with an average of $13,810 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 461 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 1,014 small entity facilities. For this entire group of 1,014 ESRD small entity facilities, a decrease of 0.57 percent in aggregate ESRD payments is observed.

Splints, casts and intraocular lenses (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 would take effect on January 1, 2014, for splints and casts would be the same as the reasonable charge amounts that would take effect on January 1, 2014, for these items. This rule would have no impact on small businesses that furnish these items. Given that Medicare pays for very few intraocular lenses 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 January 1, 2014, for intraocular

lenses 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 proposed rule will have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 159 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 159 rural hospital-based dialysis facilities will experience an estimated 10.1 percent decrease in payments. As a result, this proposed rule is estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will 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 proposed rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $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 proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XIV. Congressional Review Act

This proposed 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 proposed rule. Beginning in CY 2012, the Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet. We will continue to post the Addenda through the Internet.

Readers who experience any problems accessing the Addenda that are posted on the CMS website at http://www.cms.gov/ESRDPayment/PAY/list.asp, should contact 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, and Reporting and recordkeeping requirements

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

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL 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) 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)).

2. 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)

5. 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.

6. 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 January 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.

5. 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.

7. 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.

8. Revise the heading to Subpart D to read as follows:

Subpart D – Payment for Durable Medical Equipment, Prosthetic and Orthotic Devices, and Surgical Dressings

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9. 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.

10. 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: June 19, 2013

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Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: June 26, 2013

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Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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