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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413 and 414

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Medicare Program; End-Stage Renal Disease Prospective Payment System

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

ACTION: Final rule.

SUMMARY: This final rule implements a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011 (ESRD PPS), in compliance with the statutory requirement of the Medicare Improvements for Patients and Providers Act (MIPPA), enacted July 15, 2008. This ESRD PPS also replaces the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

DATES: *Effective Date:* These regulations are effective on January 1, 2011, except for § 413.174(f)(6), which will be effective on January 1, 2014 and § 413.232(f) and § 413.239(b), which will be effective November 1, 2010.

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Acronym List

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

Act The Social Security Act
ASC Ambulatory surgical center
AV Arteriovenous
BIPA Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)
BMI Body mass index
BSA Body surface area
BLS Bureau of Labor Statistics
CAH Critical assess hospitals
CAPD Continuous ambulatory peritoneal dialysis
CBC Complete blood count
CBSA Core-Based Statistical Area
CCPD Continuous cycling peritoneal dialysis
CDC Centers for Disease Control and Prevention
CFC Conditions for Coverage
CFR Code of Federal Regulations
CKD Chronic kidney disease
CMS Centers for Medicare & Medicaid Services
COLA Cost of living allowance
CPM Clinical performance measure
CR Composite rate
CROWN Consolidated Renal Operations in a Web-Enabled Network
CY Calendar year
DFC Dialysis facility compare
DME Durable medical equipment
EDB Enrollment Data Base
EPO Epoetin alfa
ESA Erythropoiesis stimulating agent
ESRD End-stage renal disease
FI Fiscal intermediary
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
HD Hemodialysis
IDPN Intradialytic parenteral nutrition
IEF Isolated essential facility
IHS Indian Health Service
IPD Intermittent peritoneal dialysis
IPN Intraperitoneal parenteral nutrition
IPPS Inpatient prospective payment system
IQR Interquartile range
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large dialysis organization
LPN Licensed practical nurse
LTC Long term care
MAC Medicare Administrative Contractor
MAP Medicare allowable payment
MBR Master beneficiary record
MCP Monthly capitation payment
MCR Medical cost reports
MedPAC Medicare Payment Advisory Commission
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MRSA Methylcyline resistance staphylococcus aurues
MSA Metropolitan Statistical Area
MUE Medically unbelievable edit
NAICS North American Industry Classification Systems
NIH National Institutes of Health
NKF–KDOQI National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines
NOS Not otherwise specified
NQF National Quality Forum
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OSCAR Online State Certification and Reporting System
PD Peritoneal dialysis
PDE Prescription drug event
PFS Physician fee schedule
PPI Producer price index
PPS Prospective payment system
PRS Practice-related risk score
PVD Peripheral vascular disease
QIP Quality Incentive Program
REMIS Renal Management Information System
RN Registered nurse
RRB Railroad Retirement Board
RRT Renal replacement therapy
SAF Standard analytical file
SB Separately billable
SDO Small dialysis organization
SIMS ESRD Standard Information Management System
SSA Social Security Administration
UM–KECC University of Michigan, Kidney Epidemiology & Cost Center
URR Urea reduction ratio
USRDS United States Renal Data System
WAC Wholesale acquisition cost

I. Background

A. Overview of the Proposed ESRD PPS

On September 29, 2009, we published in the **Federal Register** a proposed rule entitled "End-Stage Renal Disease Prospective Payment System" (74 FR 49922). In that rule, we proposed that the ESRD PPS would combine payments for composite rate and separately billable services into a single base rate of $198.64 developed from CY 2007 claims data (74 FR 49944). Under the proposed rule, the base rate would be adjusted using patient-specific case-mix adjustment factors developed from separate equations for composite rate and separately billable services (74 FR 49949). The case-mix adjusters would include variables for age, body surface area (BSA), low body mass index (BMI), patient sex, eleven co-morbidity categories, and the onset of renal dialysis. The proposed adjustment factors were developed using standard techniques of multiple regression analysis to yield case-mix adjusted payments per treatment. The per treatment payment amounts would also be adjusted to reflect urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Area (CBSA) definitions (74 FR 49968). The proposed rule also provided that ESRD facilities treating patients with unusually high resource requirements as measured through their utilization of identified services beyond a specified threshold would be entitled to outlier payments, that is, additional payments beyond the otherwise applicable case-mix adjusted prospective payment amount (74 FR 49988). The proposed ESRD PPS also provided for special adjustments for pediatric patients (74 FR 49981) and for facilities treating a low-volume of ESRD patients) 74 FR 49969), as well as a 4-year transition (phase-in) period under which facilities would receive a blend of payments under the prior case-mix adjusted composite payment system and the new ESRD PPS (74 FR 50003). This final rule will implement a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis patients beginning January 1, 2011, in accordance with the statutory provisions set forth in section 153(b) of MIPPA.

B. Legislative History and Statutory Authority for the ESRD Prospective Payment System

Section 299I of the Social Security Amendments of 1972, Public Law 92–603, established the ESRD program under Medicare. That law extended Medicare coverage to individuals regardless of age who have permanent kidney failure, requiring either dialysis or kidney transplantation to maintain life, and meet certain other eligibility criteria.

The enactment of the Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, resulted in changes to the ESRD payment system. Section 2145 of Public Law 97–35 amended section 1881 of the Act by requiring the Secretary to provide by regulation a method for determining prospectively

the amounts of payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility, and to such individuals at home. In particular, the law required that such method be based on a single composite weighted formula ("composite rate") (which takes into account the mix of patients who receive services at a facility or at home and the relative costs for furnishing such services) for hospital-based facilities and such a single composite rate for other renal dialysis facilities, or that payment be based on such other method or combination of methods which differentiate between hospital-based and other renal dialysis facilities, and which would more effectively encourage more efficient delivery of dialysis services and would provide greater incentives for increased use of home dialysis.

As a result of these statutory requirements, on February 12, 1982, we published a proposed rule on reimbursement for outpatient dialysis services (47 FR 6556) to implement section 1881 of the Act, as amended by section 2145 of Public Law 97–35. The regulations provided that each facility would receive a payment rate per dialysis treatment ("composite rate"), that is adjusted for geographic differences in area wage levels for the treatment furnished in the facility or at home. We refer to the methodology for payment of outpatient maintenance dialysis services on a per-treatment basis as the "composite payment system".

Final regulations implementing the composite payment system were published on May 11, 1983 (48 FR 21254). The initial payment rates, which were developed from Medicare cost reports for fiscal years ending in 1977, 1978, and 1979, were established at $127 per treatment for independent facilities and $131 for hospital-based facilities. The composite payment system was effective August 1, 1983. It was limited to payments for the costs incurred by dialysis facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether furnished by hospital-based and independent facilities in a facility or at home. We established separate rates for hospital-based and independent dialysis facilities, and provided a process under which facilities with costs in excess of their payment rates could seek exceptions to those rates under specified circumstances.

With regard to home dialysis, this system was the basis for reimbursing home dialysis furnished by hospital-based and independent facilities (Method I). (The other is Method II, under which the beneficiary works directly with a durable medical equipment (DME) supplier to obtain the supplies and equipment needed.) For further information on the distinctions between Method I and Method II, *see* section II.A.7. of this final rule.

The composite payment system implemented in 1983 was relatively comprehensive with respect to the renal dialysis services included as part of the composite payment bundle. However, over time a substantial portion of expenditures for renal dialysis services became excluded from the composite payment system and reimbursed in accordance with the respective fee schedules or other payment methodologies. For example, payments for erythropoiesis stimulating agents (ESAs) such as epoetin alfa (EPO, for example, Epogen®) and darbepoetin alfa (ARANESP®) used to treat anemia, and vitamin D analogues (paracalcitol, doxercalciferol, calcitriol), are made outside of the composite payment system as separately billable services. These separately billable services currently comprise about 40 percent of total spending for outpatient maintenance dialysis. Thus, the current payment for outpatient maintenance dialysis under Medicare represents a mix of prospective payment, fee-for-service, and other payment rules.

Subsequent inflation increases to the composite payment system occurred only in response to specific statutory directives. For example, between 1983 and 2001, the payment rates were increased only three times. A $1.00 increase per treatment was effective January 1, 1991 as a result of the enactment of the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508. The rates were not revised again until the enactment of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113, which increased the payments by 1.2 percent effective January 1, 2000 and January 1, 2001, respectively.

During the last few years, policymakers and other interested parties, including the Medicare Payment Advisory Commission (MedPac) and the Government Accountability Office (GAO), have examined the Medicare outpatient maintenance dialysis payment system and suggested a bundled prospective payment approach. *See Medicare Payment Advisory Commission (MedPAC): Report to the Congress: Medicare Payment Policy,* March 2001, March 2005, and March 2007, and GAO Report GAO–07–77, *End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility,* November 2006. The ESRD PPS would combine composite rate dialysis services with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix. As in any PPS, dialysis facilities would keep the difference if Medicare payments exceeded costs for the bundled services, and would be liable for the difference if costs exceeded Medicare payments.

Aside from resulting in a single comprehensive payment for all services included in the bundle, we believe the ESRD PPS would meet several objectives. These include reducing incentives to overuse profitable separately billable drugs, particularly EPO, the targeting of greater payments to ESRD facilities with more costly patients to promote both equitable payment and access to services, and the promotion of operational efficiency. Because of the increased flexibility a bundled PPS would provide in the delivery of outpatient maintenance dialysis services, we believe that it could also increase desirable clinical outcomes, resulting in an enhanced quality of care.

The Congress has twice required studies on the bundling of additional services into the composite payment system. In section 422(c)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554, the Congress required the Secretary to issue a report on a bundled system that would include separately billable drugs and clinical laboratory services routinely used in furnishing dialysis. The Secretary submitted this report, *Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System,* to Congress in May 2003. That report contained three major findings that would form the basis for the subsequent development of the ESRD PPS:

1. Currently available administrative data are adequate for proceeding with the development of an expanded outpatient ESRD PPS.

2. Case-mix adjustment is potentially feasible based on available clinical information for ESRD patients in order to pay facilities appropriately for treating more costly resource intensive patients.

3. Current quality review initiatives provide a basis for monitoring the impact of a bundled ESRD PPS after implementation, to ensure quality of

care does not deteriorate in response to the system's efficiency incentives.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, also required the Secretary to submit to the Congress a report detailing the elements and features for the design and implementation of a bundled ESRD PPS. Section 623(f)(1) of the MMA specified that such a system should include the bundling of separately billed drugs, clinical laboratory tests, and other items "to the maximum extent feasible". That section also required the report to include a description of the methodology to be used to establish payment rates and that the report, detailing the design of an appropriate bundled payment system, be submitted to the Congress by October 1, 2005. Section 623(e) of the MMA also required a demonstration project testing the feasibility of using a fully bundled case-mix adjusted ESRD PPS.

In addition to requiring a report on a bundled ESRD PPS, section 623 of the MMA amended section 1881(b) of the Act, by requiring significant revisions to the composite payment system. Specifically, section 623 of the MMA required:

- An increase of 1.6 percent to the composite payment rates effective January 1, 2005.
- An add-on to composite rate payments to account for the difference in payments for separately billable drugs based on a revised drug pricing methodology compared to the previous method.
- A "basic" case-mix adjustment to an ESRD facility's composite payment rate reflecting a "limited number of patient characteristics."
- That total payments under the basic case-mix adjusted composite payment system be budget neutral.
- An annual increase to the basic case mix adjusted payment amounts based on projected growth in expenditures for separately billed drugs (the "growth update").
- That payment rates be adjusted by a geographic index, as determined appropriate by the Secretary (and phased-in to the extent such index differed from the previous payment system).
- Reinstatement of the composite rate exceptions process, eliminated for most dialysis facilities beginning December 31, 2000 under BIPA, for ESRD pediatric facilities, effective October 1, 2002.

On August 5, 2004 and November 15, 2004, we published a proposed rule and final rule (69 FR 47487 through 47730 and 69 FR 66235 through 66915), respectively, implementing the provisions affecting the composite payment system effective January 1, 2005, as set forth in section 623 of the MMA. We refer to the modified composite payment system as the "basic case-mix adjusted composite payment system". The development and application of the basic case-mix adjustments, using regression based adjustment factors for the patient variables of age, BMI, and low BMI, are explained in each of those rules. (For more information, we refer readers to 69 FR 47529 and 69 FR 66323, respectively.) The product of the specific adjusters for each patient, multiplied by the otherwise applicable composite payment rate, yielded the basic case-mix adjustment required by the MMA. The basic case-mix adjusted composite payment system was effective April 1, 2005, and was developed from research conducted by the University of Michigan Kidney Epidemiology and Cost Center (UM–KECC) and summarized in its report, *Methodology for Developing a Basic Case-Mix Adjustment for the Medicare ESRD Prospective Payment System* (May 19, 2004 report and April 1, 2005 addendum).

Subsequent to our implementation of the MMA requirements discussed above, UM–KECC continued its research to develop a case-mix adjusted ESRD PPS that would combine composite rate and separately billable services. UM–KECC reported its findings and recommendations in a final report submitted to CMS in February 2008, *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle.* That report is available on the internet at: *http://www.sph.umich.edu/kecc/assets/documents/UM-KECC%20ESRD%20Bundle%20Report.pdf.* UM–KECC's final report formed the basis for the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System,* mandated under section 623(f)(1) of the MMA.

The aspects of the basic case-mix adjusted composite payment system implemented as a result of section 1881(b)(12) of the Act are important because they provide a foundation for the development of the case-mix adjusted bundled ESRD PPS required under Public Law 110–275, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The basic case-mix adjustment mandated under the MMA is described in detail in the next section and only affects the composite rate. It does not reflect costs associated with separately billable services. Separately billable services, particularly injectable drugs, are a significant component of the total dialysis resources used for each patient.

The implementation of the basic case-mix adjustments to the composite payment system effective April 1, 2005, and the Secretary's February 2008 Report to Congress, suggested that a bundled ESRD PPS which combined composite rate and separately billable services to yield case-mix adjusted payments was technically feasible. The report defined a payment bundle of dialysis-related services, described the methodology used to develop the regression based case-mix adjusters and the base period payment rates to which the case-mix adjusters would be applied, and discussed numerous other issues relevant to the bundling of outpatient dialysis services under a system of prospective payments.

As a result of the July 15, 2008 enactment of MIPPA, section 153(b) of MIPPA amended section 1881(b) of the Act to require the implementation of an ESRD bundled payment system effective January 1, 2011 (herein referred to as the "ESRD PPS"). Consistent with the language under the statute, we will refer to hospital-based and independent renal dialysis facilities as "providers" and "facilities", respectively, and when addressing both types of facilities, we will collectively refer to such entities as "ESRD facilities", as set forth in § 413.171. Section 153(b) of MIPPA specifies the following:

- The Secretary must 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, and for such services and items furnished for home dialysis and self-care home dialysis support services.
- A definition for the "renal dialysis services" that are included in the payment bundle.
- The estimated amount of total payments under the ESRD PPS for 2011 must be equal to 98 percent of the estimated total amount of payments for renal dialysis services paid under Medicare, including payments for drugs, that would have been made with regard to services in 2011 if the new system was not implemented. Such estimate must be made based on per patient utilization data from 2007, 2008, or 2009, whichever year has the lowest per patient utilization.
- The ESRD PPS must include adjustments for case-mix variables, high cost outlier payments, and low-volume facilities and provide for a four-year transition (phase-in) period, with all facilities transitioned into the ESRD PPS

on January 1, 2014. ESRD facilities may make a one-time election before January 1, 2011, to be paid under the ESRD PPS and not go through the transition period.

- The ESRD PPS may include other payment adjustments, as the Secretary determines appropriate, including the use of a geographic index, and potential adjustments for pediatric patients and rural ESRD facilities, and may provide for a unit of payment as the Secretary specifies (for example, per treatment or per unit of time).
- The ESRD PPS payment amounts must be annually increased by an ESRD bundled market basket beginning in 2012, and during the transition.
- Section 623(e) of the MMA, which requires a demonstration project of the use of a case-mix adjusted bundled ESRD PPS, was repealed.

Section 153(a)(1) of MIPPA also requires that the composite payment rates be increased by 1.0 percent effective for services furnished on or after January 1, 2009, and before January 1, 2010, and increased by 1.0 percent for services furnished on or after January 1, 2010. In addition, section 153(a)(2) of MIPPA requires that the payment rate for dialysis services furnished on or after January 1, 2009, by ESRD providers of services, be the same as the payment rate for such services furnished by renal dialysis facilities. On November 19, 2008, we published the CY 2009 Physician Fee Schedule final rule (73 FR 69754), implementing the site neutral composite rate for ESRD facilities and the CY 2009 1.0 percent increase to the composite rate. On November 25, 2009, we published in the **Federal Register** the CY 2010 1.0 percent increase to the composite rate in the CY 2010 Physician Fee Schedule final rule (74 FR 61901).

In the following sections of this final rule, we describe the ESRD PPS we are implementing effective January 1, 2011, in compliance with the statutory requirements of MIPPA, and in response to the comments received in connection with the proposed rule published September 29, 2009.

C. Existing Basic Case-Mix Adjustments

Resources required to furnish routine dialysis such as staff and equipment time vary by patient. Because of the variation in resources required to furnish routine dialysis to individuals with varying patient characteristics, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate based on average resources. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite payment rate could create a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more resource-intensive patients, according to objective quantifiable criteria.

The costs of providing the routine maintenance dialysis services that are paid under the composite rate are reported on the Medicare cost reports for hospital-based and independent ESRD facilities (Forms CMS 2552–96 and CMS 265–94, respectively). In order to determine a basic case-mix adjustment that could be applied to each ESRD facility's composite rate, UM–KECC further examined the relationship between facility-level costs for composite rate services based on the Medicare cost reports for hospital-based and independent facilities, and the average characteristics of patients treated by the facility. The research used data from Medicare cost reports for 3,254 ESRD facilities for 2000 to 2002, patient characteristics/co-morbidity data from CMS's Medical Evidence Form 2728 (Form 2728) for 1995 through 2002, and Medicare claims for approximately 360,000 ESRD patients. Based on standard techniques of multiple regression analysis, UM–KECC found that age and body size had significant relationships to composite rate costs. The body size variables were BSA and low BMI, calculated based on a patient's height and weight which is reported on Medicare claims.

A BMI less than 18.5 kg/m^2 is considered a clinical measure of underweight status and is an indicator of patients who are malnourished or suffering from co-morbidities such as wasting syndrome. BSA is closely associated with the duration and intensity of dialysis required to achieve targets for dialysis adequacy. Facilities with a larger proportion of patients with a greater than average BSA, or with a BMI lower than 18.5, were found to have greater composite rate costs. The research also revealed a U-shaped relationship between age and composite rate costs, with the youngest and oldest age groups incurring greater costs for composite rate services due to resource needs.

The outcome of UM–KECC's research was a set of basic case-mix adjusters or multipliers for ESRD patients based on three variables. These variables were: (1) The patient's age (five groups), (2) BSA (a patient-specific value based on incremental differences from the national patient average), and (3) BMI category (two groups, value either less than, or equal to/greater than 18.5 kg/m^2). CMS also developed a special adjuster for pediatric patients outside of UM–KECC's research methodology based on analysis of a sample of Medicare cost reports. The adjuster for each of these three variables is multiplied by the facility's composite rate to yield the current "basic" case-mix adjustment for each ESRD patient according to the specified patient characteristics.

These adjusters are as follows:

Table 1: Basic Case-Mix Adjustments Used Under the Current Composite Payment System

Age group	Composite Rate Multiplier
< 18	*1.62
18-44	1.223
45-59	1.055
60-69 (reference group)	1.000
70-79	1.094
80+	1.174
Body Surface Area (BSA): (per 0.1m² change in BSA from national average of 1.84)	1.037
Low Body Mass Index (BMI): (<18.5kg/m²)	1.112

* Developed by CMS. The age, BSA, and BMI multipliers do not apply under the basic case-mix adjustments for patients under age 18.

The above multipliers were derived from the coefficients of the regression model used to predict facility differences in composite rate costs based on UM–KECC's research. For example, the case-mix adjuster for a 47 year old ESRD patient who is underweight (BMI < 18.5 kg/m²) and has a BSA of 2.0 m² would be calculated as follows:

Age Adjuster 1.055

BSA Adjuster $1.037^{(2.0-1.84)/0.1} = 1.060$

Low BMI Adjuster 1.112

Case-Mix Adjuster $1.055 \times 1.060 \times 1.112 = 1.244$

The resulting case-mix adjustment factor of 1.244 for this patient would be multiplied by the facility's otherwise applicable wage adjusted composite payment rate.

The basic case-mix adjustment mandated under the MMA only affects the composite rate. It does not reflect costs associated with separately billable services. Separately billable services, particularly injectable drugs, are a significant component of the total dialysis resources used for each patient. Prior to the enactment of MIPPA on July 15, 2008, however, CMS did not have authority to bundle those services into a case-mix adjusted PPS.

II. Summary of the Proposed Provisions and Responses to Comments on the Proposed Rule

The proposed rule was published in the **Federal Register** on September 29, 2009 with a comment period that ended on November 16, 2009 (74 FR 49922). We received approximately 1475 public comments, including comments resulting from a large write-in campaign regarding oral Part D drugs. Interested parties that submitted comments included numerous dialysis facilities, the national organizations representing dialysis facilities, nephrologists, and patients, the major chain facilities, clinical laboratories, pharmaceutical manufacturers, hospitals and their representatives, individual dialysis patients, and MedPAC. Following publication of the proposed rule, we received several requests to extend the comment period to allow time for stakeholders to understand the proposed ESRD payment changes and to formulate comments that would be meaningful to CMS. On November 4, 2009 we published a notice (74 FR 57127) in the **Federal Register** extending the public comment period an additional 30 days to December 16, 2009, to provide additional time for the public to examine the proposed rule and provide meaningful comments on its provisions. In this final rule we provide a summary of each proposed provision, a summary of the public comments received, our responses to them, and any changes to the proposed ESRD PPS we are implementing in this final rule as a result of comments received. Below we address general comments received regarding the proposed rule.

Comment: Clinicians, health systems, medical supply companies, patients, and hospital-based and independent ESRD facilities from small, medium, and large dialysis organizations requested that rather than proceeding by issuing a final rule, CMS issue its next public notice as an interim final rule with an additional opportunity for public comment prior to the implementation deadline. Commenters provided several reasons for this position including:

- A lack of clarity and specificity with regard to the proposals in the proposed rule will make implementation difficult and compromise ESRD facilities' viability. Specifically, operational questions remain unanswered such as the way in which billing for laboratory tests would occur during the transition, the way in which medical history would be retrieved for purposes of the co-morbidity adjustments, and the way in which ESRD facilities would provide patients with oral drugs. Commenters noted that absent additional clarification in these areas it would be difficult to implement the provisions of the ESRD PPS in the short timeframe between the expected publication of a final rule and its implementation on January 1, 2011.
- A lack of transparency with regard to the data used in developing the proposed rule. Specifically, some commenters noted that they did not have access to Part D data or CMS' rate setting data file that would have facilitated their ability to fully analyze the impact of the ESRD PPS.
- The absence of administrative or judicial reviews, a feature mandated by MIPPA, would mean there would be an inability to challenge payment making it

even more important that the provisions of the final ESRD PPS rule are correct.

- The additional time associated with issuing an interim final rule would help bring to light inequities between ESRD provider types and the level of owned service lines including laboratory, pharmacy, equipment and supplies.
- Concern about the potential for unintended patient and provider consequences that may result from the ESRD PPS and believed that issuing an interim final rule would reduce this risk by allowing additional time to address stakeholder concerns.

Response: We understand the commenters' interest in ensuring that potential unintended negative consequences associated with the new ESRD PPS are minimized. However, we believe that we have adequately reflected the essential elements of the ESRD PPS in the proposed rule including basic issues associated with implementing the system and have received a comprehensive collection of public comments from a wide array of stakeholders to which we have responded in this rule. Specifically, as noted in section II.K.2. of this final rule, we have clarified the way in which provider billing for laboratory tests would occur during the transition. We have also clarified our position with respect to co-morbidity adjustments and their associated administrative burden in section II.F.3. of this final rule. As noted in section II.K.2. of this final rule, we have addressed implementation issues associated with ESRD facility provision of oral drugs.

With regard to the lack of transparency in sharing the data that was used in developing the ESRD PPS proposed rule, we note that the files to which commenters refer contain patient-specific data. To maintain patient confidentiality and privacy we are unable to share such data. However, we posted detailed information by facility which was used for purposes of assessing facility-level impact.

In addition, we note that following publication of the ESRD PPS proposed rule, we posted the CY 2011 Proposed Rule ESRD PPS Facility Level Impact File to the ESRD Payment Web site (*http://www.cms.hhs.gov/ESRDPayment/PAY/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=4&sortOrder=descending&itemID=CMS1228517&intNumPerPage=10*). This file includes facility level data that was used by CMS to assess the impact of the proposed ESRD PPS.

Given that we have issued a proposed rule containing a detailed proposal for an ESRD PPS, allowed for an extended 90-day public comment period, and carefully considered the comments received, we believe that a final rule is appropriate. In addition, because of the January 1, 2011 implementation deadline mandated by MIPPA, we believe that finalizing the rule now will maximize the amount of time ESRD facilities will have to implement the provisions of this rule prior to the implementation deadline. For these reasons we are issuing this document as a final rule.

A. The Proposed ESRD PPS Bundle

Section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS must represent a single payment to ESRD facilities for "renal dialysis services" in lieu of any other payment, and home dialysis supplies, equipment, and support services furnished pursuant to section 1881(b)(4) of the Act. Section 1881(b)(14)(B) of the Act, which identifies the renal dialysis services that are to be included in the ESRD PPS payment bundle, provides the following:

* * * the term "renal dialysis services" includes—

(i) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) Other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was(before application of this [new ESRD PPS]) made separately under this title, and any oral equivalent form of such drug or biological; and

(iv) Diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

1. Composite Rate Services

Section 1881(b)(14)(B)(i) of the Act requires that the ESRD PPS payment bundle include composite rate services. As we indicated in the proposed rule, the current case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). Therefore, consistent with the statute, we proposed to include the items and services included in the composite rate for renal dialysis services as of December 31, 2010, (including self-dialysis training services), such as labor, supplies, and equipment.

We proposed to define composite rate services at proposed § 413.171. We also proposed that the composite rate services would not only include payments for the costs of services directly related to dialysis, but would also include payments authorized in accordance with the composite payment rate exception provisions set forth in 42 CFR 413.180 through 413.186 (74 FR 49928). The costs for such composite rate services were included in our computation of the proposed ESRD PPS base rate, as explained in section II.E. of this final rule, as well as in the development of the proposed composite rate regression model used to create the two equation patient specific case-mix adjusters that would be applied to the base rate. We did not receive any public comments on our proposed inclusion of the renal dialysis services currently covered under the composite payment system for inclusion under the bundled ESRD PPS. Therefore, we are finalizing our definition of composite rate services as renal dialysis services as proposed in § 413.171.

2. ESAs and Their Oral Forms

Section 1881(b)(14)(B)(ii) of the Act requires that ESAs and any oral form of such agents that are furnished to individuals for the treatment of ESRD be included in the ESRD PPS payment bundle. We proposed that payments for injectable ESAs, (for example, Epoetin® and ARANESP®) would be included in the calculation of the proposed ESRD PPS base rate, as well as in the separately billable regression model used to create the two equation patient specific case-mix adjusters for the proposed ESRD PPS (74 FR 49928). Therefore, consistent with our interpretation of the statute, we proposed that no additional payment would be provided for ESAs and their oral forms outside of the bundle of renal dialysis services included in the ESRD PPS. We also noted that oral versions of ESAs do not currently exist, but we further proposed that to the extent oral forms are approved after the implementation of the ESRD PPS, those drugs would be paid under the ESRD PPS (74 FR 49928). We set forth provisions regarding the inclusion of ESAs and their oral forms as renal dialysis services in the ESRD PPS payment bundle at proposed § 413.171.

We received a few comments regarding our proposal to bundle ESAs and those comments are addressed below.

Comment: Some commenters expressed concern that bundling drugs

will restrict nephrologists' ability to prescribe necessary medications. One commenter stated that including medications like EPO and oral medications will limit nephrologists from prescribing what is necessary.

Response: We believe that the ESRD PPS will establish a bundled payment system based on the average cost of care with adjustments that target more payment to more resource intensive ESRD patients. In situations where costs for treating patients exceed an established threshold, the outlier policy would apply. The outlier policy is discussed in detail in section II.F.4. of this final rule. We expect that ESRD facilities and health care providers will continue to advocate on behalf of patients who require more than the average utilization of ESRD-related items and services. We note that the responsibility for determining the appropriateness of medical care resides with the ESRD facility, physicians, and the interdisciplinary team as stipulated by the ESRD Conditions for Coverage. Under § 494.90, an ESRD facility would be out of compliance if it did not meet the patient's documented needs as shown in the patient plan of care.

Comment: Several commenters expressed concern that the inclusion of ESAs in the payment bundle will result in dialysis facilities decreasing the amounts of EPO given to patients, resulting in an increase in blood transfusions for anemia management, and increased stress on the nation's blood supply.

Response: Section 1881(b)(14)(B)(ii) of the Act requires that ESAs be included in the ESRD PPS. While the inclusion of any item or dialysis service in the payment bundle provides an incentive for dialysis facilities to maximize profits by skimping on the provision of that item or service, we point out that an important part of our Quality Incentive Program (QIP) is the monitoring of hemoglobin levels among dialysis patients to ensure that target levels are met, and that anemia management does not deteriorate under the ESRD PPS (see section II.M. of this final rule). We also plan to monitor the incidence of transfusions among dialysis patients subsequent to the implementation of the PPS to ensure that blood transfusions do not replace effective anemia management with ESAs as a result of the system's payment incentives. More information about monitoring efforts planned due to the implementation of the ESRD PPS appears in section II.L. of this final rule and in future issuances.

Comment: A few commenters opposed the inclusion of EPO or intravenous iron in the bundle, claiming that if included, there will be a decrease in the use of these drugs resulting in decreased hemoglobin levels, necessitating more in-hospital blood transfusions. Another commenter stated that bundling would result in a shift to subcutaneous administration of ESAs with additional needle sticks, decreases in hemoglobin levels, and an increase in transfusions. Several commenters cited the USRDS 2008 Annual Data report as showing a large decrease in the use of red blood cell transfusions since 1992. One commenter questioned how patients will obtain EPO as it is expensive. One commenter referenced National Kidney Foundation (NKF) guidelines to support their statement that "intravenous iron is * * * more efficacious at helping patients maintain adequate iron levels in clinical studies of patients * * * undergoing hemodialysis and therefore is generally the preferred recommended therapy." Another commenter claimed, based on their analysis of two patients' reimbursement under the proposed ESRD PPS, that their facility would face significant financial loss, especially for those receiving large doses of EPO. Some commenters suggested that we include only intravenous ESAs. One commenter stated that ESRD-related intravenous drugs include those used in the treatment of anemia, and therefore, their oral equivalents should be included in the bundle.

Response: We have no authority to exclude ESAs from the ESRD PPS bundled payment. As we explained in the proposed rule (74 FR 49928), section 1881(b)(14)(B)(ii) of the Act requires that ESAs and any oral form of such agents that are furnished to individuals for the treatment of ESRD be included in the ESRD PPS payment bundle. We explained that the payments for injectable ESAs (for example Epoetin alfa (Epogen®) and darbepoetin (ARANESP®), which are separately payable outside of the current basic case-mix adjusted composite payment system, would be included in the calculation of the proposed ESRD PPS base rate. We also noted in the proposed rule that while we were currently unaware of any other injectable ESAs or oral forms of such ESAs used for the treatment of ESRD, if any such agents would become available subsequent to the implementation of the ESRD PPS on January 1, 2011, they would be considered renal dialysis services and subject to payment under the ESRD PPS (74 FR 49928). We are not aware that a shift to subcutaneous administration of ESAs from intravenous administration will lead to decreases in hemoglobin levels and increases in transfusions.

Although several commenters suggested that ESRD beneficiaries may be denied appropriate and necessary treatment because of the perceived negative financial impact of the ESRD bundled payment system, we point out that section 1881(b)(14)(B)(ii) is clear in requiring that ESAs and any oral forms of ESAs must be included in the ESRD PPS payment bundle. In addition, as discussed in section II.M. of this final rule, we will monitor anemia management as part of the ESRD QIP.

Comment: Several commenters expressed concern that the bundling of ESAs poses a financial disincentive for adequate anemia management, and will lead to the maintenance of hemoglobins at the lowest possible level, resulting in worse outcomes for patients.

Response: Section 1881(b)(14)(B)(ii) of the Act is very clear in requiring that ESAs and any oral equivalent forms of ESAs furnished for the treatment of ESRD must be included in the ESRD PPS payment bundle. We have no discretion with respect to their inclusion or exclusion.

We do not understand the commenters' conclusion that maintaining hemoglobins at the least possible level will result in worse patient outcomes. We expect ESRD facilities to provide the appropriate medications at the appropriate dosage to maintain patient hemoglobins at the required level. We note that we will be closely monitoring the anemia management of ESRD patients subsequent to the implementation of the ESRD PPS as part of CMS's QIP.

Therefore, after considering the public comments and for the reasons stated above, we are not making changes to the proposed Medicare regulation at § 413.171 and are finalizing the inclusion of ESAs and their oral forms as renal dialysis services in the ESRD PPS payment bundle.

3. Other Drugs and Biologicals and Their Oral Forms

Section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle. In the proposed rule, we noted the reference to "this title," in the statutory language, and we interpreted clause (iii) as requiring the inclusion in the ESRD PPS payment bundle of all drugs and biologicals that were

separately payable under title XVIII of the Act prior to the implementation of MIPPA (74 FR 49928). We proposed at § 413.171 that drugs and biologicals used to treat ESRD that were separately payable prior to January 1, 2011, be included as part of the proposed ESRD PPS payment bundle (74 FR 50022). Accordingly, we proposed to include such drugs and biologicals in the development of the proposed patient-specific case-mix adjusters and in the calculation of the proposed ESRD base rate to which the adjusters would be applied. In the proposed rule, we identified the top eleven injectable drugs furnished to Medicare ESRD beneficiaries which we proposed to include in the payment bundle (*See* Table 8 at 74 FR 49940). Table 8 also contained a category of miscellaneous other injectable drugs, as well as a line item reflecting other services furnished by ESRD facilities. The identification and treatment of these other injectable drugs and services are addressed in later in this section.

We identified specific National Drug Codes (NDCs) for drugs and biologicals previously payable under Part D that we proposed to include in the payment bundle. However, we proposed that the ESRD PPS would apply, regardless of the emergence of new drugs or biologicals or different NDCs for the classes of drugs and biologicals included in the ESRD PPS bundle. Finally, we noted that section 1881(b)(14)(B) of the Act specifically excludes vaccines from the payment bundle and, therefore, we did not include vaccines in the proposed ESRD PPS. We requested comments on our proposals above.

We received numerous public comments related to inclusion of ESRD-related injectable drugs and biologicals; the inclusion of oral equivalents of ESRD injectable drugs; and the inclusion of oral-only ESRD-related drugs (that is, drugs for which there is no injectable equivalent or other form of administration) currently paid under Part D in the payment bundle. Most of the commenters were opposed to the inclusion of all oral drugs and biologicals, claiming that their inclusion would lead to poorer patient outcomes because the proposed amount per treatment of $12.47 reflected in the calculation of the base rate (Table 8 at 74 FR 49940) was claimed to be inadequate to cover the average cost of these drugs. The comments received are summarized below.

a. Oral-Only ESRD–Related Drugs

Comment: Several commenters agreed with CMS that clause (iii) of section 1881(b)(14)(B) of the Act can be interpreted broadly to encompass all drugs furnished to individuals for the treatment of ESRD, including oral drugs. In particular, the commenters did not interpret the subsequent reference to "any oral equivalent form of such drug or biological" as limiting the scope of oral drugs that may be included. Another commenter stated that one possible interpretation of MIPPA gives CMS authority to broaden the bundle to include former Part D oral drugs. Finally, another commenter strongly endorsed the agency's proposal to include all ESRD-related drugs and concurred with CMS's rationale and statutory interpretation set forth in the proposed rule. In particular, the commenter stated that the plain language of the statute with respect to clauses (iii) and (iv) gave CMS clear authority to include ESRD drugs, regardless of the route of administration, agreeing with the agency's interpretation of the reference to the word "title", and also noting that the phrase "other drugs and biologicals" included no qualifier that would limit clause (iii) to only separately reimbursable injectable drugs.

Response: We appreciate the comments on our proposal to bundle oral-only drugs, which support our interpretation of the statute.

Comment: One commenter suggested that CMS implement an expeditious appeals process for physicians to challenge payment for drugs that may be excluded from dialysis companies' formularies.

Response: ESRD facility formularies are beyond the scope of this final rule. However, we expect ESRD facilities to provide the appropriate medications, at the appropriate dosage, based upon individual patient needs. We expect the patient's nephrologist and the interdisciplinary team to identify medication needs in accordance with the individual patient's plan of care.

Comment: Many comments indicated that CMS's decision to include oral drugs with no injectable equivalent ("oral-only" drugs) within the statutory definition of "renal dialysis services" represents a misreading of statutory intent and violates principles of statutory construction. One commenter asserted that CMS's inclusion of oral-only drugs in the ESRD PPS appeared to hinge entirely on the reference to the words "this title" under section 1881(b)(14)(B)(iii) of the Act. The commenter stated that this interpretation represented too narrow a reading of the statute, and was inconsistent with the intended meaning of "this title" set forth elsewhere in section 1881 of the Act. Other commenters stated that CMS's reasoning that the use of "this title" in section 1881(b)(14)(B)(iii) of the Act means that all ESRD drugs payable under title XVIII of the Act must be included in the payment bundle, including drugs payable under Part D, represents a selective reading of the statute, and that the more appropriate approach is to read the language as a whole. The commenters asserted that the entirety of section 1881(b) of the Act focuses on payments to ESRD facilities, and that the four categories of renal dialysis services specified in section 1881(b)(14)(B) of the Act only pertain to services furnished for which payment is made to ESRD facilities.

A few commenters compared references to "this title" in other subparagraphs of section 1881(b) of the Act and argued that our prior implementation of payment to dialysis facilities did not include oral-only drugs when the same reference to "this title" was used, stating that the reference has been interpreted previously to mean separately billable Part B drugs (with separate payment to dialysis facilities). Consequently, commenters claimed that such oral-only products do not fall within clause (iii) because they are not separately billable Part B drugs (which are limited to those products that cannot be self-administered by a patient and must be furnished in the facility by staff), and are not oral equivalents of separately billable drugs. Commenters claimed that because the oral-only drugs (calcimemetics and phosphate binders) proposed for inclusion in the ESRD PPS payment bundle are currently dispensed by a pharmacy for home use, are not furnished by ESRD facilities, and are not the oral equivalent of an injectable drug under clause (iii), such drugs must be excluded from the bundle. Therefore, these commenters maintained that inclusion of such oral-only drugs in the expanded bundle under the proposed ESRD PPS is inappropriate. Although most commenters opposed the inclusion of former Part D drugs, several stated that there appeared to be sufficient statutory support for including them.

Response: We agree that section 1881(b) of the Act addresses payments to dialysis facilities for dialysis services furnished Medicare ESRD beneficiaries, either directly by the facility, by a supplier (for example, DMEPOS supplier), or under arrangement (for example, clinical laboratory). However, in our view, the intent of section 1881(b)(14)(B) of the Act was not to limit the renal dialysis services included in the ESRD PPS payment bundle to services for which only ESRD

facilities are currently paid. Clause (iii) of that section specifies that drugs and biologicals for which separate payment is made, and their oral equivalents, must be included in the bundle as renal dialysis services. We have interpreted clause (iii) as encompassing 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. Under this interpretation, the "any oral equivalent form of such drug or biological" language pertains to the oral versions of injectable drugs other than ESAs. All other ESRD-related drugs and biologicals, regardless of the route of administration, are addressed by the "other drugs * * * under this title" portion of clause (iii). We disagree with the commenters' argument that we have incorrectly expanded the scope of clause (iii) to include drugs and biologicals based on an inconsistent interpretation of "this title" as used elsewhere in the Act. Accordingly, we continue to believe that the entirety of clause (iii) gives us sufficient statutory authority to include all ESRD-related drugs and biologicals, regardless of whether they are furnished by a dialysis facility, under the ESRD PPS payment bundle.

Another issue is whether the "other items and services" language in clause (iv) of section 1881(b)(14)(B) of the Act encompasses oral-only drugs furnished for the treatment of ESRD. Commenters argue that oral-only drugs would not be excluded from the definition of renal dialysis services under the reasoning that the scope of the bundle was intended to cover only services for which ESRD facilities currently are being paid, as payments for the oral equivalents of injectables are not made to ESRD facilities.

We do not believe that construing the "other items and services" language in clause (iv) as applying to oral-only drugs violates a principle of statutory construction, by making clauses (ii) and (iii) otherwise redundant. The language in clause (iv) does not mean all drugs currently available to Medicare beneficiaries for the treatment of ESRD as the commenters suggest. Rather, we believe that it can be interpreted as a residual or catch all category for drugs which do not fall under the scope of those specified renal dialysis services identified in clauses (ii) and (iii). Medicare regulation under § 400.202 defines "services" as follows in pertinent part:

> Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, * * *

Thus, we are interpreting the use of the word services in clause (iv) consistent with how we interpret and define services under Medicare which supports including other oral-only drugs not specified in the preceding clauses in the bundle, not the exclusion of those drugs from the payment bundle. We believe that this interpretation of clause (iv) neither represents a selective reading of the statute, nor an overly expansive definition of the scope of the renal dialysis services intended to be included in the payment bundle.

Comment: Another commenter stated that the reference to "separate payment" under section 1881(b)(14)(B)(iii) of the Act would exclude Part D drugs because under Part D, Medicare is not making separate payment for drugs. The commenter reasoned that the Medicare program makes per beneficiary payments to plans, and plans use such payments to reimburse pharmacies that fill prescriptions for covered Part D drugs. The commenter argued that the focus of section 1881(b) of the Act is on payments to dialysis facilities for services furnished to beneficiaries. Therefore, the first part of clause (iii) pertains to Medicare payments separately made to dialysis facilities for separately payable Part B drugs and biologicals, and does not include Part D products.

Response: We disagree with the commenter with regard to the meaning of the language in clause (iii) of the statutory definition for renal dialysis services under section 1881(b)(14)(B) of the Act. We believe that such language was intended to be broadly interpreted given that all drugs are reimbursable under Medicare by virtue of being authorized for payment under Title XVIII. Therefore, drugs covered under Part B and formerly covered under Part D would be included regardless of whether payment was made directly by us or by a plan.

Comment: Several commenters agreed with CMS that clause (iv) of section 1881(b)(14)(B) of the Act is a catch all provision that permits inclusion of any additional products and services, including oral drugs furnished to treat individuals with ESRD, and agreed with the agency's interpretation and rationale that the inclusion of oral-only drugs in the bundle is supported by clause (iv). One commenter noted that the term "services" is used in clause (iv) of the definition for renal dialysis services, and that for purposes of Medicare such term is defined under § 400.202 as "medical care or other services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and the use of hospital, CAH, or SNF facilities [emphasis added]." The commenter noted that services and items encompass drugs and biologicals. The commenter further stated that a plain reading of clause (iv) leads to the conclusion that clause (iv) is inclusive of all other drugs and biologicals not reimbursed under the ESRD composite rate as of December 31, 2010, that are furnished to individuals for the treatment of ESRD.

Other commenters disagreed with our interpretation, stating that clause (iv) should not apply to oral-only drugs, as it would render the other clauses of the definition unnecessary. Those commenters claimed that an interpretation of clause (iv) that includes all drugs and biologicals fails to consider the entire context of the statute, and that this reading would negate clauses (ii) and (iii) of the statutory definition for renal dialysis services. Commenters stated that under rules of statutory construction, a statute should be construed to give meaning to all aspects of it, such that "other items and services" cannot be read to include drugs that are currently used for treatment of chronic renal failure, but are excluded from clauses (ii) and (iii).

Response: We believe that clause (iv) of the definition for renal dialysis services under section 1881(b)(14)(B) of the Act could include certain other items and services such as "oral-only" drugs. We agree with the commenter that the definition should be viewed as a whole when considering each of the four clauses, and particularly, clause (iv). With regard to the concerns of statutory interpretation that commenters have identified, we believe we have followed them when interpreting the statute. We note, however, that such rules must be taken into context based on the underlying statutory language at issue. In particular, we note that the definition for renal dialysis services has overlapping categories of services, and that certain clauses included arguably are unnecessary. For example, given that several clauses of the definition contain similar types (or categories) of items and services, we find unconvincing the commenter's suggestion that clause (iv) cannot include drugs or biologicals. We note that drugs and biologicals are not limited to clauses (ii) and (iii) of the definition. In particular, clause (i) covers the composite rate, which contains some drugs.

We also agree with the commenter who pointed to the Medicare definition for "services" that such term includes drugs and biologicals. Given that clause (iv) addresses laboratory tests and other items and services not described in clause (i) (that is, non-composite rate labs, items, services, etc.), we believe that a reasonable interpretation of clause (iv) is that certain non-composite drugs and biologicals are included. We agree with commenters, however, that to ensure that meaning is attached to the other clauses, such drugs and biologicals included in clause (iv) would not be the same as those included in clauses (ii) and (iii). Accordingly, if oral-only drugs are not considered to fall within clause (iii) of the statutory definition (or clause (ii) for that matter), we believe that such drugs would appropriately fall under clause (iv), and would constitute other items and services used for the treatment of ESRD that are not described in clause (i).

In addition, as we noted, several of the clauses of the definition could be viewed as superfluous. Therefore, we believe the definition as a whole must be considered when determining whether an item or service constitutes a "renal dialysis service." In particular, we note that clause (iii) would have been broad enough to include the erythropoiesis stimulating agents (ESAs) identified in clause (ii), given that such agents would constitute "drugs and biologicals that are furnished for the treatment of ESRD and for which payment was made (before the ESRD PPS) separately under this title, and any oral equivalent of such drug or biological." Hence, clause (ii) arguably is unnecessary. Congress decided, however, to nevertheless specifically identify these agents as a separate category under the definition. Given the structure of the definition, we do not believe Congress' identification of certain "other drugs and biologicals" in clause (iii), limits the definition such that it excludes other types of drugs or biologicals from clause (iv) of the definition, if such drugs otherwise meet that prong (and are not included in clause (iii) or clause (ii)).

Moreover, we believe that when the definition is viewed as a whole, it suggests a comprehensive definition that wraps in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of ESRD. Although the definition is perhaps overlapping or redundant, we find clause (iv) to be a catchall category, and one that provides sufficient authority for bundling oral-only drugs (if such drugs do not fall under clause (iii)). For a discussion of the other items and services under clause (iv), please see the next section below.

Comment: One commenter pointed to recent legislative proposals and an analysis by the Congressional Budget Office as support that oral-only drugs are not included in the statutory definition for renal dialysis services. Another commenter pointed to legislative history by citing floor statements as evidence of Congressional intent behind the creation of a broad payment bundle, including all oral dialysis-related drugs, such as calcimimetics and phosphate binders.

Response: We are not persuaded by recent legislative proposals. We continue to interpret section 1881(b)(14)(B) of the Act as including in the ESRD PPS, all drugs and biologicals furnished for the treatment of ESRD, and we believe this interpretation reflects the intent of the statute. With regard to recent legislation, we note that the ESRD PPS proposed rule, in which we set forth our interpretation of the statute and our proposal for the scope of the bundle, was specifically noted and acknowledged by Congress in section 10336 of the Affordable Care Act passed on March 23, 2010 (Pub. L. 111–148), which requires a study by the GAO on the impact on Medicare beneficiaries of including oral-only drugs in the bundled ESRD PPS. Significantly, this new legislation imposes no restrictions or additional requirements with regard to our proposal to bundle such products.

Comment: Some commenters stated that the exclusion of oral-only drugs from the payment bundle would not make the bundle of services less comprehensive, nor would it defeat the purpose of the new payment system as CMS suggests. These commenters claim that the comprehensive bundle of renal dialysis services the Congress envisioned is a bundle of services furnished by ESRD facilities. Therefore, some commenters believed that since calcimimetics and phosphate binders are not furnished by ESRD facilities, their exclusion would not make the bundle less comprehensive than Congress intended. Commenters also stated that no cost shifting would occur between Part B and Part D, because these oral-only drugs have no Part B equivalent.

Response: We do not agree with the commenters' assertion that the intent of the payment bundle under the ESRD PPS was to include only those services furnished by dialysis facilities. For example, inclusion of diagnostic laboratory tests (which may be performed by laboratories under arrangements with dialysis facilities, for those facilities that do not have their own laboratories), and oral equivalent forms of injectable drugs, which are currently furnished by pharmacies under Part D, belie this interpretation. Therefore, we believe the exclusion of an item or service from the payment bundle solely because it is not furnished (or traditionally furnished) by ESRD facilities is inappropriate. We also disagree with the argument that excluding drugs from the bundle for which there currently is no injectable equivalent is acceptable because there is no issue of cost-shifting between Part B and Part D. Notwithstanding that there may not be injectable equivalents of certain drugs widely used for the treatment of ESRD currently that may not be the case in the future as new drugs and treatments are developed.

We also point out that apart from the goal of avoiding cost-shifting, we believe the purpose of a bundled payment system is to ensure that patient care is not skewed by financial incentives. We believe that access to and compliance with recommended care can be negatively impacted if certain drugs remain outside of the payment bundle. Although many Medicare beneficiaries may have oral-only drug coverage under Medicare Part D, others have private sources, and some lack reliable sources of coverage altogether. We do not wish to continue an uneven payment policy that favors certain types of drugs by permitting them to remain separately payable outside of the payment bundle.

Comment: Commenters indicated that several of the oral-only drugs which CMS proposes to include in the payment bundle are relatively expensive, and that the associated payment amount per treatment ($12.48 as calculated from Table 8 at 74 FR 49940) for these drugs was inadequate. Commenters stated that this will result in unintended clinical consequences for patients as ESRD facilities seek to maximize profits by resorting to cheaper but less effective alternatives.

Response: We believe that by including all drugs widely used for the treatment of ESRD in the payment bundle, we will be providing a level playing field that will benefit patient care. The purpose of a bundled payment system is to make available all treatment options under the same payment system. When drugs remain outside of the payment bundle, financial issues can influence both facility and patient behavior, as the over-utilization of EPO to the detriment of patient care in the past has demonstrated. We acknowledge

that the contrary effect can occur whereby drugs included in the payment bundle could also influence behaviors with potential underutilization. However, we expect ESRD facilities and monthly capitation payment (MCP) physicians will evaluate the potential use of less expensive equally effective alternatives for the treatment of conditions associated with ESRD, where those alternatives are available and not contraindicated by the patient's clinical status. Notwithstanding the availability of less expensive alternatives, we expect that patient care regimens will always be selected solely based on patient needs as identified in the patient's plan of care. We believe that we have developed the bundle, with the inclusion of all oral drugs, to account for the costs that ESRD facilities will incur in furnishing these drugs to patients.

Comment: Several commenters expressed concern that the inclusion of oral-only drugs in the ESRD PPS payment bundle could adversely impact beneficiaries through increased co-payments. Because the cost of these oral-drugs would be included in the payment for all of the renal dialysis services included in the bundle, commenters noted that the beneficiary would be responsible for 20 percent of the total bundled payment amount, and that this has the potential to increase the co-payment amount owed by the beneficiary. In addition, commenters stated that patients, who currently have Part D coverage and qualify for the low income subsidy, would be required to pay coinsurance on these drugs for the first time, as Part D coverage limits their financial responsibility at very low dollar amounts. The commenters believe that this will pose a financial hardship for these low income patients who will be unable to meet their new coinsurance obligation, caused by including these drugs under Part B. In addition, commenters stated that patients who are dually eligible for both Medicare and Medicaid would also see an increase in their coinsurance liability, as minimal prescription drug copayment amounts are replaced with a 20 percent coinsurance requirement under the ESRD PPS.

Response: It is inherent with the implementation of any PPS that patients who incur costs greater than the amount covered by the average PPS payment will benefit from the ESRD, because their coinsurance liability will be based on that lower average payment amount compared to the actual costs for resources consumed. Patients whose actual costs for services furnished are less than the PPS payment amount will see an increase in their coinsurance liability, because the actual payment exceeds the actual utilization of resources. Table 2 shows total Part D expenditures for drugs for CYs 2007, 2008, and the first nine months of 2009 currently available. The table reveals that the portion of these expenditures for ESRD drugs borne by the beneficiary, or otherwise paid on behalf of the beneficiary, ranges from 38 to 41 percent.

Table 2
Part D expenditures for Medicare ESRD beneficiaries undergoing dialysis

	2007	2008	Jan-Sept 2009
Total payments for Part D drugs for each year, including part of 2009	$1,108,514,200	$1,264,188,670	$1,009,761,143
Total payments for ESRD oral equivalents of injectables	$10,700,084	$15,038,895	$13,565,768
Payments made by/on behalf of beneficiary—all Part D drugs	$460,046,395	$509,917,138	$439,330,445
Payments made by/on behalf of beneficiary—ESRD drugs	$4,059,734	$5,762,986	$5,565,784
% of payments that were made by/on behalf of beneficiary—all Part D drugs	41.5%	40.3%	43.5%
% of payments that were made by/on behalf of beneficiary—ESRD drugs	37.9%	38.3%	41.0%

These amounts compare to the 20 percent coinsurance liability under Part B. We believe that this difference in coinsurance liability between Part B drugs and Part D drugs is largely caused by the beneficiary obligation incurred under the Part D "donut hole", and by various coinsurance amounts imposed by the drug plans because of formulary differences. Based on this comparison, some beneficiaries will be better off with a 20 percent coinsurance obligation under Part B compared to the range of 37.9 to 41.0 percent liability under Part D, particularly if their utilization of Part D drugs is high, and they have no low income subsidy. While there is no equivalent low income

subsidy under Part B for those patients who currently receive this benefit under Part D, we believe our interpretation of the statute is consistent with the statutory intent to bundle all renal dialysis services under Part B.

In addition, ESRD beneficiaries who currently have private market coverage of the ESRD drugs that would be included in the ESRD PPS and minimal copayments will see an increase in their copayments because of the classification of these drugs under Part B as renal dialysis services, for which the 20 percent coinsurance obligation applies. We would expect that the shift in coverage for oral drugs formerly Part D to Part B will result in drug plans and insurers modifying the scope of their drug coverage, formularies, premiums, and benefits to reflect this shift in coverage, in a competitive environment to maintain and attract beneficiaries. With respect to patients dually eligible for Medicare and Medicaid with minimal prescription drug copayment amounts under Part D, we expect that the 20 percent coinsurance for renal dialysis services included in the payment bundle under the ESRD PPS will be covered by the beneficiary's Medicaid benefit, just like other Part B coinsurance obligations. We will conduct outreach efforts to the States to ensure that States understand the changes due to the ESRD PPS, and their responsibility to process Medicare claims and determine their financial obligations under the new payment system.

Comment: One commenter proposed that oral equivalents of injectable drugs be included in the ESRD PPS effective January 1, 2011, and that CMS clearly indicate that the only currently available oral drugs with an injectable version are oral iron and oral vitamin D. The commenter suggested that if oral drugs without an injectable version are included in the payment bundle, their inclusion should not occur until the transition period expires in 2014, or later. The commenter proposed that the payment rate for oral drugs included in the bundle be set at the price which a small dialysis organization would need to pay to obtain the drug from a pharmacy under arrangements.

Response: Consistent with section 1881(b)(14)(B)(iii) of the Act, we are including the oral equivalents of ESRD injectable drugs in the payment bundle effective January 1, 2011. These drugs include the oral Vitamin D analogues (calcitriol, doxercalciferol, and paracalcitol) and levocarnitine. Oral iron is generally available over the counter and not covered under Parts B or D. Therefore, it is not included in the payment bundle. There are currently no oral versions of ESAs for inclusion in the ESRD PPS. For reasons set forth in greater detail response to the comment below, we have adopted the commenter's suggestion that the inclusion of oral-only drugs be delayed until after the end of the transition period, or until January 1, 2014.

Comment: Several commenters expressed concern that the inclusion of certain oral-only drugs and laboratory tests unrelated to dialysis in the payment bundle represented an inappropriate shifting of costs to dialysis facilities for services unrelated to the dialysis treatment.

Response: Oral-only drugs will not be implemented under the ESRD PPS until January 1, 2014 for reasons set forth in greater detail below. Neither will laboratory tests unrelated to the treatment of ESRD be included in the payment bundle. Laboratory tests ordered by a dialysis patient's MCP, nephrologist, or other practitioner for reasons unrelated to ESRD will be excluded from the ESRD PPS and will continue to be reimbursed separately.

Comment: One commenter urged CMS to implement its proposed policy to bundle all drugs January 1, 2011, as mandated by Congress, stating that statutory authority, sound public policy, and patient clinical needs support inclusion of such drugs in the bundle. The commenter stated that any delay would potentially create unintended financial incentives, leading to adverse clinical outcomes.

Other commenters stated that CMS lacks pricing data from all payers to accurately determine the payments for the inclusion of oral drugs in the bundle, and recommended that CMS should exercise its authority to delay the inclusion of oral drugs. Some commenters argued that expanding the bundle to include oral-only drugs when it had insufficient data and support would have the potential to hamper future bundling efforts. Many commenters cited various policy and operational reasons in support of a decision to delay the inclusion of oral drugs in the ESRD PPS bundle. In particular, several commenters asserted that if CMS determines that it has sufficient legal authority to include oral-only Part D drugs in the payment bundle, it should nonetheless delay the inclusion of these drugs to a subsequent year in order to permit an orderly implementation of the ESRD PPS. Commenters claimed that a delay would also give CMS the necessary time to ensure that its billing systems and software are appropriately developed and tested to make sure that the conversion of payment for Part D ESRD drugs to renal dialysis services under Part B goes smoothly for beneficiaries, facilities, and pharmacies.

Several commenters stated that CMS has the discretion to defer the inclusion of Part D oral drugs in the payment bundle and asserted various statutory bases. In particular, commenters stated that the requirement to implement the ESRD PPS on or after January 1, 2011, does not specifically state that CMS must include all drugs for which payment is made under Title XVIII prior to implementation of the ESRD PPS. Commenters pointed out that section 1881(b)(14)(B) of the Act does not time limit CMS's discretion to define renal dialysis services for the ESRD PPS, and argued that the definition of "renal dialysis services" under section 1881(b)(14)(B)(iv) provides discretion to the agency about what items and services to include in the ESRD PPS and when to include them, claiming that Congress likely would not have enacted a provision that did not allow new items and services to be added. Some commenters argued that the "breadth of the language in subparagraph (iv)" of the statutory definition suggested broad discretion to the agency in making this determination, such that we may define renal dialysis services to exclude oral drugs in 2011, while maintaining authority to define renal dialysis services as including oral drugs in a subsequent year.

Other commenters cited the 4-year phase-in (section 1881(b)(14)(E) of the Act) as permitting full implementation of that portion of the single payment at any time before January 1, 2014, provided the implementation occurs in equal increments. Commenters argued that implicit in our interpretation of section 1881(b)(14)(E) of the Act is our authority to delay inclusion of oral drugs in the new bundled payment system. Commenters maintained the position that the phase-in over equal increments relates to coverage and payment, and that if CMS interpreted the provision to include oral drugs entirely at the beginning, CMS could implement the inclusion of oral drugs in the ESRD PPS in the fourth year of the transition period and still comply with the statute, including the requirement to implement the payment system in "equal increments".

Finally, some commenters argued that CMS has a statutory obligation to defer inclusion of oral drugs in the bundle, claiming that there is an obligation to delay under section 1881(b)(14)(ii) of the Act, because it requires CMS to determine the total amount of payments for renal dialysis services. If the agency

cannot do so because of a lack of data, it would be improper to include those items and services in the definition until it is able to do so.

Response: As we stated above and in the proposed rule, we continue to believe that section 1881(b)(14)(B) of the Act supports our interpretation that ESRD drugs and biologicals, including oral-only ESRD drugs, used for the treatment of ESRD, meet the definition of "renal dialysis services" under section 1881(b)(14)(B) of the Act, and should be included under the ESRD PPS (74 FR 49928 through 49929). For this reason, we have specified that oral ESRD drugs, including oral-only ESRD drugs, are included in the ESRD PPS.

However, we disagree with commenter's claims that this statutory definition is not "time-limited" such that we could delay including under this definition certain items or services that are currently in existence. We believe that the statutory definition dictates what services constitute "renal dialysis services" and does not afford us discretion to postpone such a determination for purposes of implementing the ESRD PPS. This is not to say, as some commenters have suggested, that the definition is static with regard to new items and services. To the extent new renal dialysis items or services come onto the market in the future and meet the definition, such services would be considered "renal dialysis services" and bundled under the ESRD PPS. For example, as we pointed out in the proposed rule, if other types of injectable ESAs or new oral forms of ESAs become available subsequent to the implementation of the ESRD PPS on January 1, 2011, such agents would be considered renal dialysis services and be subject to the ESRD PPS (74 FR 49928). Accordingly, for the reasons we set forth above and in the proposed rule, and after careful consideration of the public comments, we are finalizing the proposed policy decision that ESRD drugs and biologicals, including oral drugs, be identified as renal dialysis services under section 1881(b)(14)(B) of the Act.

With regard to the issue of inadequate data to price for payment oral drugs and biologicals, including oral-only drugs used for the treatment of ESRD, we agree with the commenters in part. We have included the Part B injectable drugs and biologicals used for the treatment of ESRD in the calculation of the base rate. Total payments for these drugs and biologicals were divided by the total number of hemodialysis (HD) equivalent treatments to obtain the amount of the payment per treatment for these drugs and biologicals reflected in the base rate. Injectable drugs are priced at ASP + 6 percent. Oral drugs with an injectable version were included in the payment bundle by taking total payments for these drugs based on Part D claims, and dividing that total by the total number of HD-equivalent treatment for Medicare ESRD beneficiaries enrolled in Part D. As explained in section II.K. of this final rule, prices for these drugs will be based on the national average drug prices developed from the Medicare Prescription Drug Plan Finder. These prices reflect pharmacy dispensing and administration fees and will be applied to only a limited number of drugs (three vitamin D analogues and levocarnitine).

While this pricing mechanism is also available for oral-only ESRD drugs, we believe that before we consider its adoption in connection with pricing these drugs for payment, we should evaluate its potential impact on dialysis facilities, particularly small dialysis facilities who may not be able to obtain drugs and biologicals at prices similar to those of the larger chains with greater purchasing power. Because payments for oral ESRD drugs with an injectable version in 2007 was about $10.7 million, while total payments for all oral ESRD drugs was about $455.7 million, we believe a careful assessment of the use of the Medicare Prescription Drug Plan Finder as a basis for pricing oral-equivalent ESRD drugs is appropriate before extending its application to oral-only drugs. Accordingly, we are delaying the implementation of oral drugs with no injectable equivalent or other form of administration (oral-only drugs), pending this evaluation.

As we discuss in more detail below and in the section II.K.2. of this final rule, we also agree that commenters' concerns about operational and safety issues with regard to furnishing oral-only agents should be further examined. We believe a delay would allow time to examine such issues and address as appropriate. For example, we agree with the commenters that a delay in implementing the inclusion of oral-only drugs under the ESRD PPS would provide sufficient time for ESRD facilities to establish a pharmacy in accordance with state licensure requirements, or establish arrangements with pharmacies to provide oral-only drugs to their patients and ensure a smoother transition to the dispensing of these drugs under Part B.

We disagree with the commenters who have suggested that the 4-year phase-in under section 1881(b)(14)(E)(i) of the Act provides authority to delay inclusion of certain types of renal dialysis services such as oral-only drugs beyond January 1, 2014. We believe that section 1881(b)(14)(E)(i) of the Act requires a phase-in of payments under the new system for facilities that do not opt to go all-in under the new ESRD PPS, allows for a blended payment under the old and new payment systems in equal increments over a 4-year period to allow facilities opportunity to transition to the new payment under the ESRD PPS. It does not, however, authorize a phase-in of renal dialysis services.

We also do not agree that the requirement under section 1881(b)(14)(A)(i) of the Act that the ESRD PPS be implemented by January 1, 2011, affords the agency discretion to delay identification of renal dialysis services to be included in the ESRD PPS. Section 1881(b)(14)(A)(i) of the Act requires implementation of a payment system in which a single payment is made for home dialysis and renal dialysis services which, as we discussed above, represent a specific set of services currently in existence that must be identified as renal dialysis services for the payment bundle.

We agree, however, with commenters with regard to our obligations under section 1881(b)(14)(A)(ii) of the Act, which requires that we make certain estimates about total payments for renal dialysis services based on certain data (that is, per patient utilization data). We agree that we must perform an assessment of the use of the Medicare Prescription Drug Plan Finder as a basis for the pricing of oral equivalent ESRD drugs before that pricing mechanism is potentially extended to oral-only ESRD drugs in order to develop payment rates for those drugs. Therefore, it would not be appropriate to implement oral-only ESRD drugs in the ESRD PPS at this time.

We believe that there are several advantages to delaying the implementation of oral-only drugs. A delay would—

- Provide additional time to determine the propriety of the Medicare Prescription Drug Plan Finder for the pricing of oral-equivalent ESRD drugs, before we consider extending that pricing mechanism to include all oral ESRD drugs and biologicals. CY 2007 data reveal that expenditures for the oral equivalents of injectable ESRD drugs totaled $10,700,083 for Medicare ESRD beneficiaries enrolled in Part D. *See* Table 9. Subtracting this amount from the total figure of $455,683,740, the total payments for all ESRD Part D drugs identified in Table 8 of the proposed rule (74 FR 49940), reveals that the comparable figure for oral-only ESRD drugs was $444,983,657. Given the

potential impact on the oral drug component of the payment bundle, evaluating the Medicare Prescription Drug Plan Finder and other potential alternative data sources for the pricing of oral ESRD drugs is essential.

- Allow ESRD facilities additional time to develop the arrangements or infrastructure necessary to provide oral-only drugs and negotiate prices with drug companies.
- Provide additional time for CMS to thoroughly educate beneficiaries, ESRD facilities, and pharmacies on those aspects of the bundled ESRD PPS involving the furnishing of non-injectable drugs to ensure as smooth a transition as possible.
- Given that oral drugs with an injectable version are included in the payment bundle as of January 1, 2011, provide CMS an opportunity to assess potential problems which may arise in connection with the provision of oral drugs prior to the system's expansion to include oral-only ESRD drugs beginning January 1, 2014.
- Allow time for additional analysis regarding the ability of ESRD facilities to provide oral-only ESRD drugs.
- Provide additional time to evaluate the need for additional clinical indicators applicable to the monitoring of certain patient conditions treated with oral-only drugs, such as bone loss and mineral metabolism associated with the provision of calcimimetics and phosphate binders. This could assist in determining the impact of the fully bundled ESRD PPS, and any unintentional consequences that might ensue, on quality of care.
- Allow Part D plans sufficient time to prepare bids for 2014 that excludes those oral-only drugs identified as "ESRD related". CMS will specify the oral-only drugs that are for the treatment of ESRD in connection with a proposed rule Beneficiaries will have access to more accurate premium quotes to assist them in making decisions about their Part D coverage.
- Allow Part D plans and pharmacies additional time to establish, test, and modify the infrastructure necessary to identify ESRD patients, as the oral equivalents of injectable drugs are bundled beginning January 1, 2011. Part D sponsors will gain several years of experience in identifying ESRD patients within CMS systems in order to ensure that Part D payments are not made for ESRD related drugs.

Beginning January 1, 2011, 18 oral drugs (as discussed below), will be included in the ESRD PPS base rate. Specifically, facilities will furnish such oral drugs beginning January 1, 2011. Until comprehensive beneficiary protections can be developed in anticipation of the inclusion of all ESRD-related oral-only drugs in the payment bundle under the ESRD PPS beginning January 1, 2014, patients will have access to these drugs under Part D. After considering the public comments and for the reasons we discussed above, we are retaining the definition of renal dialysis services as proposed in § 413.171, including with respect to the inclusion of oral-only drugs and biologicals. However, we are revising the implementation date for oral-only ESRD drugs and biologicals to be January 1, 2014 in § 413.174(f)(2). We believe that the transition period will give us sufficient time to address the data/pricing issues identified above, and to evaluate and correct any potential concerns that may emerge as a result of the inclusion of the oral drugs and biologicals with other forms of administration in the payment bundle effective January 1, 2011.

b. Other Drugs and Biologicals

Below we discuss comments regarding drugs and biologicals other than oral-only drugs and biologicals (for example, injectable drugs, oral drugs with some other form of administration, etc.). Oral-only drugs are separately addressed above.

Comment: Most commenters who expressed opposition to our proposed inclusion of oral-only Part D drugs in the ESRD PPS payment bundle were careful to distinguish these drugs from oral equivalents of injectable drugs, for which they conceded statutory authority existed for their inclusion under section 1881(b)(14)(B) of the Act. Although the commenters maintained that the inclusion of any oral drugs in the payment bundle would pose administrative burdens on dialysis facilities, they generally did not challenge our authority to include in the payment bundle the oral equivalents of injectable drugs used to treat ESRD in order to prevent the shifting of costs from Medicare Part B to Part D. The commenters, however, stated that if such drugs and biologicals were included in the payment bundle, their inclusion should be adequately funded.

Response: We agree with the commenters that section 1881(b)(14)(B) of the Act specifically requires that oral equivalents of injectable drugs used in the treatment of ESRD must be considered renal dialysis services for inclusion in the payment bundle. Accordingly, we have included those drugs, as described later in this section of this final rule. We have also revised the methodology for calculating the average amount per treatment for these drugs and biologicals included in the base rate, as described elsewhere in this final rule.

Comment: One commenter pointed out that dialysis patients take numerous oral medications, many of which are not related to ESRD. The commenter stated that the inclusion of oral equivalent drugs with an injectable version in the payment bundle could result in the patient receiving these drugs from a pharmacy with which the dialysis facility has established a relationship for the dispensing of these drugs to its patients, while the other medications are received from a different pharmacy of the patient's choice. Because multiple pharmacies would be involved, this could result in less attention paid to potential adverse consequences resulting from drug interactions and less coordination of care.

Response: We agree that under the circumstances which the commenter has described, multiple pharmacies could be involved in the dispensing of drugs to dialysis patients. However, the prescriptions for these drugs are prepared by the patient's nephrologist, primary care physician, or specialist, each of whom should be aware of the patient's medications for potential adverse interactions. The dialysis facility should also be aware of the patient's oral medications as an additional safeguard and therefore, we expect dialysis facilities to collect comprehensive information on patients' oral medications to identify any potential drug interactions that might otherwise occur. Finally, patients can always advise their pharmacist of the oral drugs they take when filling a prescription, and inquire about potential drug interactions as well. Therefore, we believe that there are sufficient safeguards to ensure that the use of several pharmacies to obtain oral drugs does not result in adverse consequences for dialysis patients.

Comment: Many commenters expressed concern about what they believed would occur if drugs were included in the ESRD PPS. Some commenters were opposed to including oral drugs in the bundled payment, particularly vitamin D used for bone and mineral metabolism. Commenters cited negative effects on patients' health because ESRD facilities may consider cost saving measures such as purchasing less costly and less effective drugs (for example, over-the-counter calcium binders or vitamin D); limiting the use of the more expensive drugs; using oral drugs which they believe are not as effective as intravenous drugs; switching to generic drugs or to drugs used in the past, which the commenters believed are not as effective; and using

lower cost oral drugs instead of intravenous drugs resulting in various complications as vascular calcification, anemia, blood transfusions, and hospitalizations. Some commenters predicted an increase in the number of parathyroidectomies due to poor control of hyperparathyroidism. One commenter expressed concern that cost cutting changes in medication practices at his ESRD facility have already begun to occur in preparation for the implementation of the ESRD PPS.

Some commenters indicated that certain patients would be negatively affected by the inclusion of drugs in the ESRD PPS bundled base rate. The commenters believed that older patients would be discriminated against by being given less expensive and less effective medications. Others believed patients needing more medications than others would be unable to receive the appropriate dose of their medications. One commenter believed that patients receiving dialysis twice weekly or those who miss treatments will be considered financially undesirable because ESRD facilities will be responsible for the entire month for their medications while receiving payment for the dialysis treatments only.

Response: We are concerned by the issues raised by commenters who believe ESRD facilities would intentionally and knowingly deny medications or provide less effective drugs because of the inclusion of drugs in the ESRD PPS bundle. We do not agree that the inclusion of drugs in the ESRD PPS would result in facilities denying drugs to patients or necessarily using less effective drugs. In particular, we do not agree that the use of alternative less costly drugs necessarily constitutes the use of less effective drugs. We expect that ESRD facilities will continue to provide necessary care to patients with ESRD, and we will be monitoring the implementation of the ESRD PPS very closely.

As with any prospective payment system, there are patients whose medical treatment results in more costly care as well as those with less costly care. As we have discussed in other sections of this final rule, the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient. We have incorporated payments under the current composite rate payment system as well as payments for separately billable items and services into the ESRD PPS base rate. As a result, we believe the ESRD PPS payments are sufficient and reflect the average cost of providing care to the average patient with ESRD and therefore, we expect that, on average, high cost patients would be offset by low cost patients. We have provided for higher acuity patients with patient case-mix adjusters as discussed in section II.F. and with outlier payments for high cost patients as discussed in section II.H. of this final rule.

Section 494.80(a)(5)of the regulations requires an ESRD patient's comprehensive assessment include an "[e]valuation of factors associated with renal bone disease." Section 494.80 outlines other requirements for assessing and reassessing patients, as well as creating and implementing an individual patient plan of care as described in § 494.90. Section 494.90(a)(3) requires all ESRD facilities to "* * * provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease." Patient rights, including the mechanisms for filing grievances, are established at § 494.70. This means that ESRD facilities are required to provide care necessary to treat patients. We are confident that ESRD facilities will act responsibly to provide appropriate care under the ESRD PPS and oversight activities will identify any ESRD facility that may not do so. Therefore, we plan to monitor utilization of renal dialysis items and services to ensure that quality care is being provided. We will discuss monitoring in the implementation section II.K. of this final rule and in the future.

Comment: One commenter believed that separating the dispensing of oral renal drugs from oral drugs used for non-renal conditions will cause confusion for patients, their families, and other providers that provide care to ESRD patients.

Response: We believe the commenter is referring to ESRD-related drugs and biologicals included in the ESRD PPS base rate. We do not agree that the bundling of ESRD-related drugs or biologicals will result in confusion. Currently patients may receive medications or prescriptions from multiple sources especially if they require medical specialists for non-ESRD conditions. We do not see any difference in this process under the ESRD PPS.

Comment: Some commenters believe patients will be involuntary discharged from ESRD facilities if the patients are noncompliant and drugs are included in the ESRD bundle.

Response: As discussed earlier in this section of the final rule, the statute requires that renal dialysis services included in the ESRD PPS include specified ESRD-related services including injectable and oral drugs and biologicals. Because ESRD-related drugs and biologicals are in the ESRD PPS bundle, ESRD facilities will be responsible for furnishing ESRD-related drugs and biologicals that their patients require. We appreciate the commenter's concern that patients may be involuntarily discharged. However, § 494.180 of the ESRD Conditions for Coverage explicitly addresses the discharge procedure, the acceptable circumstances for an involuntary discharge or transfer, the required actions that must be completed by the ESRD facility prior to ceasing treatment, as well as the requirement to inform patients of their rights and protections.

Comment: One commenter stated that because of the ESRD PPS, patients with vascular access dysfunction, who are currently treated in the ESRD facility, would instead be referred to the emergency department in order to be able to receive separate payment for drugs used to maintain vascular access. Other commenters indicated that patients would be referred to other health care settings such as infusion centers or other health care providers to administer medications such as antibiotics and thrombolytic agents, for the purpose of being reimbursed for medications.

Response: We believe that the commenter is implying that as a result of including anti-thrombolytic drugs and antibiotics in the bundled ESRD PPS base rate, ESRD facilities would refer patients with any difficulties with vascular access to the emergency department or to other settings rather than ensuring that vascular access patency is addressed in the ESRD facility at the time of dialysis (as is currently being done). We believe that maintaining vascular access is a renal dialysis service and therefore, would be included in the ESRD PPS and ESRD facilities would continue to be responsible for furnishing the service. In other words, as ESRD facilities have been maintaining vascular access sites under the current basic case-mix adjusted composite rate system and receiving separate payment for anti-thrombolytic drugs, we will expect that they would continue to maintain vascular access under the ESRD PPS, with payment for anti-thrombolytic agents included in the ESRD PPS base rate. Accordingly, we expect that ESRD facilities would not refer patients to another health care setting for the purpose of maintaining vascular access. We note, we would expect patients to be referred to another setting if medically necessary and we are not implying that ESRD facilities are expected to address any and all vascular access complications, if doing so would be

unsafe for the patient. We merely are indicating that we expect ESRD facilities to perform the same procedures to maintain vascular access that they currently perform, and not refer patients to other settings for the purpose of obtaining additional payment. We will monitor ESRD facilities to determine whether they are continuing to perform the same procedures to maintain vascular access that they currently perform.

Comment: Some commenters cited patient non-compliance for their opposition to including oral drugs in the bundle. The commenters believed that dialysis facilities could control intravenous drugs and dosing but could not determine patient compliance with pill taking; that inclusion of oral drugs would require patients to take responsibility for their own care; and that patient compliance in inner cities is already poor. Others stated that reverting to oral medications in place of their intravenous forms, would result in an increase in the number of pills patients with ESRD, who are already required to take multiple pills with limited daily fluid allowance, would be required to take. Other commenters were concerned that patients might not receive their medications if they forget to obtain them during their dialysis treatment. Several commenters claimed patient non-compliance would increase due to the bundling of oral drugs. The commenters believed there would be higher spending on hospitalizations and outpatient care because of decreased control of patient's anemia and bone disease.

Response: We appreciate the concerns about patient compliance and pill burden. We do not understand the commenter's statement indicating that inner city compliance is already poor and therefore, we regret that we are unable to respond to the comment.

We do not agree that including oral drugs in the bundle will result in increased patient compliance difficulties, increased pill burden or poor control of anemia and bone disease because under the ESRD PPS there is no requirement that drugs must be administered in any particular form or by any particular route. It is the responsibility of the ESRD facility, the patient's physician, and the ESRD interdisciplinary team to develop a plan of care that is appropriate and meets each patient's needs. That includes determining the most appropriate route of administration of a drug. Although we believe we are required by statute to include oral drugs and biologicals in the payment bundle, the use of oral equivalents remains a medical decision. Section 494.90 of the ESRD Conditions for Coverage requires the development of an individualized patient plan of care to address the patient's needs. Therefore, we believe ESRD facilities should make medical decisions based on patient needs and not solely on a financial basis.

As we discussed in several responses above, we believe that ESRD facilities will act responsibly to provide appropriate care under the ESRD PPS and that continued monitoring may serve to help identify the ESRD providers who do not. Therefore, we plan to monitor utilization of renal dialysis items and services to ensure the quality care continues to be provided. We will discuss monitoring in the implementation section II.K. of this final rule and in the future.

Comment: Commenters were divided in expressing their support or opposition to the inclusion of intravenous drugs and their oral equivalents in the ESRD PPS base rate. Some commenters expressed concern that bundling drugs will restrict nephrologists' ability to prescribe necessary medications. One commenter suggested removing all oral drugs from the bundle to allow nephrologists to decide what is in the best clinical interest of the patient without reimbursement concerns. Others expressed concern that physicians would not prescribe drugs that could put a facility at financial disadvantage or would be forced to use the "cheapest available therapy which might be harmful to patients and further increase their cardiovascular mortality." Another commenter believed that disparities in care will occur when physicians will need to determine which patients are "most deserving or have the greatest need for certain medications" placing physicians in an adversarial position with ESRD facilities. Several commenters believed physicians should have autonomy to prescribe the most appropriate drugs within classes of medications.

Some commenters supported inclusion of all drugs and biologicals used to treat ESRD regardless of the route of administration noting that oral and injectable drugs are routinely given during the course of dialysis treatment. Other commenters indicated that inclusion of all drugs, regardless of route of administration in the bundle was "* * * critical to achieving optimal patient care." These commenters believed that allowing certain drugs and biologicals to be unbundled while others are bundled would establish incentives to select treatment options contrary to patient's clinical needs and results in medications from different sources jeopardizing adherence to care regimens and undermining quality of care.

Response: We thank the commenters for their views of the impact of including ESRD-related drugs and biologicals in the bundle. The general premise of the ESRD PPS is that the ESRD payments reflect the average cost of furnishing renal dialysis items and services to patients. In situations where costs for treating patients exceed an established threshold under the ESRD PPS, the outlier policy would apply. The outlier policy is discussed in detail in section II.H. of this final rule.

We continue to believe that the responsibility for determining the appropriateness of medical care resides with the ESRD facility, physicians, and the interdisciplinary team as stipulated by the ESRD Conditions for Coverage. We also believe that physicians, the interdisciplinary team, and ESRD facilities should make medical decisions based on patient needs and not solely on a financial basis. We plan to monitor utilization of renal dialysis items and services to ensure the quality care continues to be provided. We will discuss monitoring in the implementation section II.K. of this final rule and in the future.

We note that we do not have the discretion to exclude services from the ESRD payment system that meet the statutory definition of a renal dialysis service. We discuss the definition of renal dialysis services earlier in this section and in section II.D. of this final rule. We also discuss the delay in implementation of oral-only drugs earlier in this section.

Comment: Several commenters expressed concern that there are no quality measures for calcium, phosphorus, and parathyroid control. Others recommended tracking changes in transfusion utilization. One commenter urged that necessary steps be taken to ensure access to drugs appropriate for patients and not the "least costly alternative." Another commenter suggested that MedPAC and other entities track drug utilization to avoid unintended consequences.

Response: We agree with the commenters that there needs to be overall monitoring, tracking measures to monitor utilization and measure outcomes, and specifically to eventually track and report patient levels of calcium, phosphorus and parathyroidism prior to implementing the oral-only drugs in the ESRD PPS in 2014. We are currently working to develop measures for the initial year of the QIP and beyond. We note that, as set

forth in section 1881(h)(2)(A) of the Act, additional measures are being considered and developed such as patient satisfaction, iron management, bone mineral metabolism, and vascular access.

We are currently developing a comprehensive monitoring plan which includes tracking drug utilization. We will discuss monitoring in the implementation section II.K. of this final rule and in the future. We also plan to ensure that patients are educated about the ESRD PPS including the mechanisms they can use to report grievances. We believe that other entities such as MedPAC, the GAO, and the OIG will be looking into the effects of the ESRD PPS. We note that quality measures are discussed in section II.M. of this final rule. Additionally, we will include a discussion of future QIP measures forecasting in the ESRD QIP proposed rule.

Comment: One commenter believed that if the concern is cost shifting from injectable vitamin D to the oral vitamin D analogs, it would be better to address that issue directly.

Response: We do not understand what the commenter is suggesting with the statement about addressing the issue of injectable versus the oral version of vitamin D directly. However, we believe that the ESRD PPS provides an opportunity for ESRD facilities to make financially sound decisions while providing necessary care recognizing that some patients may utilize less renal dialysis items and services while others may use more. In addition, under the QIP, we are working towards developing quality measures for bone and mineral metabolism. Further discussion on quality measures are found in section II.M. of this final rule.

Comment: One commenter stated that certain injectable drugs used to treat ESRD may not have oral equivalents. Therefore, the patient would not be able to afford obtaining these drugs outside of the payment bundle, resulting in a lower quality of care.

Response: We are not clear about the point the commenter was attempting to make, as ESRD-related injectable drugs without oral equivalents would be furnished by the dialysis facility. In addition, all injectable drugs used to treat ESRD are included in the payment bundle as Part B renal dialysis services, regardless of whether they have an oral equivalent.

Comment: Many commenters indicated that they did not know which drugs were in the bundled base rate. Some commenters questioned whether non-dialysis-related drugs are included, such as those drugs used to treat diabetes, high blood pressure, cardiac drugs, or renal vitamins.

Response: We thank the commenters for their suggestions on which drugs should be included in the ESRD PPS. We also agree that in the proposed rule, we did not explicitly indicate which drugs would be in the proposed ESRD PPS base rate.

We proposed that payments for all drugs and biologicals furnished to ESRD patients and separately billable prior to January 1, 2011, would be included in the ESRD PPS payment bundle as renal dialysis services (74 FR 49929). Therefore, in the proposed rule, we included all drugs and biologicals on ESRD claims for 2007 for which separate payment was made in computing the proposed ESRD PPS base rate because the presumption was that all drugs and biologicals on ESRD claims were ESRD-related. We explained in the proposed rule (74 FR 49940 through 49941), our methodology of using CY 2007 claims data for determining the Medicare Allowable Amounts (MAPs) for the Part B and former Part D ESRD-related drugs and biologicals components of the ESRD PPS bundle, including the use of NDC codes for purposes of identifying by oral drugs covered under Part D by class.

With regard to the drugs and biologicals we proposed to bundle in the ESRD PPS, we identified in the proposed rule the top 11 Part B drugs and biologicals that accounted for 99.7 percent of total spending for Part B ESRD drugs and biologicals and identified the classes of oral ESRD-related drugs and biologicals currently covered under Part D that would be bundled. When listing the amount of spending for ESRD-related drugs and biologicals, we combined the products that accounted for the remaining 0.3 percent of total spending for Part B ESRD drugs and biologicals in a general category ("Other injectables" Part B drugs and biologicals) included in the proposed base rate (74 FR 49940 through 49941).

With regard to commenters' concerns about the inclusion of certain drugs, including non-ESRD related drugs, in the proposed bundle, in developing the proposed rule, we presumed that all separately billable items were drugs and biologicals on the ESRD claims were ESRD-related and therefore, all separately billable items on ESRD claims were included in the proposed ESRD PPS bundled base rate.

As a result of comments, for this final rule, we performed an extensive analysis of Medicare payments for Part B drugs and biologicals billed on ESRD claims in 2007, 2008, and 2009 to identify drugs or biologicals that are ESRD-related and therefore meet the definition of renal dialysis services under section 1881(b)(14)(B) of the Act, and would be included in the ESRD bundled base rate. Drugs and biologicals that are generally not ESRD-related (for example drugs and biologicals used to treat diabetes, cardiac conditions and hypertension), would not be renal dialysis services and would be excluded from the ESRD bundled base rate.

We believe that categorizing drugs and biologicals on the basis of drug action would allow us to determine which categories (and therefore, the drugs and biologicals within the categories) would be ESRD-related. We evaluated each drug and biological to identify its category by indication or mode of action. We then analyzed the categories to determine those that would be expected to be utilized for ESRD-related conditions in a dialysis unit (and therefore would be a renal dialysis service).

We note that the current ESRD claims form does not differentiate between drugs and biologicals administered for an ESRD condition from drugs and biologicals administered during dialysis for non-ESRD related conditions. During this extensive analysis, we discovered that our presumption that all drugs and biologicals on the ESRD claims were ESRD-related was incorrect. In fact, there were categories of drugs and biologicals (and therefore specific drugs on ESRD claims for which separate payment had been made) that were not ESRD-related. These non-ESRD-related drugs and biologicals are discussed in detail below. Later in this section, we also discuss in detail the method used to identify ESRD-related drug and biological categories and drugs and biologicals included in the final ESRD PPS base rate below. Table C in the Appendix provides a listing of the specific drugs which were included in the proposed ESRD PPS base rate and how those drugs were treated in the final ESRD PPS base rate.

Specifically, we identified drugs and biologicals on the ESRD claims which are classified as chemotherapeutic drugs, immunosuppressant drugs, and vaccines. These drugs and biologicals, with the exception of hepatitis B and flu vaccines, had been included in the proposed ESRD PPS base rate. As these are not ESRD-related drugs and biologicals because they are not used for ESRD-related conditions and therefore, are not renal dialysis services, we excluded them from the final ESRD bundled base rate. As a result, we excluded the payments from the 2007 ESRD facility claims for these drugs and

biologicals in computing the final ESRD PPS base rate.

In performing our analysis of the ESRD claims for this final rule, we also identified drugs and biologicals that are included in the current composite payment rate but for which ESRD facilities received separate payment in addition to the composite rate payment. Because these composite rate drugs and biologicals were listed separately on the ESRD claims, separate payment was inadvertently made and we included these payments in the proposed ESRD PPS base rate. However, for this final rule, we excluded those inadvertently made payments from the final ESRD PPS base rate calculation.

We note that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 lists the drugs and fluids included under the current composite payment system as heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, verapamil and antibiotics used at home by patients being treated for catheter site infection or peritonitis associated with peritoneal dialysis. The Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 also explicitly states, "* * * drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate." The manual further provides that "Administration of these items (both staff time and supplies) is covered under the current composite rate and may not be billed separately."

Also, in our analysis of drugs and biologicals for this final rule, we identified ESRD claims that included payments for drugs and biologicals, but did not include any dialysis treatments. Because ESRD facilities receive a payment under the current basic case-mix adjusted composite payment system which is treatment based (that is, based on the provision of a dialysis treatment) and separate payment is made for any items or services provided that are not considered part of the composite rate, payment for claims without treatments should not be paid. Therefore, for this final rule, payments for drugs and biologicals listed separately on the ESRD claim where there was no dialysis treatment included on the claim were excluded from the computation of the base rate.

In the analysis conducted for this final rule, we also identified drugs and biologicals on ESRD claims that were not identifiable because they were billed using unspecified or unclassified HCPCS codes. These codes are used when a HCPCS code has not yet been assigned. As a result, we were unable to determine the name of the drug or biological or if they were ESRD-related or administered for non-ESRD-related conditions. Because ESRD-related drugs and biologicals have HCPCS codes, we considered any drug or biological billed using an unclassified or unspecified HCPCS code as being non-ESRD-related. Therefore, any payments attributed to these unspecified codes were not included in computing the final ESRD base rate. We note that ESRD facilities should be using valid HCPCS codes for the drugs that they administer and should only use the unclassified codes for those drugs that do not have codes.

During our analysis for this final rule, we also identified drugs and biologicals as well as procedures which would not be considered renal dialysis services. For example, low molecular weight contrast administered for radiological purposes; pharmacy and administrative pharmacy code for administration of oral anti-emetics for cancer treatment; chemotherapy; and chest x-rays were reported on the ESRD claims. Because these procedures are not renal dialysis services (that is, they are not procedures that are used for the treatment of ESRD), we excluded the payments associated with these procedures from the final ESRD PPS base rate.

We also identified drugs, biologicals and procedures reported on ESRD claims which are unlikely to be performed or provided in an ESRD facility. For example, there were claims that included paralytic agents used to intubate patients. Because we do not believe that these drugs would be used to treat ESRD-related conditions, they would not be considered to be renal dialysis services. As a result, we excluded the payments made for these drugs in computing the final ESRD PPS bundled base rate.

We list the categories of drugs and biologicals that we would not consider ESRD-related and therefore would not be renal dialysis services included in the ESRD PPS base rate in Table 3 below. We note that the drugs, biologicals, and procedures that were excluded from the final ESRD PPS base rate represent a very small dollar amount accounting for less than one cent per dialysis treatment and represent less than 0.2 percent of payments made for separately billable drugs and biologicals. Table C in the Appendix identifies the Part B injectable drugs that were included in the proposed base rate and in the final base rate.

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Table 3 - ESRD Drug Category Excluded From the Final ESRD PPS Base Rate

Drug Category	Rationale for Exclusion
Anticoagulant	Drugs labeled for non renal dialysis conditions and not for vascular access
Antidiuretic	Used to prevent fluid loss
Antiepileptic	Used to prevent seizures
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions
Antipsychotic	Used to treat psychosis
Antiviral	Used to treat viral conditions such as shingles
Cancer management	Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category
Cardiac management	Drugs that manage blood pressure and cardiac conditions
Cartilage	Used to replace synovial fluid in a joint space
Coagulants	Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency
Cytoprotective agents	Used after chemotherapy treatment
Endocrine/metabolic management	Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia and hyperglycemia
Erectile dysfunction management	Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction
Gastrointestinal management	Used to treat gastrointestinal conditions such as ulcers and gallbladder disease
Immune system management	Anti-rejection drugs covered under a separate benefit category.
Migraine management	Used to treat migraine headaches and symptoms
Musculoskeletal management	Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions
Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs	Not a function performed by an ESRD facility
Pulmonary system management	Used for respiratory/lung conditions such as opening airways and newborn apnea
Radiopharmaceutical procedures	Includes contrasts and procedure preparation
Unclassified drugs	Should only be used for drugs that do not have a HCPCs code and therefore cannot be identified
Vaccines	Covered under a separate benefit category

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Comment: Commenters noted that CMS needs to clearly delineate what is covered in the bundle. One commenter suggested differentiating between medications used for acute rather than chronic complications. One commenter recommended that a list of specific ESRD-only related drugs for inclusion in the bundle and that these be periodically updated to account for new technology and innovation. Some commenters suggested that we include only intravenous ESAs, iron, and vitamin D. One commenter stated that ESRD facilities separately bill and are reimbursed for ESAs, iron, vitamin D, alteplase and antibiotics for the treatment of access-related infections and peritonitis. Other commenters suggested that we include only intravenous ESAs, iron and vitamin D. One commenter believed that ESRD-related drugs used in the treatment of anemia, bone disease and iron deficiency should be included in the bundle. Some commenters suggested that only oral drugs that have "equivalent injectables" or other "equivalent non-oral forms" should be in the bundle. One commenter suggested that only ESRD intravenous drugs and their oral equivalents that are well known and most manageable be included.

Response: As we discussed in the previous response, we identified categories of drugs and biologicals which were not ESRD-related and

therefore, we excluded the payments for drugs in those categories from the final ESRD PPS base rate. We agree with the commenters that drug categories used for the treatment of anemia and iron deficiency (which includes ESAs and intravenous iron), access management (which includes alteplase), and bone and mineral metabolism (which includes vitamin D) would be renal dialysis services under the ESRD PPS. We also agree that antibiotics used for the treatment of venous access infections and peritonitis (specifically, vancomycin and daptomycin) and cellular management (specifically, levocarnitine) are renal dialysis services under the ESRD PPS. Therefore, payments for drugs in these categories in injectable forms (covered under Part B) and oral or other forms of administration (covered under Part D), were included in computing the final ESRD PPS base rate. We note one exception. We understand that the oral versions of vancomycin are not used for ESRD-related conditions and therefore, would not be a renal dialysis service. It is also our understanding that daptomycin does not have an oral equivalent. The categories and drugs which are renal dialysis services under the ESRD PPS are shown in Table 4 below.

Table 4 - Renal Dialysis Service ESRD Drug Categories Included in the Final ESRD PPS Base Rate

Drug Category	Rationale for Inclusion
Access management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Anti-infectives	Vancomycin and daptomycin used to treat access site infections. .
Bone and mineral metabolism	Drugs used to prevent/treat bone disease secondary to dialysis.
Cellular management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

With regard to the suggestion that there be a differentiation between acute and chronic complications, we do not believe that such a differentiation is required as the definition of renal dialysis services does not distinguish between renal dialysis services provided for acute or for chronic conditions. For example, anemia management is a chronic condition and access management is more acute and the drugs and biologicals used for both are considered renal dialysis services.

With regard to the commenter's request to provide a list of specific ESRD-only drugs, we recognize that drugs and biologicals used for ESRD-related conditions may change over time based upon many factors including new developments, evidence-based medicine, and patient outcomes. By categorizing drugs and biologicals based on mechanism of action, we will account for other drugs and biologicals that may be used for those actions in the future under the ESRD PPS. In other words, while we have included drugs and biologicals used in 2007 in the final ESRD base rate, we recognize that these may change. Because there are many drugs and biologicals that have many uses and because new drugs and biologicals are being developed, we do not believe that a drug-specific list of drugs would be beneficial. We have provided a list of the specific drugs that were included in the ESRD PPS base rate in Table C in the Appendix. However, any drug or biological furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered renal dialysis services under the ESRD PPS.

We note that any ESRD drugs developed in the future that are administered by a route of administration other than injection or oral would be considered renal dialysis services and would be in the ESRD bundled base rate. Any drug or biological used as a substitute for a drug or biological that was included in the ESRD PPS bundled base rate would also be a renal dialysis service and would not be eligible for separate payment.

We believe that categories of drugs and biological used for access management, anemia management, bone and mineral metabolism, and cellular management would always be considered ESRD-related when furnished to an ESRD patient unless the ESRD facility indicates a drug or biological is non-ESRD-related through the use of a modifier. However, because anti-infectives are routinely furnished for ESRD-related reasons related to access infections and peritonitis, we included vancomycin and daptomycin and all other antibiotics on the 2007 ESRD claims in computing the final ESRD PPS base rate. Therefore, if any other anti-infective (including oral or other forms used as a substitute for an injectable anti-infective) is used for vascular access infections or peritonitis, the drug would be a renal dialysis service and separate payment would not be made.

Under this approach, we are presuming these drugs and biologicals are renal dialysis services because they were included on the ESRD facility claims and furnished in conjunction with a dialysis treatment. In addition, these drugs represent 99.8 percent of payments for separately billable drugs and biologicals furnished to ESRD patients.

In our analysis for this final rule of the drugs and biologicals on the ESRD facility claims, we analyzed the remain 0.2 percent of payments for separately billable drugs and identified drug categories that we believe could be ESRD-related, but are commonly used for non-ESRD-related conditions (for example, antiemetics and pain medications). These are shown in Table 5. Because these drug and biological categories could be ESRD-related, we included the payments made under Part B for these drugs and biologicals in 2007 in the final ESRD bundled base rate. In other words, for the purpose of the ESRD bundle, as of January 1, 2011, these drugs are presumed to be renal dialysis services unless the ESRD facility indicates on the claim (by using

a modifier) that a drug or biological in these categories is not ESRD-related and, separate payment would be made. (We discuss the use of the modifier in section II.K. of this final rule.)

Where these drugs are furnished and billed by ESRD facilities in conjunction with dialysis treatments, we presume these drugs and biologicals in whatever form they are furnished, to be renal dialysis services. As a result, we identified the drugs and biologicals for these categories and included the payments made under Part B for these drugs in computing the final ESRD PPS base rate. As ESRD facilities are required to report all drugs and biologicals they furnish and will be able to designate drugs and biologicals as being ESRD-related or non-ESRD-related through the use of a modifier, we will be able to monitor the drugs and biologicals to identify those that are being used for ESRD-related conditions and those that are not.

However, as the oral (or other form of administration) substitutes for the drugs and biological described above were not furnished or billed by ESRD facilities nor furnished in conjunction with dialysis treatments, we presume that these drugs and biologicals currently paid under Part D were prescribed for non-ESRD-related conditions and are not renal dialysis services. Therefore, we did not include payment for these oral drugs and biologicals with other forms of administration in the ESRD PPS base rate. However, if these drugs and biologicals currently paid under Part D are furnished by an ESRD facility for ESRD-related purposes, they would be considered renal dialysis services.

We will monitor the use of drugs and biologicals in these categories for the treatment of ESRD and may add categories of drugs and biologicals that constitute renal dialysis services (or if applicable, eliminate categories of drugs and biologicals that no longer constitute renal dialysis services) in the future.

Table 5 - ESRD Drug Categories Included in the ESRD Base Rate But May Be Used for Dialysis and Non-Dialysis Purposes.

Antiemetic	Used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications but are included for their action to treat itching secondary to dialysis.
Anxiolytic	Drugs in this classification have multiple actions but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess fluid management	Drugs/fluids used to treat fluid excess/overload
Fluid and electrolyte management including volume expanders	Intravenous Drugs/fluids used to treat fluid and electrolyte needs
Pain management	Drugs used to treat graft site pain and to treat pain medication overdose

Comment: One commenter questioned whether midodrine used to maintain blood pressure on dialysis was included in the bundle and would the bundle be expanded to include all blood pressure medications. Another commenter noted that the average patient is on 3 to 5 different anti-hypertensive drugs and suggested that if anti-hypertensive drugs were in the bundle, that more focus on optimal fluid management should occur.

Response: As we discussed above, the separately billable Part B payments made for cardiac drugs (including anti-hypertensive drugs) were not included in the final ESRD PPS base rate because cardiac drugs are included under the current basic case-mix adjusted composite payment rate. In addition, we note that we did not see midodrine reported in the 2007 ESRD claims data. However, to the extent that that any cardiac drug or biological (including anti-hypertensive drugs and biologicals) are furnished by an ESRD facility for ESRD-related conditions, the drug or biological would be considered a renal dialysis service and separate payment will not be made.

Comment: Some commenters indicated that in cooperation with other physicians and transplant centers and in the patients' interest, they administer medications that are not part of dialysis care, such as immunosuppressants and antibiotics. One commenter indicated that providers will have to undertake an expensive appeals process that could impair access if there is no recognition of non-ESRD-related drugs. The commenter further stated if the ESRD PPS does not consider that non-ESRD-related drugs and biologicals are furnished by ESRD facilities, nephrologists will only be permitted to order medications that are included in the final ESRD PPS base rate, and directly related to dialysis. This outcome would make it impossible for nephrologists to serve as primary care physicians and would force patients to see internists and family practice physicians incurring additional costs to insurers and patients. The commenter believed that this will result in repetition of unnecessary and expensive procedures resulting in higher costs, morbidity, and mortality.

Response: We are aware that drugs and biologicals may be administered for reasons unrelated to the treatment of ESRD or dialysis and would not be renal dialysis services covered under the ESRD PPS. As discussed above, because the 2007 ESRD claims do not distinguish between ESRD-related and non-ESRD-related drugs and biologicals, we were unable to exclude payments for those drugs and biologicals from the base rate with certainty. To the extent that we were able to presume a drug or biological was not ESRD-related, we excluded the payments. We identify the drugs and biologicals that were included in the base rate in Table C in the Appendix. We have developed a mechanism to be used by ESRD

facilities to identify and be paid separately for non-ESRD-related drugs and biological which is discussed in section II.K. of this final rule.

Comment: One commenter recommended that we develop a list of specific ESRD-only related drugs for inclusion in the bundle and that the list be periodically updated to account for new technology and innovation.

Response: As discussed above, rather than specifying the specific ESRD-related drugs and biologicals, we identified categories based on the mechanism of action of these drugs and biologicals. We did not specify all of the drugs and biologicals within these categories because, as we noted above, we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified and we wanted the ability to reflect new drugs and biologicals developed or changes in standards of practice. Therefore, we are not restricting or limiting the tables to specific drugs or biologicals. However, the categories of drugs and biologicals which we identified as renal dialysis services were included in the final ESRD PPS base rate and are shown in Table 5. We will monitor the use of drugs and biologicals for the treatment of ESRD and may add categories of drugs and biologicals that constitute renal dialysis services (or if applicable, eliminate categories of drugs and biologicals that no longer constitute renal dialysis services) in the future.

Comment: Some commenters suggested that we include levocarnitine in the ESRD bundle.

Response: We agree that levocarnitine is used in the treatment of ESRD and meets the definition of a renal dialysis service. Levocarnitine is included in the drug categories shown in Table 4.

Comment: Some commenters indicated that the top 11 ESRD drugs and biologicals account for 99.7 percent of Part B payments for intravenous drugs and biologicals furnished to ESRD patients in 2007. The commenters believed that the Congress intended that only these drugs and their equivalents be included in the bundled rate, as these drugs normally are administered during the course of dialysis treatment.

Response: We do not agree with the commenters that only the top 11 drugs and biologicals should be included in the ESRD base rate. As we discussed above, the top 11 drugs, which in the analysis conducted for this final rule account for 99.8 percent of ESRD Part B separately billable drug payments, are included in the ESRD bundled base rate.

However, there are drugs and biologicals (and therefore, categories of drugs and biologicals) that were not among the top 11 ESRD drugs and biologicals, but were determined to be renal dialysis services. We discuss these categories of drugs and biologicals (for example, the pain management category), in the discussion above concerning categories of drugs that are ESRD-related but could be used for non-ESRD conditions.

Comment: A few pediatric dialysis facilities noted that drugs administered to children usually include antibiotics for peritonitis; peritoneal dialysis or hemodialysis central venous catheter infections; hemodialysis catheter related septicemia; alteplase for hemodialysis catheter de-clotting; anti-seizure medications; ESAs; and vitamin D analogs. The commenters indicated that antibiotic and alteplase use was more prevalent in younger children as well as higher ESA dosing per kilogram of body weight. Some of these commenters provided a list of the pediatric drugs and their costs.

Response: As we discussed above, we concur that drugs and biologicals that are used for anemia management (ESAs), bone and mineral management (vitamin D), access infections and peritonitis (vancomycin and daptomycin), and access management (alteplase) are renal dialysis services and payments for the drugs in these categories have been included in the ESRD PPS base rate. However, we did not include anti-seizure medications in the ESRD PPS base rate because we believed that anti-seizure drugs and biologicals were used for many conditions and were not likely to be renal dialysis services. We are not clear if the commenter was indicating that anti-seizure medications were administered to pediatric patients because of ESRD-related conditions or for other non-ESRD-related conditions.

However, we will monitor the use of anti-seizure drugs and biologicals for the treatment of ESRD and may add this category of drugs and biologicals that constitute renal dialysis services in the future. We expect that ESRD facilities that treat ESRD patients under the age of 18 will report the ESRD-related seizure medications on the ESRD claims. Where an anti-seizure drug or biological is furnished by the ESRD facility and reported without a modifier, separate payment would not be made. Further discussions on pediatric ESRD patients are in section II.G. of this final rule.

Comment: Many commenters opposed the inclusion of antibiotics in the bundled payment indicating that antibiotics are often administered during dialysis for non-renal reasons such as pneumonia or wound infection and, therefore, should remain separately billable. Others explained that antibiotics are administered when an infection is suspected in patients receiving dialysis treatment, noting that administration of antibiotics decreases hospitalizations, emergency room visits, shortens hospital days, and decreases mortality. These commenters believed that if antibiotics are included in the bundle, it would serve as a disincentive for early infection intervention. Others explained that antibiotics are often not prescribed by nephrologists and, therefore, would not be renal dialysis services. Still others noted that administering antibiotics during dialysis is less expensive to administer because there is vascular access readily available.

Another commenter indicated that antibiotics are administered to severely ill patients prior to transfer to the emergency department. Several commenters explained that dialysis "clears many antibiotics" and indicated that if patients do not receive antibiotics during or at the end of dialysis, there is a likelihood that their blood levels would be subtherapeutic, increasing the risk of recurrent infection and hospitalization. One commenter provided a case example. Some commenters predict that providers will decline to administer medications not directly related to kidney failure, such as antibiotics for infected foot ulcers, or will use less proven oral regimens to complete treatment.

Response: We acknowledge that antibiotics may be administered in an ESRD facility for purposes other than dialysis or ESRD-related conditions as well as for treatment of vascular access infections. Included in the top 11 drugs and biological are vancomycin and daptomycin. We believe that there are other antibiotics that may be administered for vascular access related infections and peritonitis. Therefore, we included all antibiotics, with the exception of antivirals, that were on the 2007 ESRD claims, into the ESRD bundled base rate. ESRD facilities will be able to identify on the ESRD claims any antibiotic administered for non-ESRD related reasons, and receive payment for those non-ESRD related antibiotics. We note, if an anti-infective (including anti-bacterials and anti-fungals) are administered for the purpose of a vascular access infection or peritonitis, the drug would be considered a renal dialysis service and not eligible for separate payment. This also applies to any drugs or biologicals that may be developed in the future.

Comment: In general, commenters supported the agency's reading of the

statute with regard to oral drugs with injectable equivalents (or some other form of administration). In particular, several commenters fully supported inclusion of oral drugs that are equivalent, full replacement products for injectable Part B drugs in the ESRD PPS.

Response: We appreciate these comments and agree that such oral drugs are required to be included in the ESRD PPS because such drugs meet the definition of "renal dialysis services" under section 1881(b)(14)(B) of the Act.

Comment: One commenter suggested that the bundle include oral drugs with intravenous equivalents, phosphate binders, and calcimimetics essential for bone health and mineral metabolism. A few commenters provided a list of drugs and cost amounts. One commenter believed bundling of intravenous drugs is straightforward with bundling of oral equivalents being less logical. Some commenters believed that oral drugs such as cinacalcet HCL, lanthanum carbonate, calcium acetate, sevelamar HCL, and sevelemar carbonate commonly taken by patients on dialysis and non-dialysis days, should not be in the bundle. One commenter acknowledged that zemplar and other vitamin D products belong in the bundle as they are oral equivalents of intravenous vitamin D. Another commenter believed that vitamin D and oral iron were the only currently available oral drugs with intravenous equivalents and therefore the only oral drugs in the bundle. One commenter stated that oral drugs with injectable equivalents are primarily prescribed for peritoneal dialysis and home hemodialysis patients. Other commenters supported the need to revisit the issue and ensure that the only drugs in the bundle are those that are separately billable by dialysis facilities and have an intravenous equivalent.

Response: As explained in section II.A.3. of this final rule, oral-only ESRD-related drugs and biologicals currently paid under Part D meet the definition of a renal dialysis service, but implementation of these drugs under the ESRD PPS is delayed until January 1, 2014. We do not agree with the comment that bundling of oral equivalents is less logical than bundling injectable drugs. As we have discussed above, section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD, and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle.

Based upon our determination of the categories of drugs and biologicals that are renal dialysis services, at this time there are oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. As discussed earlier in this section, we did not include the non-injectable form of vancomycin because we believe that the oral or other forms of these anti-infectives are not used for ESRD-related access infections. In addition, we were not able to identify any oral or other form of administration for iron prescriptions. Therefore, payments related to the oral or other forms of these injectable drugs were not included in the ESRD PPS base rate. As a result, for purposes of calculating the ESRD PPS base rate, we included the payments under Part D for oral vitamin D (calcitrol, doxercalcitrol and paracalcitrol) and oral levocarnitine. To the extent an ESRD facility furnishes an injectable, oral or other form of a drug or biological that is ESRD-related, the facility should report the drug or biological on the ESRD claim without a modifier and no separate payment would be made.

Therefore, we are finalizing the definition of renal dialysis services under § 413.171 as proposed.

4. Diagnostic Laboratory Tests and Other Items and Services

Section 1881(b)(14)(B)(iv) of the Act requires that diagnostic laboratory tests not included under the composite payment rate (that is, currently separately billable laboratory tests) must be included as part of the ESRD PPS payment bundle. We proposed to define such laboratory tests as laboratory tests that are separately billed by ESRD facilities as of December 31, 2010, and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that are separately billed by independent laboratories (74 FR 49929). We proposed that payments for these laboratory services would be included in the development of the proposed patient-specific case-mix adjusters and in the proposed ESRD base rate to which the adjusters would be applied.

Section 1881(b)(14)(B)(iv) of the Act also requires that the ESRD PPS payment bundle include "other items and services not described in clause (i)." In the proposed rule, we noted that this language can be reasonably interpreted to include other separately billable items and services used in the treatment of ESRD, such as supplies and other self-dialysis services (74 FR 49929). We noted that examples of such items and services would include, but would not be limited to, items such as syringes, specialized tubing, as well as blood and blood products, which facilities may furnish during the dialysis treatment. We also stated that we believe that the statutory language can be interpreted to include the cost of other self-dialysis training services in the ESRD PPS (for further detail on self-dialysis training (74 FR 49930)). We proposed that such items and services be included in the ESRD PPS bundle and that the inclusion of diagnostic laboratory tests and other items and services as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed § 413.171.

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

Comment: We received many comments addressing our methodology for the inclusion of diagnostic laboratory tests in the ESRD PPS payment bundle. Commenters noted that the inclusion of such tests in the bundled ESRD PPS will subject Medicare beneficiaries for the first time to a 20 percent coinsurance payment obligation. The commenters reasoned that our proposal that Medicare pay for 80 percent of diagnostic laboratory tests through their inclusion in the payment bundle violates the statutory requirement that the Secretary ensure that the estimated amount of total payments under title XVIII for renal dialysis services in 2011 equal 98 percent of the amount of payments that would have been made, but for the PPS. Some commenters stated that section 1833(a)(2)(D)(ii) of the Act specifies that for clinical laboratory tests paid under Medicare Part B on the basis of negotiated rates, the payment amount must equal 100 percent of the negotiated rate (incidentally, we note that a few commenters cited to section 1883(a)(2)(D)(ii) of the Act, but we presume those commenters intended to instead reference section 1833(a)(2)(D)(ii) of the Act). Accordingly, the commenters requested that we revise the payment amount for laboratory tests included in the bundle to reflect 100 percent of the allowable amount.

Response: Cost sharing with respect to laboratory services is addressed in section 1833(a)(2)(D) of the Act. We note that nothing changes in terms of the cost-sharing structure for non-ESRD-related laboratory tests. Under the definition of renal dialysis services under section 1881(b)(14)(B)(iv) of the Act, ESRD-related laboratory tests

would be considered to be renal dialysis services under the new ESRD PPS, subject to the usual coinsurance applied to such Part B services. A few commenters appeared to be under the impression that only 80 percent of payments for laboratory tests were included in the calculation of the base rate. This is incorrect. We included 100 percent of payments for laboratory services in the ESRD PPS base rate. As with all other renal dialysis services included in the payment bundle, these laboratory services will be part of the ESRD PPS payment rate and would be subject to the customary 20 percent Part B coinsurance amount.

Comment: Many commenters took issue with our proposal to include laboratory tests ordered by MCP physicians for treating ESRD beneficiaries, and that are billed separately by independent laboratories, and our proposal to include all these tests billed by independent laboratories for ESRD patients in the payment bundle. Numerous commenters pointed out that in many instances the MCP physician is the primary care physician for the ESRD patient and often has laboratory tests performed for conditions unrelated to ESRD. The commenters asserted that requiring ESRD facilities to pay for such tests would result in a potentially vast number of tests unrelated to the treatment of ESRD being inappropriately included in the ESRD payment bundle.

Response: Section 1881(b)(14)(B)(iv) of the Act specifies that the ESRD PPS must include "diagnostic laboratory tests * * * that are furnished to individuals for the treatment of end-stage renal disease." We interpreted this language to include laboratory tests ordered by MCP physicians for treating ESRD beneficiaries and that are currently billed separately by independent laboratories. We recognize that there is a small subset of laboratory tests that are typically performed in connection with a patient's ESRD, and that are appropriately considered renal dialysis services because they are furnished for the treatment of ESRD, but that can also be done for non-ESRD reasons. For example, a complete blood count (CBC) could be ordered for an ESRD patient in connection with routine testing for hemoglobin or hematocrit to ensure appropriate management of anemia, an ESRD-related purposes. However, a CBC could also be ordered for an ESRD beneficiary to measure the amount of blood loss in response to a suspected lower gastrointestinal bleed, or to measure infection (for example, white blood cell count for a suspected pneumonia), non-ESRD purposes.

The 2007 ESRD facility claims do not distinguish between ESRD-related and non-ESRD-related laboratory services. We included payments for all tests billed by independent laboratories for ESRD patients in calculating the final base rate in order to appropriately account for such tests as renal dialysis services. We presumed that MCP physicians, for the most part, order laboratory tests for ESRD beneficiaries for ESRD-related purposes. However, as we recognize that certain non-ESRD laboratory tests may be ordered in conjunction with ESRD-related laboratory tests, we have developed billing modifiers to provide for separate payment where the testing is not ESRD-related (section II.K.2. of this final rule).

Comment: Several commenters recommended that we include in the ESRD PPS payment bundle, only those laboratory tests that are generally furnished for the treatment of ESRD, and included lists of approximately 50 tests which they believe account for about 95 percent of the laboratory tests ordered by ESRD facilities for ESRD patients. The commenters pointed out that such specificity would leave no doubt as to whether a particular laboratory test would be included or excluded from the payment bundle, would not create billing rules other than the list of 50 to 60 current procedural technology (CPT) codes that would not be separately billable, and would not result in the attachment of testing frequencies to the included tests. The commenters also stated that there is precedent for their recommendation, pointing out that CMS excluded ESRD-related clinical laboratory tests from the skilled nursing facility consolidated payment, and published a list of those ESRD-related tests, which closely resemble the tests which the commenters submitted for consideration as ESRD-related for inclusion in the ESRD PPS. Other commenters submitted their recommended list of ESRD-related laboratory tests.

Response: We agree with the commenters that limiting the laboratory tests for payment under the ESRD PPS payment bundle to specific tests that are customarily performed in connection with the treatment of ESRD comports with section 1881(b)(14)(B)(iv) of the Act and would be a straight forward method of capturing only ESRD-related laboratory testing. In addition, we needed to develop a list of ESRD-related laboratory tests for consolidating billing edits to ensure that payment is not made to independent laboratories for ESRD-related laboratory tests. However, based on a review of the lists of ESRD-related laboratory tests in the Medicare Claims Processing Manual and received in public comments, it appears there is currently not consensus among the various stakeholders about the laboratory testing commonly furnished to ESRD patients.

Therefore, in order to develop a list of ESRD-related laboratory tests, we identified those laboratory tests that were most frequently identified on the lists we reviewed. Then, we received input from physicians working with UM–KECC. Lastly, CMS physicians and other clinical staff finalized the list which is contained in Table F of the Appendix. As discussed in more detail in section II.K.2. of this final rule, we will be implementing consolidated billing edits to prevent payment to independent laboratories for tests on the list of ESRD-related laboratory tests unless a modifier is reported indicating the test is not ESRD-related.

ESRD facilities should report on their claims all laboratory tests ordered by the MCP physician. We will establish a modifier so that ESRD facilities may continue to be paid separately for non-ESRD-related laboratory tests. We plan to review the ESRD-related laboratory tests reported by ESRD facilities to ensure that the laboratory list continues to reflect common ESRD-related laboratory testing.

Comment: Commenters noted that we proposed to include in the ESRD PPS blood and blood products to the extent these items were furnished by ESRD facilities and reported on the type ESRD claims. One commenter pointed out that patients are transfused infrequently in ESRD facilities, and that most transfusions occur in hospital outpatient settings. The commenter stated that if ESRD facilities are to be held responsible for blood transfusions administered to dialysis patients, then the costs from other outpatient settings need to be captured and added to the payments developed from dialysis facility claims to compute the ESRD PPS base rate.

Another commenter opposed the inclusion of blood and blood products in the payment bundle. This commenter stated that blood transfusions for outpatient dialysis patients do not represent the current first line standard-of-care intervention for the treatment of ESRD, having largely been replaced by anemia management drugs. Because their administration in dialysis facilities is relatively infrequent, the commenter requested that to the extent dialysis facilities furnish blood or blood products ordered by an MCP physician, these costs should be excluded from the

ESRD PPS payment bundle and remain separately billable.

Response: We agree with the commenter that the furnishing of blood and blood products by ESRD facilities to ESRD beneficiaries is a relatively infrequent and unusual occurrence, and we believe that it does not represent standard clinical practice for the management of anemia in connection with the treatment of ESRD. ESRD facilities may also furnish blood and blood products for non-ESRD reasons ordered by an MCP physician for the convenience of the patient undergoing dialysis. We also agree that the administration of blood and blood products is usually performed in a hospital outpatient setting, generally for non-ESRD reasons.

For these reasons, we do not consider the furnishing of blood and blood products to be renal dialysis services under the statute and, therefore, these services would be excluded from the ESRD PPS payment bundle. The furnishing of blood, blood products, and blood supplies in connection with transfusions will remain separately billable when they are administered in an ESRD facility. The total payments for blood and blood products to ESRD facilities as reported on available ESRD claims in CY 2007 was $1,504,831. We have excluded this amount from the computation of the final ESRD PPS base rate, consistent with our determination that blood and blood products are not renal dialysis services.

We note that the incentives under the ESRD PPS may lead to under treatment of anemia, a critical clinical indicator for ESRD patients, necessitating blood transfusions for patients whose hemoglobin levels drop too low. We plan to monitor the extent to which dialysis patients receive transfusions after implementation of the ESRD PPS. If practice patterns change such that the administration of transfusions and furnishing of blood and blood products substantially increase, we may subsequently reexamine whether these services should be considered renal dialysis services used for the treatment of ESRD and included in the ESRD PPS payment bundle.

With respect to the laboratory tests included in developing the ESRD PPS base rate, we are finalizing our proposal to include payments for outpatient laboratory tests billed on ESRD facility claims, as well as payments for laboratory tests ordered by physicians receiving MCP amounts and billed on carrier claims. We used the list of CY 2007 MCP physicians for this purpose. The ESRD related laboratory tests that will be subject to the ESRD PPS are identified in Appendix Table F of this final rule.

5. Physicians' Services

Section 1881(b)(14)(A)(i), as added by MIPPA, states as follows in pertinent part:

> * * * the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment * * * and for such services and items furnished pursuant to [section 1881(b)(4)].

As we indicated in the proposed rule, we believe this provision generally governs payment to ESRD facilities (74 FR 49931). With regard to physicians' services related to renal dialysis, such services are addressed separately in section 1881(b)(3) of the Act. In the ESRD PPS proposed rule, we indicated that we did not intend to significantly modify payment for physicians' services, and stated that any changes with regard to the payment for physicians' services related to renal dialysis would be addressed in future rulemaking (74 FR 49931).

Comment: Numerous commenters supported our decision in the proposed rule to exclude physician services from the ESRD PPS payment bundle. We received no comments endorsing the inclusion of these services in the bundle.

Response: We appreciate the views of the commenters. As we indicated in the proposed rule, we are limiting the scope of this rulemaking to payment for home dialysis and renal dialysis services furnished by ESRD facilities. Therefore, we do not, at this time, intend to modify payment for physicians' services. Any changes in payment for physicians' services related to renal dialysis would be addressed in future rulemaking.

6. Other Services

The comments and our responses are set forth below.

Comment: One commenter requested that we clarify that services that may be furnished to beneficiaries at the time of a dialysis session, but not furnished specifically for the treatment of ESRD, would be excluded from the proposed ESRD bundled payment system. The commenter cited apheresis treatment as an example. Because apheresis, like dialysis, filters a patient's blood, the commenter was concerned that this treatment regimen may be incorrectly viewed as a treatment for ESRD. The commenter further explained that although both dialysis and apheresis filter the patient's blood, the procedures accomplish different objectives. The commenter stated that in dialysis the purpose is to clear wastes from the blood, restore electrolyte balance, and eliminate excess bodily fluid, whereas the purpose of apheresis is to remove from the blood certain blood components such as abnormal proteins implicated in a disease.

The commenter recommended that Medicare policy take no steps that would financially incentivize fracturing dialysis and apheresis into separate patient visits, but encouraged service alignments.

Response: As described in greater detail in section II.A. of this final rule, items and services included within the ESRD PPS are home dialysis and those items and services that meet the definition of "renal dialysis services" and are furnished to individuals for the treatment of ESRD. Moreover, such services are considered essential for the delivery of outpatient maintenance dialysis. Therefore, the fact that an unrelated, non-ESRD item or service is furnished at the time of a maintenance dialysis treatment would not mean that the particular item or service would be bundled into the ESRD PPS.

Because at this time, we do not consider apheresis to be a renal dialyisis service that is furnished to individuals for the treatment of ESRD, or to be essential for the delivery of maintenance dialysis, we have not included apheresis services in the ESRD PPS. As a result, we would expect that the delivery of apheresis in the ESRD facility setting would occur infrequently. However, we note that to the extent that the coverage provisions for apheresis are met, as set forth in the National Coverage Determination (NCD) Manual, apheresis services may be payable outside the scope of ESRD facility payment, and in accordance with hospital or nonhospital setting payment policies (for example, hospital inpatient prospective payment system (IPPS), outpatient prospective payment system (OPPS), or the physicians' fee schedule).

Medicare coverage provisions for apheresis procedures for certain indications are set forth in the CMS Internet Only Manual (Pub. L. 100–03; Chapter 1, Part 2, section 110.14), available online at: *http://www.cms.hhs.gov/Manuals/IOM/list.asp?listpage=1*. Please note that indications not specifically addressed in section 110.14 of the NCD Manual are left to local contractor discretion.

Comment: One commenter pointed out that occasionally a hospital or ambulatory surgical center (ASC) may furnish services to an ESRD patient. The commenter expressed concern that the

"other items and services" language in section 1881(b)(14)(B)(iv) of the Act could be interpreted as including such services in the ESRD PPS payment bundle. The commenter requested that CMS clarify that the definition of "renal dialysis services" excludes inpatient services, emergency hospital services (including dialysis furnished to ESRD patients), and hospital or ASC services relating to the creation or maintenance of a patient's vascular access.

Response: None of the services which the commenter described were included in developing the ESRD PPS base rate, and none of them are considered renal dialysis services for inclusion in the PPS payment bundle. Moreover, these services are reimbursed under other Medicare payment systems. Hospital inpatient services, emergency services (including emergency dialysis) furnished to ESRD patients, and certain outpatient procedures necessary to maintain vascular access (that is, those which cannot be addressed by the ESRD facilities using procedures that are considered part of routine vascular access), are excluded from the definition of renal dialysis services and are not included in the ESRD PPS payment bundle. We note that currently ESRD facilities utilize medications to maintain vascular access. We would consider the administration of medications that are currently performed by ESRD facilities to fall within the definition of renal dialysis services and paid for under the ESRD PPS.

Comment: Several commenters requested confirmation that nutritional supplements such as intradialytic parenteral nutrition (IDPN) and intraperitoneal parenteral nutrition (IPN) are not included in the ESRD PPS payment bundle.

Response: We do not consider nutritional therapies, even though (as in the case of IDPN) they are often administered during a patient's dialysis treatment, to be related to the treatment of ESRD. Nutritional supplements have never been considered part of the ESRD benefit, because they have not been considered integral to the furnishing of outpatient maintenance dialysis, and are not included in the ESRD PPS as Part B renal dialysis services.

Comment: One commenter stated that when adding up the numbers in Table 8 of the proposed rule (74 FR 49940), the total expenditures for composite rate and separately billable services included in payment bundle was $9,876,466,063, more than $636 million higher than the total shown of $9,239,987,362. The commenter inquired as to the reason for the discrepancy.

Response: There is no discrepancy. The totals shown in Table 8 of the proposed rule for vitamin D ($402,447,416) and injectable iron ($234,031,283) are each subdivided to show the payment amounts for each of the drugs which comprise these categories. The commenter has inadvertently added the component amounts for each of these payment categories along with the totals for the two categories, resulting in an overstatement of ESRD expenditures of $636,478,699.

7. Home Dialysis Patients (Method I and II) and Self Dialysis Training

Section 1881(b)(4) of the Act authorizes the Secretary to make payment to providers of services and renal dialysis facilities, and to suppliers of home dialysis supplies and equipment, for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients for self-care home dialysis under the supervision of such provider or facility. Currently, hemodialysis, continuous cycling peritoneal dialysis (CCPD), intermittent peritoneal dialysis (IPD) and continuous ambulatory peritoneal dialysis (CAPD) treatment modalities may be performed at home by appropriately trained patients. Medicare beneficiaries dialyzing at home must complete a Medicare Beneficiary Form (CMS–382) selecting between two methods of payment (Method I or Method II) as described in detail in the ESRD PPS proposed rule (74 FR 49929).

a. Payment for Home Dialysis (Method I and Method II)

As a result of the enactment of section 153(b) of MIPPA, we proposed that payment for home dialysis services (excluding physician services) furnished to both Method I and Method II home dialysis patients under the current basic case-mix adjusted composite payment system would be included in the bundled payment to the ESRD facility under the ESRD PPS (74 FR 49929 through 49930). We also proposed that the costs of home dialysis training be included in the composite rate portion of the two-equation regression model for determining payment adjustments under the ESRD PPS (74 FR 49930 through 49931).

Below we address the general comments we received on home dialysis, but in subsequent subsections we address more specific comments on the proposals on Method I and Method II and self-dialysis training.

Comment: A commenter noted that section 1881(b)(14)(D)(iv) of the Act gives the Secretary the discretionary authority to include payment adjustments to the ESRD PPS as the Secretary determines appropriate. The commenter requested that CMS provide a separate adjustment that would account for the unique cost associated with providing home dialysis that would include: (1) Training for home dialysis; (2) support services; and (3) emergency home dialysis supplies, so that dialysis facilities do not neglect their responsibility to the care of ESRD home dialysis patients for financial reasons. The commenter stated that in the proposed rule, the training reimbursement for home dialysis services was fashioned to apply to all patients regardless of whether training services were actually provided to them. The commenter stated that the current system fosters a financial disincentive for home dialysis by encouraging providers to minimize the number of home dialysis patients they accept. To eliminate this financial disincentive, the commenter recommended that CMS remove home dialysis costs from the bundled rate and include this reimbursement in a separate adjustment.

Response: Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made under this title to an ESRD facility for renal dialysis services for such services and items furnished pursuant to section 1881(b)(4) of the Act. Therefore, we are required to include payment for home dialysis training, equipment and supplies, and support services in computing the single bundled payment base rate.

As we explained in the ESRD PPS proposed rule (74 FR 59930), when ESRD facilities furnish home dialysis training, Medicare pays the ESRD facility its case-mix adjusted composite rate plus a training add-on of $12 for peritoneal dialysis and $20 for hemodialysis and CCPD to account for the staff time, supplies, and equipment associated with training treatments. We believe the ESRD PPS base rate adequately accounts for the costs associated with equipment and supplies. However, we agree with the commenter, that the base rate does not capture the unique staffing costs associated with home dialysis training. Section 494.100(a) of the ESRD Conditions for Coverage requires that training be conducted by a registered nurse. Thus, as training involves one-on-one training sessions with a nurse, we believe a separate adjustment to reflect those costs are warranted.

We discuss the training payment adjustment we are finalizing in

subsection (b) of this section of the final rule.

Comment: A commenter suggested that CMS evaluate the cost of care for nursing home hemodialysis patients and create an adjustment for these patients under the ESRD PPS. The commenter stated that nursing home hemodialysis patients incur unique costs that pertain to one-machine per patient, administrative burdens, co-morbidities, higher turn-over rates, and require nursing caregiver assistance for dialysis administration. The commenter asserted that despite certain co-morbidities not being included in the ESRD PPS for case-mix adjustments, a nursing caregiver staff assistant is still required for dialysis administration. The commenter further stated that CMS failed to explain how the inclusion of home dialysis costs in the ESRD PPS bundled payment system creates an incentive to provide home dialysis in cases where the costs to treat patients is greater than the reimbursement CMS proposed. The commenter suggested that a special adjustment be afforded to cover these unique costs.

Response: Nursing home patients are regarded as home dialysis patients because they are considered residents of the nursing home and receive dialysis treatments at the nursing homes and not at dialysis facilities. We disagree with this commenter's assertions because the unique costs they described are no different from any other home dialysis patient where there is one-machine per patient, co-morbidities, and patient turn-over occurs due to kidney transplantation. We, therefore, do not believe that a separate adjustment for nursing home ESRD patients is warranted.

The other unique costs identified by this commenter pertained to nursing-related caregiver services. The commenter stated that all nursing home dialysis patients must have a trained caregiver in order to dialyze at a nursing home and that these caregiver services are not covered under the ESRD benefit. The commenter is correct that caregiver services are not covered under the ESRD benefit, including caregiver services furnished to nursing home dialysis patients. Thus, caregiver services are not considered to be renal dialysis services and are not reflected in the ESRD PPS base rate nor in the payment adjustments.

Comment: Some commenters suggested that CMS allow for self-administration of injectable ESRD-related drugs at home by home dialysis patients. The commenters indicated that home dialysis patients would prefer to self-administer all injectable ESRD-related drugs at home to include EPO, rather than traveling to the dialysis facility to receive the injectable drugs. The commenters reasoned that since injectable drugs such as EPO, Vitamin D, and IV iron are included in the ESRD PPS bundle, patients should have the option to self-administer these drugs at home.

Response: Under section 1861(s)(2)(O) of the Act, self-administration of erythropoietin (EPO) is permitted for dialysis patients who are competent to use such drug without medical or other supervision with regard to the administration of such drug. If a dialysis patient meets this requirement, then he or she can self-administer erythropoietin at home. Payment for erythropoietin and supplies needed to self-administer the drug would be included in the ESRD PPS payment.

The ESRD PPS does not fundamentally alter how other injectable drugs are administered under Part B. Thus, under the ESRD PPS, home dialysis patients would continue to go to the dialysis facility for the administration of other injectable drugs.

Comment: Some commenters expressed concern that CMS did not fully account for supplies in estimating the cost of home dialysis programs. They indicated that there is a one-time cost associated with certain supplies and equipment (scales, thermometer, blood pressure equipment, etc.) and continuing costs for daily treatment including disposable supplies for peritoneal dialysis (dialysate, syringes, needles, masks, latex gloves, etc.).

The commenters were also concerned that since supplies are delivered monthly, the facility pays up front for those supplies. Commenters claimed that should a patient discontinue treatment, change modalities, or for other reasons stop using the delivered supplies, the dialysis facility cannot move supplies from one patient to another because of infection control issues. Commenters stated that the cost of these supplies is borne by the facility. The commenter stated that these cost are not recognized in the proposed ESRD PPS, and facilities will no longer be able to bill separately for supplies without a treatment.

Response: In accordance with § 410.52 and § 414.330, Medicare Part B pays for all medically necessary home equipment and supplies for the effective performance of a patient's dialysis in the ESRD patients home. Medicare currently pays for home dialysis equipment and supplies under the basic case-mix adjusted composite rate (Method I) and for claims submitted by the DME supplier of home dialysis equipment and supplies (Method II). We proposed that the costs of home dialysis services furnished under Method I and Method II, regardless of home treatment modality, would be included in the proposed ESRD PPS (74 FR 49929).

As explained in great detail in the data section of the proposed rule (74 FR 49934 through 49935), we obtained cost information from 4,573 CY 2006 cost reports, for both hospital-based and independent ESRD facilities. Cost data obtained from these cost reports included all costs necessary to furnish home dialysis treatments including staff, equipment and supplies. Even though a dialysis facility could incur some up-front costs for supplies for home dialysis patients, these costs are reported as supply costs on the provider's cost report and were included in the composite rate part of the model. Therefore, by including home dialysis costs in the composite rate portion of the two-equation ESRD PPS model (described in section II.D. of this final rule), we believe we have appropriately accounted for the cost of home dialysis services and supplies.

Comment: A number of commenters indicated that CMS should actively monitor home dialysis utilization after the ESRD PPS is implemented via a formal plan consistent with the GAO's recommendation, which CMS has publically supported.

Another commenter recommended that CMS monitor the effect of the new payment system on use of training services and home dialysis. Also, commenters suggested that more specific coding would facilitate such an effort by enabling CMS and researchers to better analyze trends in the use of these services. For example, commenters indicated that specific codes on facility claims could identify particular types of training services, home dialysis services, and in-facility dialysis services. Commenters also believe that a strengthened monitoring plan should help CMS assess the use of dialysis services, identify lapses in care, give providers an incentive to furnish all clinically necessary care, and lead to quality improvement.

Response: We agree with the commenters that increased monitoring will be needed to monitor the effects of the new ESRD PPS. We concurred with the GAO's recommendation in its May 2009 report and we intend to assess the effect of the expanded bundled payment on home dialysis utilization rates. We also agreed with GAO on the need to establish a monitoring plan under the new bundled ESRD PPS that includes an examination of home dialysis utilization. We expect to establish such

a plan after we promulgate this final ESRD PPS. With regard to establishing more specific code for home dialysis equipment, supplies, and services, we will take these comments into consideration as we make changes to the cost report to reflect the ESRD PPS. Changes in coding will be established through administrative issuances.

i. Method I—The Composite Rate

In accordance with § 414.330(a), under the basic case-mix adjusted composite payment system, the ESRD facility receives the same Medicare payment rate for a home dialysis treatment as it would receive for an in-facility treatment. Under Method I, the ESRD facility bills the fiscal intermediary Medicare administration contractor (FI/MAC) for needed supplies, equipment, and drugs, and the beneficiary is responsible for paying the Medicare Part B deductible and the 20 percent coinsurance on the total Medicare payment made to the facility. Although we proposed that the costs for home dialysis services furnished under Method I would be included in the single payment rate under the proposed ESRD PPS, we did not propose any changes to Method I as this approach could continue to be used under the ESRD PPS (74 FR 49930).

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

Comment: Several commenters expressed support for continuing to provide the same payment for home dialysis and in-facility treatments, which commenters believe will support CMS's goal of increasing the number of patients that elect the various home dialysis therapies. The commenters applauded CMS's move to a bundled payment system and our interest in encouraging patient access to home dialysis services.

Response: We appreciate the commenters' support of our move to a bundled payment system that we believe will encourage patient access to home dialysis and recognize the importance of various home dialysis therapies.

Comment: Commenters from individual home dialysis patients thanked CMS for including all home dialysis options in the ESRD PPS and recognizing the importance of home dialysis. Many of the patients stated that they have access to more frequent dialysis that decrease hospitalizations and medications and increase their quality of life, which allows them to work or go to school and contribute to society.

Another commenter generally pointed out that there are no transportation costs incurred for home hemodialysis patients. Commenters stated that decreased hospitalizations are typical of home dialysis patients, which further reduced the costs within the system. Additionally, commenters pointed out that early discharge from acute and sub-acute care facilities to either the patient's home or a nursing home has allowed patients to receive care in less expensive and more appropriate settings.

Response: We appreciate the comments from individual home dialysis patients who support our recognition of the importance of home dialysis which we believe results in a better quality of life for the patient.

We did not receive any public comments objecting to our proposal for payment under the ESRD PPS of home dialysis services furnished under Method I payment. As we described above, numerous commenters supported payment under the bundle for Method I home dialysis patients stating it would increase beneficiary access to home dialysis services, which would increase their quality of life. Therefore, consistent with section 1881(b)(14)(A)(i) of the Act, we are finalizing our proposal to bundle home dialysis furnished under Method I and pay the bundled ESRD PPS rate for such home dialysis services, as set forth in § 413.210, § 413.217, and § 414.330, respectively.

ii. Method II—Dealing Directly With Suppliers

Currently, in accordance with regulations at § 414.330(a)(2), a Medicare ESRD beneficiary can elect to obtain home dialysis equipment and supplies from a supplier, that is not a Medicare approved dialysis facility (Method II). If a beneficiary elects Method II, the beneficiary deals directly with a single Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier to secure the necessary supplies and equipment to dialyze at home. The selected DMEPOS supplier must accept assignment and bills the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The beneficiary is financially responsible to the supplier for any unmet Medicare Part B deductible and for the 20 percent Medicare Part B coinsurance requirement. Currently, the amount of Medicare payment under Method II for home dialysis equipment and supplies may not exceed $1,974.25 per month for CCPD and $1,490.85 per month for all other modalities of home dialysis (*see* 57 FR 54186, published on November 17, 1992).

For each beneficiary it serves, the supplier is required to maintain a written agreement with an approved ESRD facility to provide backup and support services. An ESRD facility that has a written agreement to supply backup and support services bills the FI/MAC for services provided under the agreement. Under Method II, an ESRD facility may be paid up to $121.15 per month for home dialysis support services, such as arranging for the provision of all ESRD-related laboratory tests and billing for the laboratory tests that are included in the composite payment rate (*see* 57 FR 54186, published on November 17, 1992). An ESRD facility may not be paid for home dialysis equipment or supplies under Method II.

As we indicated previously, section 1881(b)(14)(A)(i) of the Act requires that a single payment for renal dialysis services and items and services under section 1881(b)(4) be made to an ESRD facility. As a result, we proposed: (1) That payment for all home dialysis services excluding physicians' services would be included in the bundled payment to the ESRD facility; (2) that all payments made for home dialysis services furnished under Method I and Method II, regardless of home treatment modality, would be included in computing the proposed ESRD PPS base rate; and (3) that the Method II home dialysis approach in its present form would no longer exist when the ESRD PPS is implemented January 1, 2011. We proposed to revise § 414.330 to reflect that the ESRD PPS payment as established in section 1881(b)(14) of the Act will be the basis of payment for home dialysis supplies, equipment, and home support services and that payment limits applicable for such services would no longer apply (74 FR 49930). We noted that effective January 1, 2011, a supplier could only furnish, home dialysis equipment and supplies to a Medicare home dialysis beneficiary under an arrangement with the ESRD facility, and that the supplier would need to look to the ESRD facility for payment.

We received several comments from various ESRD organizations and individuals who rely on the Method II home dialysis payment approach who oppose our proposed elimination of Method II. These and other comments we received on our proposals, including our responses, are set forth below.

Comment: One commenter stated that working with Method II supply companies is vital to their home dialysis program because the supply companies

take on the costs and responsibility of furnishing home dialysis supplies and equipment.

Response: Under the ESRD PPS, the supplier could still furnish, under arrangement with the dialysis facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary. However, effective January 1, 2011, the supplier would be required to look to the ESRD facility for payment since the ESRD PPS payment would be made to the facility. As such, under the ESRD PPS, DME MACs would no longer make payment to suppliers of home dialysis equipment and supplies. All payments previously paid to DME MACs for home dialysis supplies and equipment has been built into the ESRD PPS base rate so that ESRD facilities can pay for the supply and equipment costs for their home dialysis patients.

Comment: A commenter stated that the elimination of Method II is a complete contradiction of the CMS goals for promoting better outcomes and increased utilization of more cost effective home dialysis treatment modalities.

Response: We do not agree that the elimination of Method II will undermine our goals for increased use of home modalities and better outcomes. We will continue to support home dialysis as indicated in our decision to pay the same under the ESRD PPS for home and in-center treatments even though home dialysis is less costly for ESRD facilities and our decisions regarding payment for home dialysis training discussed later in this section.

Comment: Some commenters stated that the loss of the Method II payment system will result in higher administrative costs and logistical burdens that will greatly increase the cost of providing treatment to home dialysis patients and create a disincentive for ESRD facilities to provide home modalities.

Response: We do not believe that the elimination of Method II will result in significant increased burdens to ESRD facilities such that it would create disincentives for ESRD facilities to provide home treatment modalities. Most ESRD facilities currently have arrangements with DME suppliers to furnish dialysis equipment and supplies for their in-facility dialysis patients and home dialysis patients. Under the ESRD PPS, in order to minimize the impact on patients of the requirement that DME suppliers now must look to the ESRD facility for payment, home patients could continue with these same arrangements. We believe that ESRD facilities will have a financial incentive to provide home treatment modalities since we will pay the same base rate for less expensive home modalities than we pay for in-facility treatments.

Comment: Commenters from pediatric facilities that use Method II suppliers expressed concern that the specialty products they use are not available through the major manufacturers of dialysis products and that pediatric products are more expensive to purchase due to the limited demand and negotiating power of pediatric facilities.

Response: We do not believe that the elimination of Method II option under the ESRD PPS will have a negative effect on pediatric dialysis facilities. The pediatric facilities have indicated that their home dialysis patients are mostly peritoneal dialysis (PD) patients. As discussed in the proposed rule, we described a comparison of composite rate costs by modality for CYs 2004 through 2006 which showed that PD is a substantially less costly mode of dialysis compared to in-facility hemodialysis (74 FR 49967 through 49968). Data from the Medicare cost report and Medicare claims data showed a significant difference in resource utilization, with PD patients incurring significantly lower composite rate and separately billable expenses. Since payment under the ESRD PPS for home dialysis patients will be based on Method I, we believe that paying the same amount for all types of dialysis modalities will not disadvantage pediatric facilities. We believe that pediatric facilities will still be able to make arrangements with their current DME suppliers to furnish the special supplies and equipment that are needed for small children and infants. The only difference is that the DME supplier must look to the pediatric ESRD facility for payment. Also, we note that pediatric facilities could form a group purchasing arrangement to enhance their negotiating power when purchasing supplies and equipment for their home patients.

Comment: Commenters claim that the elimination of Method II under the ESRD PPS would require children's hospitals to become a "flow-through" for supplies and equipment that previously would have been obtained by patients directly from Method II suppliers.

Response: We agree with this "flow-through" description made by the commenter because under the ESRD PPS, the payments for the equipment and for supplies will be made to the ESRD facility which then buys the equipment and supplies from a DME supplier.

Comment: Commenters from pediatric facilities requested that CMS perform further analysis to determine whether the elimination of Method II billing under the ESRD PPS will have a negative effect on pediatric dialysis facilities.

Response: Since publication of the proposed rule, we have continued to examine the ESRD data in order to refine the model. The cumulative effect of the changes we have made to the ESRD PPS is projected to beneficially impact pediatric facilities. *See* section IV. of this final rule for specific impacts.

Comment: Some commenters had concerns with the elimination of Method II and the resulting change in incentives for dialysis facilities. The commenters suggested that CMS needs to understand the adverse effects that eliminating Method II would have on the dialysis facilities' ability to furnish home treatment modalities.

Response: Effective January 1, 2011, Medicare will pay the ESRD PPS base rate to ESRD facilities for home dialysis services furnished to home dialysis patients under Method I . Under Method I, the incentives will be different because we will only pay the ESRD facility the ESRD PPS base rate which includes the costs of all dialysis services such as staff time, equipment, and supplies. Despite the elimination of Method II under the ESRD PPS on January 1, 2011, the Method I payment includes the following provisions were supported by many other commenters.

First, Medicare will continue to pay on a per treatment unit of payment. Second, Medicare will pay the same base rate for both in-facility and home dialysis. Third, the same base rate will also be paid for all dialysis treatment modalities furnished by a dialysis facility (hemodialysis and the various forms of peritoneal dialysis). Since home dialysis treatment modalities cost less than in-facility dialysis (especially home PD, which is the primary home dialysis treatment modality for pediatric home patients) ESRD facilities that have home dialysis programs should continue to benefit by providing home dialysis under ESRD PPS Method I payments.

We believe there are also some administrative benefits for dialysis facilities with the elimination of the Method II home dialysis. Dialysis facilities and home patients will have less burden because they will no longer need to complete or file the CMS Form-382 which is the form currently used to determine whether the dialysis patient has selected Method I or Method II home dialysis. Under the ESRD PPS, dialysis facilities will no longer be required to submit separate bills for home support services and suppliers no longer need to bill Medicare for home

dialysis equipment and supplies furnished to Method II home dialysis patients. The costs of home dialysis services for all home dialysis treatment modalities have been included in the composite rate part of the bundled ESRD PPS payment.

Comment: Commenters expressed concerns that the elimination of Method II payment system will affect the ability of ESRD facilities to establish and grow their home dialysis program. Commenters stated that using the Method II approach allows the dialysis facility to remove the supply and equipment costs associated with a home program from their total costs, making the utilization of home modalities more economically feasible and available to their patient population. Another commenter stated that CMS created financial disincentives for the provision of home hemodialysis because the cost of treating hemodialysis patients is generally higher than the cost of treating facility-based patients.

Response: We disagree with this commenter. We do not believe that financial disincentives have been created because, based on our cost report data, the cost for home hemodialysis is less costly than in-facility. As we noted in the proposed rule, the reliance on separately billable services as a source of revenue growth for ESRD facilities has potentially impeded the greater use of less costly PD (which typically uses fewer separately billable drugs and less provider and facility overhead expense) (74 FR 49931). We also noted that others have argued that constraining payment based on number of treatments may reduce the use of alternative treatment regimens such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis sessions (for example, 1.5 to 2 hours, five or six days per week).

We do not agree that a financial disincentive has been created for the provision of home hemodialysis. Under the ESRD PPS, payment for all home dialysis services (excluding physician services) would be included in the bundled payment to the ESRD facility and would not be subject to the current composite payment limits on what Medicare would pay for home dialysis supplies, equipment, and home support services as described in § 413.330(c). We disagree with the commenter that the elimination of the Method II payment system will affect the ability of ESRD facilities to establish and grow their home dialysis program, because the ESRD PPS takes into account the supplies and equipments costs associated with a home program. The intent is to continue to preserve the utilization of home modalities under Method I of the ESRD PPS, and to make home dialysis economically feasible and available to the ESRD patient population.

Comment: A commenter expressed concern that the elimination of Method II would deprive beneficiaries of access to specialty products, recent technologies, and cost effective home modalities.

Response: Although Method II would be eliminated under the ESRD PPS, we note that the suppliers would still be able to play a role under the new ESRD PPS. The supplier could still furnish, under arrangement with the support dialysis facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary under the ESRD PPS. However, the supplier would have to look to the ESRD facility for payment since the ESRD PPS payment would be made to the ESRD facility and DME MACs would no longer make payment for ESRD-related supplies to suppliers. As such, we disagree that because of the ESRD PPS, beneficiaries would be deprived of enjoying specialty products, recent technologies and cost effective home modalities. Dialysis facilities are encouraged to ensure that ESRD patients continue to receive all necessary supplies and equipment under the ESRD PPS. Additionally, under the ESRD PPS, lower cost patients offset the higher cost for patients who utilize specialty products and new technology.

Comment: A commenter stated that the current Method II payment system allowed a "level-playing field" in which small and medium-sized dialysis organizations have the financial flexibility to offer their patients home modality options. With the elimination of Method II under the ESRD PPS, the commenter claimed that he is now at a disadvantage because the risks are now borne by the facilities.

Response: We believe that the final base rate which is addressed in section II.E. of this final rule and the revised payment for home dialysis training add-on adjustment which is addressed later in this section, are sufficient. The goals of creating a bundled prospective payment system were to create a single comprehensive payment for all renal dialysis services. The elimination of Method II under the ESRD PPS serves to further this goal by eliminating separate payments to suppliers so that a single payment is made to ESRD facilities for all renal dialysis services. We disagree that the elimination of Method II creates a disadvantage as the commenter states as all payments for renal dialysis services, including those paid to Method II suppliers, have been included in the ESRD PPS base rate. It is our belief that such a payment system serves to allow a "level-playing field" in which all dialysis organizations regardless of size, have a single payment method.

Comment: A few commenters currently using Method II claimed that the ESRD PPS does not provide for the unique equipment and supply services costs for providing dialysis to home patients. The commenters claimed that supply companies install and maintain dialysis equipment and deliver both equipment and supplies to one patient at a time, and further noted that reimbursement is based upon a one machine per patient model. As a result, suppliers cannot achieve the economies of scale enjoyed by ESRD facilities.

Response: We note that having to install and maintain dialysis equipment and deliver both equipment and supplies to individual patients is not unique to Method II home dialysis patients. Currently all home dialysis patients, whether under Method I or Method II are impacted by "economies of scale" described by the commenter in a one patient-one machine application. Under the ESRD PPS, while home dialysis suppliers may not achieve the same economies of scale as dialysis facilities, suppliers remain able to provide equipment and supplies to multiple dialysis facilities and can negotiate competitive prices with the ESRD equipment and supply manufacturers. We note that all payments related to Method II suppliers and amounts paid by ESRD facilities to Method I suppliers have been included in the ESRD PPS base rate which we believe is sufficient to account for the equipment and supply costs of home dialysis patients.

Comment: Several commenters expressed concern that the ESRD PPS payment and elimination of Method II will make them less able to offer nursing caregiver staff-assisted dialysis to patients in nursing homes. The commenters indicated that Method II enables beneficiaries with secondary private insurance that includes nursing caregiver dialysis staff-assistance coverage, the opportunity to dialyze in their homes or in a nursing home and have the cost of a nurse caregiver dialysis assistant covered under their secondary insurance. Some of the commenters suggested that CMS create an adjustment or exception to the bundled payment rate for home hemodialysis patients receiving nursing caregiver staff-assisted care in their homes or in a nursing home setting.

Other commenters suggested that CMS offer an alternative that meets the equivalent of the current Method II mechanism that would serve to deny coverage of nursing home caregiver dialysis assistance or offer an additional Method I option at a reduced PPS rate. Because Medicare does not cover payment for nursing caregiver staff-assistance to dialysis patients, an Explanation of Benefits (EOB) denial is automatically generated by the FI/MAC. The EOB denial would allow suppliers to continue to bill for nurse caregiver staff-assistance to home hemodialysis patients paid by private insurers secondary to Medicare.

Response: Once the ESRD PPS takes effect January 1, 2011, DME suppliers will no longer be able to bill Medicare for ESRD equipment, supplies, and nurse caregiver staff-assistance. We will consider the commenter's suggestion to create a Medicare denial of these services as we develop billing instructions later this year.

Comment: One commenter urged that we retain Method II and indicated that the costs to Medicare are lower for nursing staff-assisted dialysis for home dialysis patients than in-facility dialysis patients. The commenter believed that Method II supply companies dedicated to dialysis supplies and services have saved the Medicare Program significant amounts of money because the DME supplier is paid 80 percent of the amount paid for supplies, which is less than $1,200 each month. The remainder is paid by the secondary insurance, as a secondary for the supplies and, in some cases, as a primary for the nursing services.

Response: Section 1881(b)(14)(A)(i) of the Act specifies that the Secretary must 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, and for such services and items furnished for home dialysis and self-care home dialysis support services. The Method II home dialysis option where the supplier of dialysis equipment and supplies bills the DME MAC is no longer authorized under the Act after January 1, 2011.

Comment: A few commenters encouraged CMS to clarify that only DME supplies and equipment related to the provision of renal dialysis services are included in the ESRD PPS payment. The commenters further stated that there are many DME supplies and equipment utilized by ESRD beneficiaries that are unrelated to their dialysis and should not be included in the ESRD PPS such as wheelchairs, diabetic testing supplies, oxygen, wound care, ostomy and urological supplies and equipment.

Response: We agree with the commenters and have clarified in section II.A.4. of this final rule that renal dialysis services include only DME supplies and equipment, necessary for the delivery of home dialysis services under the ESRD PPS. Although we did not provide a specific listing of the supplies and equipment, they were in fact considered and included. The Medicare Claims Processing Manual Chapter 8, Section 90.3.2, identifies the home dialysis supplies and equipment that are (currently) separately billable by DME suppliers.

Comment: Some commenters were concerned that under the ESRD PPS, the ESRD facility would become responsible for the billing of a variety of items and services that patients now receive directly from other suppliers. The commenter stated that the new ESRD PPS may create confusion for ESRD facilities, Method II suppliers, and patients. For example, DME suppliers submit their claims to DME MACs for reimbursement and the DME MACs are guided by their local coverage determinations and other aspects of DME billing and payment. The commenter questioned what would apply under the new ESRD PPS during the transition period.

Response: Under the current Method II home dialysis payment system, for each beneficiary it serves, the supplier is required to accept assignment by the beneficiary, and bill the DME MAC. Suppliers are also required to maintain a written agreement with a support dialysis facility to provide backup and support services. A dialysis facility, in turn, is required to maintain a written agreement to supply backup and support services and bill the FI/MAC for services it provides under the agreement.

As explained in the proposal (74 FR 49929), section 153(b) of MIPPA, section 1881 (b)(14)(A)(1) of the Act requires the Secretary to implement a payment system under which a single payment is made to an ESRD facility under this title for renal dialysis services and items furnished pursuant to section 1881 (b)(4) of the Act.

All costs associated with home dialysis services (both Method I and Method II) are included in the composite portion of the two equation model. Effective January 1, 2011, all home ESRD patients will be considered Method I home patients and all Medicare payments for home dialysis services will be made to the ESRD facility. Medicare payment for home dialysis services will be made to the ESRD facility whether the facility elects to participate in the transition period or elects to be paid under the ESRD PPS. DME suppliers will no longer submit claims to DME/MACs for home dialysis supplies and equipment effective January 1, 2011. Since FI/MACs will be processing ESRD facility claims for Method I home dialysis patients, the reasonable charge DME payment rules are no longer applicable. After January 1, 2011, a supplier could only furnish, under an arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary, and then the supplier would need to look to the ESRD facility for payment. Payment to the DME supplier from the ESRD facility will be based upon the payment arrangements agreed to between the two parties for furnishing home dialysis equipment and supplies to the home dialysis patient.

Comment: Commenters expressed concern that Method II suppliers would no longer be permitted to bill Medicare directly for ESRD-related supplies furnished to ESRD beneficiaries. The commenters believed that suppliers, ESRD facilities, and patients would be confused about the changes made under the ESRD PPS and urged CMS to ensure that all interested parties receive adequate provider education regarding the changes it implements under the ESRD PPS.

Response: We agree that interested parties should receive adequate provider education and once the final rule is published, we intend to provide multiple opportunities for training and education to patients and ESRD facilities. We also intend to provide information at our sponsored open-door forums for other groups such as DME suppliers and laboratory providers.

Comment: Two commenters affiliated with US Military Services commented that they serve many ESRD patients who are retirees or dependents of active duty military personnel. In order to maintain war-time readiness, the commenters stated that they keep their physician and nursing staff trained by performing dialysis on a small population of ESRD dialysis patients. The commenter explained that Method II has been the means of providing seamless home care for their patients while allowing them to follow these patients and provide their ancillary care. Absent a Method II reimbursement equivalent, they would not be able to maintain a nephrology fellowship program which would impact the training of military physicians. However, another commenter affiliated with another branch of the military stated that utilization of Method II reimbursement

for home PD should have no direct effect on the quality of their nephrology fellowship training program as these patients are still required to be evaluated monthly.

Response: While both commenters raise points that relate to the ESRD PPS, the impacts they describe (military readiness training and ongoing education needs) are not germane to the intent of the legislation and not within the scope of this rulemaking.

Comment: One commenter described a study in a recent clinical journal which claimed that CMS could save more than a billion dollars in five years if the utilization of PD increased from its current 8 percent to 15 percent. The commenter questioned why Method II was to be eliminated under the ESRD PPS. He described that this was tantamount to "eliminating one of the very tools that help dialysis providers establish and expand home PD programs."

Response: Although the statute no longer provides discretion to retain Method II, we believe there remain very good reasons to develop and expand home PD programs. For example, PD treatment costs considerably less than comparable in-facility treatments.

Comment: The commenters claimed that as the new ESRD PPS will require billing changes and create other challenges, CMS should consider deferring the application of the consolidated billing edits regarding DME services until the full implementation of the ESRD PPS.

Response: Although we acknowledge that the ESRD PPS will require some billing changes, we do not have the authority to continue to pay DME suppliers directly for ESRD-related items furnished to ESRD patients.

b. Self-Dialysis Training

Currently, Medicare makes a separate payment per treatment for home hemodialysis training and two forms of PD training programs. Home dialysis and self-dialysis can only be performed after an ESRD patient has completed an appropriate course of training. The scope of training services that a certified facility provides to ESRD patients is described in § 494.100(a).

We proposed that ESRD facilities would no longer receive an add-on of $12 for CAPD and $20 for hemodialysis and CCPD to the otherwise applicable payment amount per treatment for the costs of training. We also proposed that the ESRD facility training expenses would be included in the ESRD PPS base rate to which the payment multipliers in the proposed payment model are applied (74 FR 49930).

Also, we proposed that training costs be included in the regression analysis to compute the composite rate payment adjusters. We noted that total composite rate costs included in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs (74 FR 49947). We proposed to use the ESRD facility's cost reports to identify provider costs for training and include these costs in the composite rate portion of the two-equation ESRD PPS model described in the proposed ESRD PPS (74 FR 49947.) We proposed to include training and home dialysis costs, as set forth in § 413.217. We specifically invited public comments on our proposal to include home dialysis training services in the proposed ESRD PPS base rate.

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

Comment: Numerous commenters expressed strong opposition to our proposal to include payments for the training of patients for home dialysis in the ESRD PPS base rate. The commenters pointed out that treatment of training payments as any other overhead expense would have the effect of giving every dialysis facility a small payment for home dialysis training regardless of whether it offered a home training program. These commenters indicated that our proposal fails to target training payments to facilities actually furnishing training treatments, and reduces the magnitude of the training payment by averaging the amount over all hemodialysis equivalent treatments. The commenters believe that the training proposal would have a devastating impact on training programs and discourage the growth of home dialysis.

Commenters also disagreed with our statements that most training treatments were likely to occur within the first four months after the onset of dialysis and that the proposed 47.3 percent adjustment (new onset adjustment) to the otherwise applicable case-mix adjusted payment for treatments occurring within this period would cover the costs of furnishing home dialysis training programs. These commenters pointed out that a high proportion of training treatments do not occur within the first four months after the start of dialysis.

Several commenters pointed out that the ESRD Conditions for Coverage result in higher training expenses, costs which commenters believe should be reimbursed through a separate training adjustment. Other commenters reasoned that failure to provide a separate training adjustment will result in disparities in care, as facilities would find it too expensive to train the elderly, patients with language difficulties, or patients with complex medical conditions.

Most of the commenters recommended that we develop a separate payment for training treatments outside of the payment bundle. However, one commenter opposed the implementation of a separate payment for training services. The commenter maintained that the proposed ESRD PPS provides an adequate incentive for PD training, while acknowledging the higher expenses for home HD training.

Response: Although we are continuing to include training payments in computing the ESRD PPS base rate, we agree with the commenters that we should treat training as an adjustment under the ESRD PPS. We believe the ESRD PPS base rate alone does not account for the staffing costs associated with one-on-one focused home dialysis training treatments furnished by a registered nurse. Because the patient-focused training requires greater nursing resources than provided for non-training treatments, we feel that a separate training add-on adjustment is warranted.

We explored whether we could develop a regression-based adjustments as we have conducted for the rest of the ESRD PPS payment adjustments. However, in analyzing training information in ESRD facility cost reports and comparing those costs to training claims submitted by ESRD facilities, we found that some training costs were under-reported by some facilities and over-reported by others. Therefore, we were unable to develop a regression-based adjustment due to a lack of cost report data for many ESRD facilities.

For purposes of developing a training adjustment under the ESRD PPS, we have decided to use a dollar add-on adjustment similar to the existing training add-on payments under the current basic case-mix adjustment payment system. We also explored various options for updating the training current add-on payment amounts under the current basic case-mix adjusted composite payment system because the training add-on amounts have not been updated since they were established in the 1970s and do not believe such amounts reflect the cost of the training nurse. We believe the training add-on amounts when first implemented, represented staff time, supplies and equipment. Thus, under the ESRD PPS, we considered various options to update the training add-on adjustment to reflect 1-hour of nursing time because home and self-dialysis training must be

conducted by a registered nurse in accordance with the ESRD Conditions for Coverage requirements at § 494.100(a).

The updated training add-on adjustment will be computed by using the national average hourly wage for nurses from Bureau of Labor Statistics data updated to 2011. The amount for the training add-on adjustment we are finalizing under the ESRD PPS will be $33.44 per treatment. This amount would be added to the ESRD PPS payment amount or ESRD PPS portion of the blended payment amount for those ESRD facilities in the ESRD PPS transition. Specifically, this amount will be added to the ESRD PPS payment rate or ESRD PPS portion of the blended payment amount for those ESRD facilities in the ESRD PPS transition, each time a training treatment is provided by the Medicare certified training ESRD facility.

As the training add-on adjustment is directly related to nursing salaries and nursing salaries differ greatly based on geographic location, we will adjust the $33.44 training add-on by the geographic area wage index applicable to the ESRD facility so that the training add-on adjustment reflects local nursing wages. Using the proposed wage index values issued in the CY 2011 PFS proposed rule, the training add-on amounts after application of the wage index would range from $20.03 to $45.84. The wage index is further described in section II.G.3.a. of this final rule.

The training add-on adjustment will only apply to training treatments furnished to dialysis patients by Medicare-certified dialysis training facilities. This amount represents one hour of nursing time to conduct one-on-one training with a patient for either hemodialysis or PD for training treatments furnished by a Medicare-certified training facility. We believe that this approach would eliminate the differential paid for hemodialysis training that accounts for supplies and equipment.

Given that payments for equipment and supplies, as required under the statute, have been captured in the base rate and training facilities would also receive the ESRD PPS base rate and all applicable adjustments, we no longer need to pay these costs as part of a training adjustment. We believe this provides for an adequate increase in the current training adjustment, and that it is appropriate to eliminate the differential paid for HD training.

For those ESRD training facilities that opt to go through the ESRD PPS transition, Medicare will continue to pay $20.00 per training treatment for hemodialysis and CCPD and $12.00 for PD for the basic case-mix adjusted composite rate portion of the ESRD PPS blended payment. These training rates will not be wage adjusted and will continue to be paid based on the maximum number of training treatments explained below.

The payment adjustments for the onset of dialysis adjustment, as well as all other adjusters we are finalizing under the ESRD PPS, are the result of the regression models for composite rate and separately billable services. The regression analysis for this final rule which used cost reports and Medicare claims for 2006–2008, indicated higher composite rate costs associated with the first four months of dialysis. As home dialysis training costs represents one-on-one staff time to train a patient for home dialysis, we believe we have captured staffing costs for training in the 4-month onset of dialysis adjustment. Since we have already accounted for training salary costs in the 4-month onset of dialysis adjustment, we believe that applying the training add-on adjustment in addition to the 4-month onset of dialysis adjustment would have the effect of compounding the composite rate costs and result in an overpayment of nursing staffing costs associated with training dialysis patients for home dialysis. Therefore, ESRD facilities will not receive the training add-on adjustment for patients who are receiving the first 4-month onset of dialysis adjustment (section II.F.3. of this final rule for more detailed explanation of the 4-month onset of dialysis adjustment).

The training add-on adjustment is not a multiplicative adjustment like the other final adjustments under the ESRD PPS. Rather, the training adjustment is added to the product of the ESRD PPS base rate or blended base rate and applicable adjustments. For further explanation, please refer to the Comprehensive Payment Model examples provided in section II.I. of this final rule.

Comment: Some commenters requested that CMS continue to make payment for retraining treatments furnished to home dialysis patients. The commenters pointed out that under some circumstances a home patient may change from one mode of dialysis to another (for example, from home hemodialysis to CAPD) or there are changes to the hemodialysis equipment which requires the home patient to be retained to continue as a self-dialysis patient.

Response: Under the ESRD PPS, we will continue to pay for self-dialysis training after a patient has completed the initial training course. The conditions under which we make payment for retraining treatments follow the same coverage rules for training under the ESRD PPS. Criteria for retraining are unchanged and explained in greater detail in the Medicare Claims Processing Manual, Chapter 8, Section 50.8 Training and Retraining. In addition, the patient must continue to be an appropriate patient for self-dialysis.

Comment: Commenters varied in their suggestions for how the training payments should be applied. For example, one commenter recommended a "hold back" in which a portion of the training payments would be withheld from the ESRD facility pending demonstration of the patient's successful transition to home dialysis. Other commenters recommended that we establish a monitoring system to determine the degree to which any separate adjustment for the provision of home training treatments results in more patients successfully transitioning to home dialysis.

Response: We will continue to require that ESRD facilities are a Medicare certified training facility in order to receive the training add-on adjustment each time a training treatment is provided. In an effort to promote more training for home dialysis, we are not limiting payment for training through a hold-back mechanism. We fully intend to monitor how the updated training add-on adjustment relates to changes in the proportion of ESRD patients on home dialysis modalities and may propose limits in the future.

Comment: We received numerous comments requesting that CMS retain the existing policy that limits coverage of the total number of training treatments at the current level of 15 for peritoneal dialysis (CAPD and CCPD) and 25 for hemodialysis.

Response: We agree with the commenters. Under the ESRD PPS, we will continue the current cap on training treatments at 15 for peritoneal dialysis (CAPD and CCPD) and 25 for hemodialysis training because most commenters indicated that they can complete training within these training treatment parameters.

In summary, we are finalizing a training add-on adjustment under the ESRD PPS in the amount of $33.38 per training treatment, adjusted based on the geographic wage index for nursing salaries to account for the hourly nursing time for dialysis training treatments. This adjustment would apply to HD and PD modalities. This training add-on adjustment is applied

after all other adjustments under the ESRD PPS have been made. We have added paragraph (c) to § 413.235 and revised the description of the per treatment payment amount in § 413.230 to reflect the training add-on adjustment.

B. Unit of Payment

Under section 1881(b)(14)(C) of the Act, as added by section 153(b) of MIPPA, the ESRD PPS may provide for payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. We proposed to establish an ESRD PPS which relies on a per treatment unit of payment (74 FR 49931). We proposed to continue the present per treatment basis of payment in which ESRD facilities would be paid for up to three treatments per week, unless there is medical justification for more than three weekly treatments (74 FR 49931). ESRD facilities treating patients on PD or home HD would also receive payments for up to three treatments for each week of dialysis, unless there is medical justification for the furnishing of additional treatments. In the proposed rule, we discussed in detail the factors and data we considered in developing our proposal (74 FR 49931 through 49934). The comments we received with regard to our proposals for the unit of payment and our responses are discussed below:

Comment: Numerous commenters supported our selection of a per treatment unit of payment for the bundled payment system. The commenters noted that a per treatment unit of payment preserved access for patients who travel, and would minimize operational difficulties and administrative complexity for the approximately 19 percent of patients who incur an interruption of service or receive treatment at more than one dialysis facility. Generally, commenters noted that a larger unit of payment, such as a monthly payment, would complicate the phase-in of the payment system. MedPAC noted that a larger unit of payment would be consistent with several aspects of dialysis care, pointing out that a weekly unit of payment corresponds to the typical weekly interval for PD. MedPAC also noted that Medicare pays nephrologists a monthly capitated payment for caring for dialysis beneficiaries. MedPAC recommended that we reconsider the unit of payment, once a strengthened dialysis quality monitoring system is implemented, to assure that quality of care does not decline.

Response: We agree with the commenters that maintaining a per treatment unit of payment is the best method to achieve the effect of the bundled payment system without adversely impacting beneficiary access to home dialysis services. As we explained in the proposed rule (74 FR 49931), we considered other units of payment such as a monthly ESRD PPS, which would provide ESRD facilities more flexibility in alternative treatment requirements, such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines and shorter but more frequent dialysis services. However, given the difficulties of implementing a monthly ESRD PPS during the transition period in which a per treatment methodology applies, we proposed to continue the current per treatment payment methodology in connection with the proposed ESRD PPS as set forth in § 413.215.

In this final rule, we are adopting the per treatment unit of payment for the ESRD PPS for the reasons set forth above. As we indicated in the proposed rule, we may reconsider this decision after the transition period has ended (74 FR 49934). At that time, we may evaluate whether the ESRD PPS has resulted in improved clinical outcomes, the degree to which home dialysis has increased, and whether interested stakeholders would favor an alternative to the per treatment approach we are finalizing in this final rule.

Comment: Several commenters recommended that we change the definition for reporting the volume of treatments to eliminate the use of hemodialysis equivalents. The commenters stated that the use of HD equivalents for the home dialysis modalities distorts the real costs associated with that modality, pointing out that home HD patients may be receiving 5–7 treatments per week, with some commercial payers paying for more than three treatments per week.

Response: The practice of converting PD treatments to HD equivalent treatments arose in the context of developing an appropriate unit of analysis for the PD modalities in which multiple exchanges of dialysate occur during the course of a day. These exchanges are not discrete treatments in the same sense that an HD session represents a treatment. In order to encourage home dialysis, the policy decision not to develop separate bundled payment rates for the in-facility and home dialysis modalities required that the base rate also be applied to home dialysis. Therefore, we believed that conversion of each week of home dialysis to three equivalent HD treatments was the most feasible approach. The alternative would have been to develop a separate bundled payment rate for each week of home dialysis. We rejected this approach in order to use a per treatment payment for all ESRD treatments, including home treatments.

To the extent that patients on home HD receive more than three treatments per week, we point out that use of the additional treatments to develop the base rate would have decreased that rate. Particularly for PD, we believe that use of three HD equivalent treatments for each week of PD represents a reasonable basis for establishing payment rates per treatment that can be applied to both in center and home dialysis modalities.

In summary, we are finalizing § 413.215(a) which established the dialysis treatment as the unit of payment under the ESRD PPS.

C. Data Sources

Section 1881(b)(14)(B) of the Act, as added by section 153(b) of MIPPA, defines the renal dialysis services that must be included in the ESRD PPS. In the proposed rule, we identified the components used to construct the payment bundle (74 FR 49934) based on the following Medicare cost and payment information:

- Composite rate services as measured using composite rate costs calculated from the Medicare cost reports;
- Drugs and biologicals (for example, injectables) that are separately billed by ESRD facilities on Medicare outpatient institutional claims;
- Drugs and biologicals (for example, oral) used to treat ESRD patients obtained from claims submitted by Part D stand alone prescription drug plans;
- Laboratory tests that are separately billed by ESRD facilities on Medicare outpatient institutional claims;
- Laboratory tests ordered by a physician who receives MCPs for treating ESRD patients, which are separately billed by independent laboratories;
- Other items and services separately billed by ESRD facilities that are used in conjunction with injectable medications or laboratory tests, such as blood products, syringes, and other dialysis supplies that are billed on Medicare outpatient institutional claims.

The cost report and claims data sources used to construct the bundled payment system, as set forth in this final rule, remain the same as described in the proposed rule, with the exception that CY 2006, 2007, and 2008 records

have been used for this final rule instead of CY 2004 through 2006 data that were used in the proposed rule. This is consistent with our statement in the proposed rule that we planned to use the latest available cost report and claims information to develop the final rule, given the lead time necessary to prepare the final rule (*see* 74 FR 49934 through 49935).

Section 1881(b)(14)(A)(ii) of the Act requires that the estimated total amount of payments for 2011 be equal to 98 percent of the estimated total amount of payments for renal dialysis services that would have been made in 2011 if the ESRD PPS had not been implemented. That section requires that we use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization. To comply with this provision, we evaluated payment data from 2007, 2008, and the first 9 months of 2009, the latest available given the lead time required to prepare this final rule, as described later in this section.

In the proposed rule, we cited the application of a statistical methodology referenced in UM–KECC's February 2008 report for removing composite rate costs with extreme values from the cost report database used to develop the composite rate portion of the ESRD PPS payment model (74 FR 49947). That methodology employed a standard outer fence definition. The outer fence is a threshold for identifying extreme outliers. The upper outer fence, which is the threshold that was used to identify outliers with extremely high costs, is defined as the 75th percentile plus three times the interquartile range (IQR). This is the 75th percentile minus the 25th percentile. The lower outer fence, which is the threshold that was used to identify outliers with extremely low costs, is the 25th percentile minus three times the IQR.

The outer fence values for average cost per treatment were calculated on the log scale, since a log transformation was used to estimate the models. When retransformed to dollars, the lower outer fence for composite rate costs was $68.81 per treatment, and the upper outer fence was $470.70 per treatment. However, a test model that applied these exclusion criteria yielded especially large prediction errors for facilities with reported composite rate costs below $100.00 per treatment. Accordingly, we applied a separate methodology to identify additional outliers that could affect the analysis and reduce the accuracy of the case-mix adjusters resulting from the model estimates.

This method was also used to develop the set of composite rate cost per treatment values analyzed in connection with the proposed rule (74 FR 49947). The method involved an analysis of studentized residuals, which are residuals divided by an estimate of their standard deviation. Approximately 95 percent of the facilities with average costs between $68.81 and $100.00 per treatment had studentized residuals less than -2, and approximately 32 percent had studentized residuals less than -4. Based on this analysis of studentized residuals, a slightly more restrictive lower limit of $100.00 was applied.

Together, these methodologies for identifying outlier values for composite rate costs resulted in the exclusion of 460 facility year records (approximately 3 percent) from the analysis of 2006–2008 data that was used to develop the composite rate portion of the ESRD PPS payment model described in this final rule.

While cost information for composite rate services is available from the Medicare cost reports, the cost report does not contain information on the costs of the separately billable categories of services noted above. The ESRD PPS described in this final rule incorporates payment for separately billable services based on separately billable payment information from Medicare claims.

The descriptive statistics, case-mix model, and other analyses presented in this final rule were based on CMS claims files for Medicare ESRD patients, and the Medicare cost reports for hospital-based ESRD outpatient dialysis providers and independent ESRD facilities. Resource utilization for separately billable services was based on patient-level Medicare outpatient claims for CYs 2006 through 2008 (the latest available claims), in order to be able to prepare this final rule. Since composite rate cost information is available only at the facility level, resource utilization for composite rate services was measured using the Medicare cost reports for CYs 2006 through 2008 for each outpatient dialysis provider and facility (that is, hospital-based and independent facilities). These years represented the latest and most complete data available for the preparation of this final rule.

As we did in the proposed rule (74 FR 49935), we also used several data sources for evaluating the patient and facility characteristics that were used with the case-mix analyses. Patient demographic information was obtained from the Renal Management Information System (REMIS)/Consolidated Renal Operations in a Web-Enabled Network (CROWN), and the ESRD Standard Information Management System (SIMS). These data sources include the Medical Evidence Report Form (Form 2728), which is completed at the onset of renal replacement therapy (RRT), which is either dialysis or transplantation to sustain life at the onset of kidney failure. Patient body size measures were developed from the height and weight values reported on the Form 2728. Beginning April 1, 2005, these values were obtained from the patient claims for outpatient dialysis. Although we have revised the proposed set of patient co-morbidities used as case-mix adjusters in the development of this final rule for reasons explained in section II.F.3. of this final rule, the cost report and paid claims data used to develop the case-mix adjusters based on co-morbidities described in the proposed rule (74 FR 49935) remain the same.

We measured dialysis facility characteristics using a combination of SIMS (ownership type and geographic location), the Medicare cost reports (facility size), the Online State Certification and Reporting System (OSCAR) (hospital affiliation for satellite units), and other available information (for example, identifying facilities with composite payment rate exceptions).

1. Patient Claims Data

The outpatient facility paid claims file is the primary source of information for payments that ESRD facilities receive for the treatment of ESRD patients. The "type 72X" claims (ESRD claims) provided the detailed data for dialysis payments. As we did in the proposed rule, the claims files used for the analyses in this final rule were based on patients with at least one claims record for dialysis. We used carrier claims and durable medical equipment (DME) claims to track dialysis-related payments to other providers such as independent laboratories.

The case-mix models were based on claims from CYs 2006, 2007, and 2008. These were the most complete CY records available for use with the Medicare cost reports from the same periods to develop the payment methodology, given the time necessary for the preparation of this final rule. As with the composite rate costs obtained from the Medicare cost reports and patient claims used to develop the proposed ESRD PPS (74 FR 49936), we similarly used the statistical outer fence methodology described previously to exclude unusually high separately billed values (statistical outliers) obtained from the claims used to develop the system as set forth in this final rule. Based on the statistical outer fence methodology, claims with total

separately billed amounts greater than $2,545.65 were excluded from the analysis of 2006 through 2008 data used to develop the separately billed portion of the ESRD PPS payment model. Application of this methodology for the analysis that was used to develop the separately billed portion of the ESRD PPS payment model for pediatric patients resulted in no exclusions. The number of Medicare claims, patients, dialysis sessions, and ESRD facilities represented in the source claims data are shown in Table 6. We have also provided the same information for CY 2005 for comparison purposes.

Table 6
Medicare Dialysis Patients, Treatments, ESRD Facilities, and Claims by Year, 2005-2008

	2005	2006	2007	2008
Medicare Dialysis Patients[1]	318,590	324,943	329,012	332,713
Hemodialysis Equivalent Dialysis Treatments[2]	35,141,558	36,004,086	36,747,662	37,550,676
ESRD Facilities	4,699	4,812	4,957	5,184
Patient Month Claims	3,038,498	3,096,880	3,156,914	3,216,416

[1]Includes home dialysis patients for whom payments were made under Method II.
[2]Hemodialysis-equivalent treatments were capped at the equivalent number of days per month. Includes PD in which one week of PD is considered equivalent to 3 HD treatments. For Method II patients, an estimate of 12.5 HD-equivalent treatments per month was used, based on the average number of treatments per month reported for Method I peritoneal dialysis patients.

We did not receive any public comments objecting to our intention to use the latest available Medicare cost report and claims data to develop the final rule. Therefore, we are finalizing § 413.220(a)(1) and (2) as proposed.

2. Medicare Cost Reports

We obtained facility-level cost and treatment data from the CMS Medicare Hospital Cost Report (Form CMS 2552–96) and the CMS Medicare Independent Renal Dialysis Facility Cost Report (Form CMS 265–94). The number of available cost reports for CYs 2006 through 2008, which contained necessary cost and treatment data for purposes of the composite rate cost analyses, are shown in Table 7. For most ESRD facilities, a single cost report encompassed the entire calendar year. For FY cost reports that spanned two CYs, we used a weighted average based on the proportion falling in each CY.

Table 7
Available Cost Reports by ESRD Facility Type, 2006-2008[1]

Facility Type	2006	2007	2008
Freestanding	4,188	4,356	4,431
Hospital Based	436	435	421
Total	4,624	4,791	4,852

[1]Based on the December 2009 quarterly update of HCRIS. Includes Cost Reports with composite rate cost and treatment fields greater than 0.

3. Patient Claim and Cost Report Summary Data 2006–2008

The case-mix models were based on data sets that linked claims and cost report records for each year from CY 2006 through CY 2008. The claims data for patients treated in hospital satellite facilities were matched to the parent hospital using OSCAR, since cost reports are only submitted by the parent facility. Table 8 shows the resulting analysis files that included both claims and cost report data for measuring separately billable and composite rate resource utilization.

Table 8
Medicare Dialysis Patients, Treatments, ESRD Facilities, and Claims for Patients and Facilities with Measured Costs per Treatment, by Year, 2006-2008[1]

	2006	2007	2008[2]
Medicare Dialysis Patients	320,652	324,063	320,380
Hemodialysis Equivalent Dialysis Treatments	35,356,748	36,008,729	35,745,487
ESRD facilities	4,529	4,683	4,744
Patient Month Claims	2,926,590	2,975,474	2,942,265

[1]Includes patient months and ESRD facilities with Medicare hemodialysis-equivalent treatments >0 from the outpatient dialysis facility claims and measured composite rate costs and treatments from the Medicare Cost Reports.
[2]Using the latest update of HCRIS that was available in time to complete these analyses, the number of patients with cost report data available for analysis of facility composite rate costs was somewhat lower in 2008 than in 2007.

In the proposed rule, we explained that we trimmed claims data to exclude statistically aberrant or clinically implausible values (74 FR 49947 through 49948). We received the following comments regarding excluded claims data.

Comment: Several commenters expressed concern that we inappropriately excluded claims from the computation of the 2007 base rate using arbitrary exclusion criteria. For example, one commenter noted that the use of 30,000 units of epoetin alfa (EPO) per treatment as a clinically implausible threshold did not comport with CMS's own EPO Claims Monitoring Policy in which 400,000 units per month is the established threshold. Another commenter stated that the capping of patient months in which more than 20 treatments were furnished at 20 treatments was an inappropriate exclusion. The commenter stated that their attempted replication of the 2007 base rate computation resulted in 1.3 and 1.45 percent more paid treatments than were included in the MAP calculation. Other commenters stated that nowhere in the proposed rule did CMS state exactly how many facilities and payments were excluded from its calculations. These commenters stated that all paid Medicare claims should be included in the computation of the MAP so as not to yield an understatement of the base rate.

Response: In response to the concerns raised by the commenters, we have reevaluated our basis for excluding certain claims from the calculation of the CY 2007 base year amount. All payments made on behalf of Medicare ESRD beneficiaries as reported on type 72X claims have now been included, but with the following modifications and exclusions:

- Payments for EPO in excess of 500,000 units per month in 2007, and 400,000 units per month in 2008 and 2009 (that is, the medically unbelievable thresholds), were capped at 500,000 units and 400,000 units, respectively, consistent with CMS's ESA monitoring policy. A similar cap was applied to claims for ARANESP®, in which the caps based on the medically unbelievable thresholds were 1500 mcg. per month in 2007, and 1200 mcg. per month in 2008 and 2009. We believe that the portion of the base rate that reflects ESA utilization should comport with the ESA dosing guidelines under CMS's ESA Claims Monitoring Policy in effect at the time.
- Claims in which the number of dialysis treatments exceeded the number of days in the month were capped so that the number of dialysis treatments equaled the number of days in the month. No adjustments were made to the paid amounts associated with these claims. Payments to dialysis facilities in connection with claims with no dialysis treatments reported were excluded. On these claims, the payments to facilities were for services other than dialysis. Accordingly, they would not be considered renal dialysis services.
- Payments for blood and blood products. ESRD facilities rarely furnish blood as part of a patient's ESRD-related anemia management. As we discuss in section II.a.4. of this final rule, we have determined that blood and blood products do not meet the definition of renal dialysis services. Therefore, payments for blood and blood products were excluded. Blood and blood products are not included in the ESRD PPS payment bundle.
- Payments for vaccines and vaccine administration were excluded. Section 1881(b)(14)(B) of the Act specifically excludes vaccines from the ESRD PPS payment bundle.
- Immunosuppressive drug payments were excluded because immunosuppressive drugs are paid under a separate Medicare benefit.
- Payments for unclassified drugs (HCPCS J3490) and unknown drugs

were excluded because we do not know whether these drugs are ESRD-related. As their status is unknown, we did not consider them renal dialysis services.

• Payments for non-ESRD-related drugs, as identified in Table C in the Appendix were excluded because such drugs would not constitute renal dialysis services.

• Payments for pharmacy supplies, procedures not considered ESRD-related, and other non-ESRD miscellaneous services were also excluded.

We believe that these revised exclusion criteria permit the inclusion of statistically aberrant but plausible payments in the calculation of the base year amounts, while ensuring that amounts paid incorrectly are excluded.

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Table 9

Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007-09*

	2007	2008	January to Sept 2009
Dialysis patients	328,787	332,509	314,056
Hemodialysis (HD)-equivalent dialysis treatments	36,747,662	37,550,676	28,377,271
Total MAP for services in the expanded ESRD PPS			
Total for Part B and Part D services	$8,809,732,068	$8,982,276,591	$6,935,728,601
Total for Part B services	$8,799,031,984	$8,967,237,697	$6,922,162,833
Composite rate services	$5,719,657,831	$5,927,753,351	$4,505,292,198
Separately billable services (Part B)			
EPO^	$1,876,926,573	$1,787,217,266	$1,438,439,497
Darbepoetin^	$167,935,970	$152,927,193	$118,173,449
Calcitriol	$3,125,613	$1,551,993	$1,587,991
Doxercalciferol	$76,901,723	$70,664,928	$61,615,143
Paricalcitol	$322,849,348	$376,986,283	$286,428,841
Iron sucrose	$166,219,339	$174,019,193	$158,134,159
Sodium ferric gluconate	$68,086,707	$69,101,908	$42,830,961
Levocarnitine	$5,026,446	$3,593,143	$2,471,497
Alteplase	$26,697,321	$27,676,417	$21,903,525
Vancomycin	$3,583,504	$2,543,805	$2,140,261
Daptomycin	$1,234,405	$2,229,550	$2,241,182
Other injectables	$4,943,934	$3,442,832	$2,047,144
Laboratory tests	$295,508,409	$320,871,175	$243,481,931
Ultrafiltration	$2,563,656	$3,268,772	$2,581,117
Dialysis facility supplies and IV fluids	$38,263,239	$35,441,489	$27,920,874
Durable medical equipment and supplies (method II)	$18,060,483	$7,374,631	$4,541,261
Dialysis support services (method II)	$1,447,484	$573,767	$331,801
Total MAP per treatment for Part B services	$239.445	$238.804	$243.933
Dialysis patients with Part D spending	221,154	229,009	212,180
HD-equivalent dialysis treatments for patients with Part D spending	24,737,326	25,916,896	19,625,085
Total MAP for Part D services	$10,700,084	$15,038,895	$13,565,768
Calcitriol (oral)	$2,678,711	$3,059,551	$2,393,787
Doxercalciferol (oral)	$4,965,189	$7,392,035	$6,744,117

Paricalcitol (oral)	$3,008,544	$4,537,404	$4,388,569
Levocarnitine (oral)	$47,639	$49,905	$39,295
Total MAP per treatment for Part D services	$0.433	$0.580	$0.691
Total MAP per treatment for services in the expanded ESRD PPS	$239.88	$239.38	$244.62
Total MAP per treatment for services in the expanded ESRD PPS, adjusted for price inflation to 2009#	$243.65	$243.08	$244.62
Total MAP for composite rate drugs that were billed separately (excluded from base rate calculation)	$17,771	$6,980	$6,546
Total MAP from type '72X' claims excluded from ESRD PPS	$40,584,378	$44,318,791	$36,860,703
Separately billed services on claims with no dialysis treatments	$2,660,008	$2,392,576	$1,984,623
EPO exceeding the medically unbelievable threshold under the CMS ESA Monitoring Policy	$993,511	$1,912,588	$1,075,260
Darbepoetin exceeding the medically unbelievable threshold under the CMS ESA Monitoring Policy	$283,569	$119,922	$50,184
Blood and blood products	$1,504,831	$1,505,337	$1,538,284
Hepatitis B vaccine	$24,388,150	$26,533,803	$23,386,921
Flu vaccine	$1,922,271	$2,047,204	$1,171,542
Pneumonia vaccine	$709,726	$1,190,564	$1,037,558
Other vaccine	$41,803	$50,374	$32,394
Vaccine administration	$4,917,878	$6,339,116	$5,058,122
Immunosuppressive drugs	$148,740	$168,140	$76,712
HCPCS J3490 (unclassified drug)	$618,745	$459,160	$566,291
Non-ESRD drugs	$143,355	$173,624	$107,410
Pharmacy supply	$784	$1,280	$912
Excluded procedures	$188,465	$132,080	$46,152
Unknown drug (drug revenue center and no HCPCS)	$1,436,055	$1,039,131	$524,298
Other dialysis facility services	$626,486	$253,891	$204,040

*The estimates above exclude patient facility months with no hemodialysis-equivalent treatments. The monthly hemodialysis-equivalent treatments were capped at the number of days in the month (e.g., 31 for January).

^Payments for EPO and darbepoetin were capped to reflect the medically unbelievable thresholds that applied at the time under the CMS ESA Monitoring Policy (500,000 and 400,000 units of EPO per month in 2007 and 2008-09, respectively, and 1,500 and 1,200 mcg of darbepoetin per month in 2007 and 2008-09, respectively).

#The price inflation adjustments to 2009 are described below for services in the ESRD PPS.

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Table 9 shows the total MAP amounts for CY 2007, 2008, and the first 9 months of 2009. The MAP amount for the first nine months of 2009 is shown because of the requirement in section 1881(b)(14)(A)(ii) of the Act that the budget neutrality per patient utilization comparison include data from 2009.

Table 9 shows the MAP amounts for each period on a per treatment basis, after adjustment for price inflation to 2009, in accordance with the inflation factors described below.

Table 9 reveals that the MAP for CY 2007, the year with the lowest per patient utilization of renal dialysis services as described in section II.C.5. of this final rule, was $243.65 per treatment.

Comment: One commenter noted that we eliminated claims from our analysis

with a missing date of birth which is necessary in order to assign patients accurately to the correct age group category for purposes of determining the impact of age on composite rate costs and separately billable payments under the two-equation model. The commenter stated that in the Standard Analytical Files (SAF), an age range is assigned to patients, and the SAF denominator file similarly assigns an age to patients. The commenter said that because their data includes an age designation for all patients, no patients were eliminated from the commenter's calculations of treatments or payments.

Response: Our elimination of patients with no valid date of birth is only relevant in connection with the development of the payment adjusters for the age variable in the two-equation model and not for purposes of the computation of the base rate. This was done in order to prevent any distortion in the age adjusters. We point out that the number of claims eliminated was extremely small. No claims were eliminated due to the lack of a valid date of birth in the calculation of the base rate because age is not a classification variable in computing that rate. We are unaware of the assignment of an age range in the SAF claims files. Rather than relying on a methodology which assigns an age to patients, which may be incorrect, we believe that the exclusion of claims where a correct determination of age is necessary for the development of payment adjusters is appropriate.

4. Data for the Case-Mix Analyses, 2006–2008

The case-mix analyses required data for several patient and facility characteristics, such as age, co-morbidities, facility size, etc. After the exclusion of statistical outliers or otherwise unusable records (such as patients with no valid date of birth), the data shown in Table 8 was refined to yield the data set used in the primary analyses for both composite rate and separately billable services.

Table 10 summarizes these records.

Table 10

Medicare Dialysis Patients, Treatments, ESRD Facilities, and Claims
Final Analysis Sample by Year, 2006-2008[1]

	2006	2007	2008	Pooled, 2006-2008
Medicare Dialysis Patients	313,151	317,322	315,412	475,491
Hemodialysis Equivalent Dialysis Treatments	34,254,928	34,997,174	35,018,357	104,270,459
ESRD Facilities	4,214	4,389	4,559	4,809
Patient Month Claims	2,839,554	2,896,020	2,885,352	8,620,926

[1]Based on the sample of dialysis patients and ESRD facilities included in the case-mix analyses for both composite rate and separately billable services.

The primary case-mix analyses relied on pooled data from CY 2006 through CY 2008, which included a total of 8,620,926 Medicare ESRD patient months. The case-mix analyses included 97.4 percent of patients with Medicare outpatient dialysis claims during CYs 2006 through 2008. Over the 3-year period, the case-mix analyses included data for 475,491 Medicare ESRD patients treated in ESRD facilities.

5. Prescription Drug Event Data, CY 2007, CY 2008, Jan–Sept 2009

We obtained the total payments for Medicare Part D drugs from Part D claims submitted by prescription drug plans (drugs formerly covered under Part D prior to the ESRD PPS). The claims were restricted to Part D claims for oral drugs with an injectable form used to treat ESRD submitted on behalf of Medicare ESRD beneficiaries with valid ESRD claims in CY 2007, CY 2008, and for the first 9 months of 2009 (the latest available in time for the preparation of this final rule). As discussed in section II.A.3. of this final rule, payment of oral-only drugs under the ESRD PPS is being delayed until 2014. Therefore, payments for such drugs were excluded from the calculations. As a result, we are finalizing § 413.220, but revising paragraph (b) to reflect the exclusion of oral-only drugs from the computation of the final base rate.

The drugs included in the ESRD bundle are the three vitamin D analogues (calcitriol, doxercalciferol, and paricalcitol), and levocarnitine. The National Drug Coes (NDCs) used to identify these drugs in the Part D claims are shown in Table D of the Appendix.

Table 11 below shows the number of Medicare ESRD beneficiaries for which valid ESRD claims were filed in CY 2007, CY 2008, and the first nine months of 2009; number of ESRD beneficiaries with Part D drug coverage from the stand alone Part D plans; and number of beneficiaries with Part D claims for the above oral drugs.

Table 11

Medicare Dialysis Patients with Payments for Part D Drugs, 2007, 2008, and January-September 2009

	2007		2008		January to September 2009	
	Patients	%	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims[1]	328,787	100.0%	332,509	100.0%	314,056	100.0%
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	221,154	67.3%	229,009	68.9%	212,180	67.6%
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS[2]	20,874	6.3%	23,422	7.0%	19,647	6.3%

[1]Includes 'type 72X' outpatient institutional claims with treatments > 0.
[2]Includes Vitamin D analogs (Calcitriol, Paracalcitol, and Doxercalciferol), and levocarnitine.

D. Analytical Approach

In the proposed rule, we presented a case-mix model that UM–KECC developed, using standard techniques of multivariate regression. In the proposed rule, we described in detail two approaches for developing the case-mix models using multivariate regression (74 FR 49938). The case mix model we proposed in the development of the proposed ESRD PPS rule was the two-equation model.

We noted that, for those interested, a more extensive and detailed mathematical explanation of the two-equation model used to develop the case-mix adjusters is contained in UM–KECC's February 2008 report, *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle* (*see* pp. 38–44 and Technical Appendix).

We did not receive any public comments in connection with our use of the two-equation model to develop the case-mix adjusters.

E. Development of ESRD PPS Base Rate

The patient-specific case-mix adjustments developed from the two-equation model for composite rate and separately billable services are applied to a base payment rate per treatment ("base rate"). We proposed that the ESRD base rate would be adjusted to reflect ESRD facility differences in area wage levels using a proposed wage index (74 FR 49947).

In this section, we describe the calculation of the ESRD base rate, as set forth in § 413.220, and the computation of the reduction factors used to adjust the ESRD 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. We define the ESRD base rate at § 413.171. The proposed ESRD base rate, which represents the average Medicare allowable payment (MAP) for composite rate and separately billable services, was developed from CY 2007 claims data.

We used claims data from CY 2007 in connection with the preparation of the proposed rule because such data were the latest available. In the proposed rule, we stated that we expected to have claims data for CY 2008 and partial claims information for CY 2009 in connection with our preparation of the final rule (74 FR 49939). We also stated that in order to comply with the statute's requirement to use per patient utilization data from 2007, 2008, or 2009 (whichever year had the lowest per patient utilization), we planned to use available claims for Medicare ESRD beneficiaries from those years, to determine which year resulted in the lowest average payment amount per treatment (74 FR 49934).

We received several comments in connection with our proposed methodology for determining the year with the lowest per patient utilization of renal dialysis services, as required under section 1881(b)(14)(A)(ii) of the

Act. The comments received, and our responses to them, are set forth below.

Comment: Several commenters pointed out that section 1881(b)(14)(A)(ii) of the Act directs the Secretary to use "per patient utilization data from 2007, 2008, or 2009" in estimating the total amount of payments that would have been made under title XVIII in 2011 for renal dialysis services. The year selected in making that estimation must be the year which has the lowest per patient utilization. The commenters explained that CMS's proposed methodology for determining the unadjusted base rate per treatment, in which the total expenditures for the specified renal dialysis services included in the payment bundle is divided by the total annual number of hemodialysis (HD)-equivalent treatments (74 FR 49940 through 49942), represents an inaccurate approach for complying with the law. The commenters maintained that the effect on the Part D drugs component of the payment bundle was to inflate the denominator (that is, total HD-equivalent treatments) to include all eligible Medicare ESRD beneficiaries, regardless of Part D participation, while the numerator with respect to Part D drugs only included ESRD drug payments for Medicare Part D enrollees. The commenters stated that this resulted in a gross understatement of the Part D drugs component of the payment bundle. The commenters asserted that in order to calculate per patient utilization accurately, the pool of patients in the numerator and denominator of the base rate per treatment computation must be congruent.

Response: We believe that the commenters are correct in concluding that our proposed methodology for calculating the base rate yielded an inappropriately low payment amount for the Part D component of the ESRD PPS payment bundle. This occurred because the total payments for the Part D drugs we proposed to include in the bundle reflected payments for those drugs for those Medicare ESRD beneficiaries enrolled in Part D, while the denominator reflected the total number of HD-equivalent treatments for all Medicare ESRD beneficiaries, regardless of their enrollment in Part D. For this final rule, we have revised the denominator in the calculation described above to reflect the total number of treatments for those ESRD beneficiaries enrolled in Part D.

In addition, given the commenters' concerns regarding our proposal for determining the lowest per patient utilization year and the calculation of the per treatment base year amount, we reevaluated our proposed methodology and adopted a revised approach. We believe our revised methodology more closely comports with the language set forth in section 1881(b)(14)(A)(ii) of the Act, requiring the determination of the year with the lowest per patient utilization of renal dialysis services by Medicare ESRD beneficiaries. The methodology is similar to the calculation used for the composite rate drug add-on, in that the effects of price and enrollment are removed from total expenditures to obtain per patient utilization. The method used is described in detail below. We have also revised our computation of the base rate with respect to the Part D drug component to yield an amount which we believe is no longer understated.

Section 1881(b)(14)(A)(ii) of the Act requires that we compare data from 2007, 2008, and 2009 to select the year with the lowest per patient utilization of renal dialysis services. Although we have complete data for 2007 and 2008, we only have partial year data for 2009. To control for the effects of potential seasonal variation in the utilization of dialysis services, we first compared renal dialysis expenditures for the first nine months of each year. We felt this approach was preferable to completing the 2009 data, in order for it to represent a full year's value, as this could introduce bias in the estimation.

We eliminated the effects of price inflation by adjusting expenditures for 2007 and 2008 to reflect 2009 price levels using the actual annual rates of inflation for the various components of the bundle. Payments for composite rate services were inflated to the 2009 base rate of $133.81 per treatment and drug add-on percentage of 15.2 percent. The inflators for Part B drugs and biologicals were based on actual ASP+6 percent prices, because that is what they were paid (see Table 12 below for the full year prices).

Payments for laboratory tests were inflated 4.5 percent from 2007 to 2009 and from 2008 to 2009. The inflators for laboratory services are based on updates to the laboratory fee schedule. The laboratory fee schedule is required to be updated using the CPI–U and any statutory adjustments to the CPI–U update factor. As the price update for laboratory services from 2007 to 2008 was statutorily set to be 0 percent, no inflator was applied for that year.

Because DME supplies and equipment, and self dialysis support services for Method II patients are subject to a monthly capitation payment that has not increased, we did not use an inflation adjustment. In addition, because supplies and other services are primarily composed of the $0.50 administration fee for separately billable Part B drugs, and this has not increased, we did not inflate this category.

Part D drugs were inflated 6.0 percent from 2007 to 2009, and 3.4 percent from 2008 to 2009, using the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections.

Table 13 shows payments per Medicare ESRD beneficiary for the first nine months of each year, for the renal dialysis services which comprise the payment bundle, excluding former Part D oral drugs, with prices inflated to 2009 levels. Table 14 shows payments for Medicare ESRD beneficiaries enrolled in Part D, for the oral drugs with an injectable equivalent based on Medicare Part D claims, similarly adjusted for price inflation to 2009.

By looking at these components separately, we are able to calculate the per capita spending based on the number of beneficiaries that are eligible for the service. By calculating the spending on a per capita basis, we are eliminating the effects of enrollment. The sum of the two values yielded the average expenditures per Medicare ESRD beneficiary for the renal dialysis services included in the payment bundle. These values are shown in Table 15. The indicated per capita spending amounts represent the per patient price and utilization of renal dialysis services. Because we are controlling for the effects of price inflation for the comparable 9 month periods in 2007, 2008, and 2009, the variability in per capita amounts is due to utilization. We believe that this methodology is responsive to the commenters' concerns in that the Part D spending amount is divided by the number of beneficiaries enrolled in Part D, and there is no understatement of this component.

Table 15 reveals that for the 9-month periods, 2007 was the year with the lowest per patient utilization, with per capita expenditures of $21,568. We performed the same computations using the full year of data for 2007 and 2008, as a check for the results obtained. (Tables 16, 17, and 18). We did not use the 2009 data in this comparison, as it is incomplete. The results revealed that per capita spending for Medicare ESRD beneficiaries was again lower in 2007, with total expenditures per beneficiary of $27,232.

Accordingly, we have determined that 2007 is the year representing the lowest per patient utilization of the renal dialysis services which comprise the ESRD payment bundle, and have used

that year to develop the base rate set forth in this final rule. For the reasons described above, we are finalizing 413.220(b)(1). However, we have revised the title to reflect per patient utilization in CY 2007, 2008 or 2009 and revised the content to clarify that we remove the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization. In addition, we have revised § 413.220(a)(3) to clarify that 2007 is the year with the lowest per patient utilization.

Table 12: ASP+6 Percent Price Updates

Drugs and biologicals	2007 to 2009	2008 to 2009
EPO	3.2%	4.5%
Paricalcitol	-3.1%	-2.6%
Sodium_ferric_glut	-0.8%	-1.8%
Iron_sucrose	3.9%	7.3%
Levocarnitine	-20.0%	2.3%
Doxercalciferol	16.8%	14.1%
Calcitriol	-15.4%	13.7%
Iron_dextran	6.4%	6.4%
Vancomycin	-11.4%	-4.6%
Alteplase	4.7%	5.2%
ARANESP®	-10.1%	3.3%
Daptomycin	15.8%	6.9%
Other injectables	1.7%	-3.7%

Table 13: Renal dialysis services, excluding former Part D drugs

9 months	Total Payments	Enrollment	Per Capita Spending
2007	6,668,151,925	309,724	21,529
2008	6,792,065,430	313,714	21,651
2009	6,922,162,833	314,056	22,041

Table 14: Oral drugs with an injectable equivalent

9 months	Total Payments	Enrollment	Per Capita Spending
2007	8,047,968	208.444	39
2008	11,341,027	216,088	52
2009	13,565,768	212,180	64

Table 15 Total Renal dialysis services

9 months	Per Capita Spending
2007	21,568
2008	21,703
2009	22,105

Table 16: Renal dialysis services, excluding former Part D drugs

Full Year	Total Payments	Enrollment	Per Capita Spending
2007	8,936,542,191	328,787	27,180
2008	9,105,145,441	332,509	27,383

Table 17: Oral drugs with an injectable equivalent

Full Year	Total Payments	Enrollment	Per Capita Spending
2007	11,340,484	221,154	51
2008	15,550,217	229,009	68

Table 18 Total Renal dialysis services

Full Year	Per Capita Spending
2007	27,232
2008	27,451

1. Calculation of the CY 2007 Unadjusted Rate Per Treatment

Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act, as added by MIPPA, specify the renal dialysis services, and other items and services, which must be included in the payment bundle of the ESRD PPS. We proposed to include payments for the various components (*see* Table 8 at 74 FR 49940), which comprise the renal dialysis services in the development of the proposed base rate. A detailed description of each of the components of the ESRD PPS payment bundle included in the CY 2007 unadjusted rate per treatment was discussed in the ESRD PPS proposed rule (74 FR 49941). We also described the adjustments used to calculate the ESRD PPS base rate from the CY 2007 unadjusted rate per treatment (74 FR 49942). Table 19 shows the various components of the ESRD PPS payment bundle based on CY 2007 claims, after adjustment for price inflation to 2009.

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Table 19

Average Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007, with adjustment for price inflation to 2009[1]

	Total	Average MAP per treatment
Dialysis patients	328,787	--
Hemodialysis (HD)-equivalent dialysis treatments	36,747,662	--
MAP for services in the expanded ESRD PPS		
Total for Part B and Part D services	$8,947,882,675	$243.65
Total for Part B services	$8,936,542,191	$243.19
Composite rate services	$5,792,196,328	$157.62
Separately billable services (Part B)		
EPO	$1,937,063,301	$52.71
Darbepoetin	$150,925,735	$4.11
Calcitriol	$2,645,644	$0.07
Doxercalciferol	$89,814,291	$2.44
Paricalcitol	$313,002,443	$8.52
Iron sucrose	$172,625,432	$4.70
Sodium ferric gluconate	$67,575,376	$1.84
Levocarnitine	$4,021,810	$0.11
Alteplase	$27,960,906	$0.76
Vancomycin	$3,176,525	$0.09
Daptomycin	$1,429,021	$0.04
Other injectables	$5,038,108	$0.14
Laboratory tests	$308,732,410	$8.40
Ultrafiltration	$2,563,656	$0.07
Dialysis facility supplies and IV fluids	$38,263,239	$1.04
Durable medical equipment and supplies (method II)	$18,060,483	$0.49
Dialysis support services (method II)	$1,447,484	$0.04
Dialysis patients with Part D spending	221,154	--
HD-equivalent dialysis treatments for patients with Part D spending	24,737,326	--
MAP for Part D services	$11,340,484	$0.46
Calcitriol (oral)	$2,839,032	$0.11
Doxercalciferol (oral)	$5,262,356	$0.21

Paricalcitol (oral)	$3,188,606	$0.13
Levocarnitine (oral)	$50,490	<$0.01

[1]The estimates above exclude patient facility months with no hemodialysis-equivalent treatments. The monthly hemodialysis-equivalent treatments were capped at the number of days in the month (e.g., 31 for January). Payments for EPO and darbepoetin were capped to reflect the medically unbelievable edit threshold that applied at the time (500,000 and 400,000 units of EPO per month in 2007 and 2008-09, respectively, and 1,500 and 1,200 mcg of darbepoetin per month in 2007 and 2008-09, respectively).

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As we explained above, we determined that CY 2007 was the year with the lowest per patient utilization of renal dialysis services. The categories which comprise the ESRD PPS payment bundle remain the same as set forth in the proposed rule (Table 8 at 74 FR 49940). The payment amounts associated with each component are presented in Table 19, and reflect the modifications and exclusions previously described (for example, the Part D drug component excludes oral-only drugs and biologiclas, payments for blood and blood products are excluded, payments for separately billed drugs which should be considered composite rate drugs were excluded, etc.).

a. Composite Rate Services

The first MAP component of the ESRD PPS payment bundle shown in Table 19 is "Composite rate services". This line item refers to total CY 2007 payments for composite rate services as obtained from ESRD facility claims (bill type 72X claims), inflated to 2009. This total includes all composite rate payments to ESRD facilities, including exception payments made in accordance with § 413.182 through § 413.186.

b. Part B Drugs and Biologicals

The next 11 line items in Table 19 reflect the categories of injectable drugs. In the proposed rule, we noted that the top 11 Part B drugs and biologicals accounted for 99.7 percent of total separately billable Part B drug payments (74 FR 49943). For this final rule, we found that total payments in 2007 for the top 11 Part B drugs and biologicals reported on ESRD claims, and used to calculate the base rate, accounted for 99.8 percent of total spending for Part B drugs. Monthly payments for EPO and ARANESP® were capped in accordance with the applicable medically unbelievable edits, described previously in this section. For all other injectable Part B drugs, we have provided a separate line item. In section II.A.3. of this final rule, we discuss Part B drugs and biologicals in detail.

c. Laboratory Tests

Another component of the ESRD PPS bundle shown in Table 19 is laboratory tests. Payments for laboratory tests represent the total amount paid to dialysis facilities for outpatient laboratory tests billed on ESRD claims, as well as payments for laboratory tests ordered by physicians receiving MCP amounts and billed on carrier claims. We identified laboratory tests ordered by physicians receiving MCP using the list of physicians for CY 2007, which was the latest list available in connection with the publication of the final rule. We discuss laboratory tests under the ESRD PPS in detail in section II.K.2. of this final rule.

d. Durable Medical Equipment (DME) and Supplies

DME and supplies is another component of the ESRD PPS payment bundle. Payments for these items and services were obtained from the form CMS 1500 claims for Method II home patients.

e. Dialysis Support Services

We computed a total amount for the next component of the ESRD PPS payment bundle shown in Table 19, "Dialysis support services." This total represents total payments for support services furnished to Method II home dialysis patients, and reported under subcategory 5 of revenue codes 082X through 085X on ESRD claims.

f. Supplies and Other Services Billed by Dialysis Facilities

This category of the ESRD PPS payment bundle primarily includes payments for syringes used in the administration of intravenous drugs during the provision of outpatient dialysis. These supplies and services were billed by the dialysis facilities on ESRD claims.

g. Former Part D Drugs

This amount represents total payments made on behalf of the ESRD beneficiaries with Part D coverage in CY 2007 (inflated to 2009), for the oral equivalents of injectable drugs and biologicals which were furnished for the treatment of ESRD. These drugs and biologicals (three vitamin D analogues and levocarnitine) were obtained from Part D claims submitted on behalf of the Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 with Part D coverage. We received several comments concerning payment for Part D drugs.

Comment: One commenter suggested that the payment amount for oral drugs included in the base rate use the Part D data for beneficiaries with the low income subsidy. The commenter stated that this amount would then be applied to all Medicare ESRD beneficiaries, regardless of their particular insurance arrangement (Part D coverage, retiree coverage, or out-of-pocket). The commenter believed that such an approach would likely produce a more robust estimate of the costs of the drugs for inclusion in the payment bundle.

Response: In calculating the component of the base rate which reflects payments for former Part D drugs (excluding oral-only drugs), we used Part D claims for 2007 for all Medicare ESRD beneficiaries who were enrolled in Part D. This included payments not only made by the Part D drug plan, but also payments made by or on behalf of the beneficiary, for which the Part D beneficiary was responsible. Total Part D drug expenditures for the oral equivalents of ESRD injectables were divided by the number of treatments for Medicare ESRD Part D enrollees. This amount per treatment was added to the per treatment amount reflecting total 2007 ESRD expenditures for all Medicare ESRD beneficiaries, divided by the number of treatments for those beneficiaries. Because total payments for Part D drugs were divided by the number of HD-equivalent treatments furnished to Part D enrollees, we believe that this methodology does not result in an understatement of the oral drug component of the payment bundle. Comparison of the price adjusted amounts for 2007, 2008, and available data for 2009 revealed that 2007 was the year with the lowest per patient utilization of renal dialysis services (see paragraph E. above). The NDC codes

used to identify these drugs are shown in Table D of the Appendix.

Comment: Several commenters asserted that even if CMS has the statutory authority to include oral-only Part D drugs in the calculation of the base rate, the proposed computed amount of $12.48 per treatment is inordinately low. The commenters believed the amount was too low because it reflected the amount of payments made for two-thirds of all beneficiaries divided by the number of Medicare HD-equivalent treatments provided to the entire universe of Medicare ESRD beneficiaries, including those not enrolled in Part D. One commenter stated that this represents the imposition of an unfunded mandate. After consideration of inflation, prescription rates, and patient compliance, the commenter presented an analysis suggesting that the proper per treatment amount in 2011 for oral Part D drugs should be about $45.00.

Response: We have revised the base rate component of the bundled ESRD PPS for Part D drugs so that it excludes oral-only ESRD drugs (*see* section II.A.2. of this final rule for a discussion of our decision to delay payment of oral-only ESRD drugs under the ESRD PPS until January 1, 2014). We have also revised the methodology for computing the portion of the base rate attributable to Part D drugs so that it represents the average Part D payment per treatment for each Part D enrollee. This revision responds to the commenter's concern that the payment amount included in the proposed rule was understated because it represented Part D payments for only two-thirds of all Medicare ESRD beneficiaries, divided by the number of HD-equivalent treatments for all Medicare ESRD beneficiaries. With respect to the suggestion that the Part D payment amount included in the base rate should also be adjusted to reflect increased inflation, prescription rates, and patient compliance, we decline to include these factors for the following reasons.

The commenter asserted that the actual rate of price inflation in Part D drugs would be about 16 percent annually from 2007 through 2011 based on historical data, but calculated a projection using a more conservative figure of 12.2 percent. We reject the magnitude of this projection as it differs significantly from forecasted rates of drug price inflation using the producer price index. Moreover, we believe that using projected increases in patient prescription rates and anticipated increases in patient compliance as a basis for calculating the Part D drug component of the base rate is highly speculative.

We believe the data we used for the Part D drugs that we are including in the base rate at this time are appropriate and reflect an adequate payment amount for this component of the base rate. Accordingly, we decline to incorporate the commenter's suggested variables. We note that we will address data issues pertaining to oral-only drugs and the base rate payment amount for such drugs in the future when we bundle oral-only drugs beginning January 1, 2014.

With respect to the commenter's concern that the per treatment amount for the Part D drugs component of the bundle is inordinately low because the number of treatments used reflected all Medicare ESRD beneficiaries, not just those enrolled in Part D, we point out in a response to a previous comment that we have addressed this concern by revising the computation of the base rate, so that the Part D drugs component reflects Part D payments divided by HD-equivalent treatments for Part D enrollees. With respect to the adequacy of Part D drug payments, we have delayed the inclusion of oral-only drugs until January 1, 2014. We will address data issues pertaining to oral-only drugs, and the per treatment payment amount for these drugs, in the future when these drugs are included in the payment bundle. For the Part D drugs which we are including in the ESRD PPS beginning January 1, 2011, the source data are the actual payments from the 2007 Part D claims for the oral drugs with an injectable version. We believe that these data are appropriate and adequate.

Comment: Several commenters pointed out that our proposed methodology for calculating the base rate resulted in an understatement of the Part D drug component of the payment bundle (74 FR 49940). This occurred because, while total payments for renal dialysis services (excluding Part D drugs) were properly divided by the total number of HD-equivalent treatments for Medicare ESRD beneficiaries, the total payments for Part D drugs for Medicare ESRD beneficiaries enrolled in Part D, was similarly divided by the same number of HD-equivalent treatments. This yielded an understatement in the amount of the payments per treatment for Part D drugs included in the payment bundle, because the number of treatments for Part D enrollees was overstated, reflecting total treatments for all ESRD beneficiaries instead of treatments for Part D enrollees only.

Response: The commenters are correct. In this final rule, for all components of the base rate excluding the portion for Part D drugs, we used the total number of CY 2007 Medicare HD-equivalent dialysis sessions (36,747,662) to calculate the portion of the base rate attributable to all composite rate and separately billable services. For the portion of the MAP attributable to oral Part D drugs with an injectable version, the number of CY 2007 HD-equivalent treatments used to compute the Part D drugs component was 24,737,326. This represents the number of treatments for Medicare ESRD beneficiaries enrolled in Part D.

Comment: Several commenters stated that based on a plain reading of the statute, the Congress intended CMS to take into account all of the costs for Part D drugs, regardless of Medicare beneficiaries' source of prescription drug coverage. Therefore, some commenters asserted that an accurate estimate of total Part D drug costs should include a determination of the cost of oral drugs for Medicare ESRD beneficiaries who obtain their drug coverage from Medicare Part D or through another source. One commenter included a specially commissioned study which purported to quantify the utilization of oral ESRD drugs (using pill counts) among three payer groups: Medicare Part D, private coverage (including employer coverage), and other/unclassified coverage. Because the average pill counts for specific oral ESRD drugs varied among the payer groups, the commenter suggested that this difference in utilization would need to be considered to adjust the Part D component of the base rate. In addition, the commenter recommended that CMS adjust this component to reflect anticipated changes in oral drug use, expected improvements in beneficiary adherence to oral drug regimens, and an appropriate inflation adjustment.

Response: For reasons expressed in the response to the preceding comment, we decline to adjust the Part D component of the base rate using expected increases in oral drug use, and increases in patient compliance. We also believe that we have appropriately inflated the base rate to 2011 to reflect price changes. Under the methodology for calculating the per treatment amount for the specified renal dialysis services included in the base rate, the sum of the composite rate and separately billable components is divided by the number of treatments for ESRD beneficiaries. Total payments for the oral equivalents of injectable drugs were divided by the number of treatments for Medicare ESRD Part D enrollees. These two

amounts were summed to obtain the unadjusted MAP per treatment. Therefore, the Part D component of the unadjusted base rate amount was calculated only using beneficiaries with Part D coverage.

The commenter's cited study suggests that differences in oral drug utilization occur depending on the source of the payment. Although the commenter's study was limited to a sample using 12,706 Medicare ESRD beneficiaries and did not control for differences in dosage (utilization was based on pill counts regardless of the dosage amount), we believe that a finding that the utilization of Part D drugs among Medicare ESRD beneficiaries differs depending on payer source would have no impact on our calculation of the base rate. Section 1881(b)(14)(A)(ii) of the Act refers to the total amount of payments "under this title," which we have interpreted as meaning under Title XVIII of the Social Security Act.

Therefore, even if differences in the utilization of Part D drugs among Medicare ESRD patients were confirmed based on non-Medicare sources of payment for these drugs, we believe this information could not be used to develop weighting factors to adjust the Part D component of the base rate based on differences in utilization across payer groups. Non-Medicare sources of payment for these drugs, such as employer groups, unions, private insurance, etc., could not be considered because we interpret section 1881(b)(14)(A) of the Act as requiring that the ESRD PPS reflect payments under Title XVIII for renal dialysis services.

h. Total Medicare Hemodialysis (HD)-Equivalent Sessions

In order to calculate the proposed ESRD PPS base rate per treatment, it was necessary to divide the total payments for each MAP amount described above by the number of corresponding Medicare HD-equivalent sessions. The number of Medicare HD-equivalent sessions represents the total Medicare treatments for outpatient dialysis as reported on ESRD claims submitted by dialysis facilities. For PD patients, patient weeks were converted to HD-equivalent sessions. For this purpose, one week of PD was considered equivalent to three HD treatments. Accordingly, a patient on PD for 21 days would have $(21/7) \times 3$ or 9 HD-equivalent sessions. In determining the total number of Medicare treatments, the number of HD-equivalent sessions was capped so as not to exceed the number of days in the month in which treatments were furnished.

i. Average MAP per Treatment

We summed the total payments for the composite rate and separately billable portions of the bundle. The total of $8,936,542,191 (which excludes all Part D drugs) was divided by the number of HD-equivalent treatments (36,747,662), to yield an average MAP per treatment of $243.19. The MAP per treatment for Part D drugs (excluding oral-only drugs) was similarly computed by dividing the total payment for those drugs ($11,340,484) by the number of HD-equivalent treatments for Medicare ESRD Part D enrollees (24,737,326), to obtain a MAP per treatment of $0.46. The sum of the MAP amount for all renal dialysis services excluding Part D drugs ($243.19), plus the MAP amount for the Part D drugs component, which excludes oral-only drugs, ($0.46), yielded the total average MAP per treatment for the renal dialysis services included in the ESRD PPS payment bundle. This amount, $243.65, is the unadjusted base rate amount and reflects price inflation to 2009. The renal dialysis services which comprise the base rate, both in terms of total payments for each component and the average payment per treatment, inflated to 2009, are shown in Table 19.

2. Determining the Update Factors for the Budget-Neutrality Calculation

In order to estimate payments under the current payment system for each facility in CY 2011, the first year of the ESRD PPS, the components of the CY 2007 unadjusted per treatment rate were updated to reflect estimated 2011 prices, using the methodology as described in the proposed ESRD PPS rule (74 FR 49942). It is necessary to estimate 2011 payments under the current ESRD payment system (including all separately billable items) for each facility in order to meet the statutory budget-neutrality requirement for the ESRD PPS.

Section 1881(b)(14)(A)(ii) of the Act requires that the ESRD PPS payment system be 98 percent budget neutral in 2011. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented. In the proposed ESRD PPS, we described the update factors used to estimate CY 2011 payments for each component (74 FR 49939).

a. Composite Rate Services

In order to update the basic case-mix adjusted composite payments to 2011, we began with the CY 2009 base composite rate ($133.81) and the CY 2009 drug add-on percentage of 15.2 percent. At the time of the proposed rule (74 FR 49942), in accordance with section 1881(b)(12)(G) of the Act, as amended by section 153(a)(1) of MIPPA and in accordance with section 1881(b)(14) of the Act, we updated the composite rate by 1.0 percent for CY 2010 and by the estimated ESRD bundled market basket percentage increase minus 1 percentage point (1.5 percent) for CY 2011, respectively, resulting in a proposed 2011 composite rate of $137.18.

We proposed (74 FR 49942 through 49943) to use this base composite rate for CY 2011, which included the ESRD bundled market basket update minus 1 percentage point to update the CY 2010 composite rate, for purposes of establishing the ESRD PPS base rate, given that we interpreted section 1881(b)(14)(F)(ii) of the Act to require us to update the composite rate portion of the blend by the market basket update minus 1.0 percentage point in all years of the transition (which included CY 2011). We stated that using the market basket in this way would be a consistent approach (74 FR 49943). At the time of the proposed rule, we proposed an ESRD bundled market basket update of 2.5 percent for CY 2011. Therefore, we proposed (74 FR 49942 through 49943) a 1.5 percent update to the composite rate for CY 2011, resulting in a proposed CY 2011 composite rate of $137.18 ($135.15 * 1.015).

We noted that the drug add-on percentage was reduced from 15.2 percent to 14.8 percent as a result of the increases to the composite rate in CYs 2010 and 2011. Since the drug add-on is calculated as a percentage of the base composite rate, the drug add-on percentage decreases with increases in the composite rate. The CY 2009 PFS final rule (73 FR 69755) explains why increases to the base composite rate require decreases to the drug add-on percentage to ensure that the total drug add-on dollar amount remains the same. We stated our intent to update the drug add-on, if necessary, for the ESRD PPS final rule (73 FR 69755).

In the proposed rule, we used the applicable facility-level and patient-level basic case-mix adjustments from the CY 2007 claims to re-compute payment using the applicable basic case-mix adjustments applied to a 100 percent CBSA wage-adjusted composite rate using the most recently available

ESRD wage index, which is the CY 2009 final rule ESRD wage index with a 0.60 floor. We stated that we did this to use the most recent wage indexes available in estimating 2011 payments (74 FR 49943). We also noted that the other components of the bundle discussed in the proposed rule do not have payments which are computed with wage indexes (74 FR 49943). In addition, we noted in the proposed rule that payment rates to facilities that have chosen to retain their exceptions under the basic case-mix composite payment system are not updated because, once approved, the exception amounts were fixed payment amounts, and hence the 2007 amounts represent the 2011 amounts (74 FR 49943).

We did not receive any public comments regarding our proposal with regard to composite rate services. However, following the release of the ESRD PPS proposed rule, section 3401(h) of the Affordable Care Act of 2010 amended section 1881(b)(14)(F) of the Act, by revising the ESRDB market basket update for CY 2011 from a market basket update minus one percent to a full market basket update. Thus, a 2.5 percent update to the composite rate for CY 2011, results in a final CY 2011 composite rate of $138.53 ($135.15 * 1.025). We note that $135.15 is the final CY 2010 composite rate, which was derived from the CY 2009 composite rate of $133.81 increased by one percent as required by section 153(a)(1) of MIPPA ($133.81 * 1.01). We also note that, as discussed in the CY 2011 PFS proposed rule issued on June 25, 2010, we have used the proposed CY 2011 drug add-on percentage of 14.7 percent, and the CY 2011 proposed ESRD wage index values with a 0.60 floor for computing the ESRD PPS budget neutral base rate. In this way, we are using the most current data available for computing the final CY 2011 ESRD PPS base rate. The final CY 2011 ESRD PPS base rate will not be adjusted to reflect final decisions regarding the drug add-on percentage and the wage index floor for CY 2011. However we note that we will use the final drug add-on and wage index floor values in computing the composite rate portion of the blended payments during the transition.

b. Self-Dialysis support services for Method II patients

Currently, the allowance per month under Method II for home dialysis support services may not exceed $121.15 per month for all forms of dialysis. Since home dialysis support services for Method II patients are subject to a monthly capitation payment that is not increased, we proposed (74 FR 49943)that the CY 2007 amounts represent the CY 2011 amounts.

We did not receive any public comments regarding our proposal. Since the monthly capitation payment has not increased, we are finalizing the approach that the CY 2007 amounts represent the CY 2011 amounts.

c. Part B Drugs and Biologicals

Under the current system, payments for ESRD drugs and biologicals under Part B are paid on average sales price plus 6 percent (ASP+6 percent) methodology. For the proposed rule, we reviewed ASP prices for four quarters of 2006, 2007, 2008, and two quarters of 2009 for the top eleven separately billable drugs. We proposed to use the 2009 prices as a proxy for 2011 values (74 FR 49943). We indicated that we would revaluate our decision with updated quarterly ASP pricing data.

For other ESRD-related Part B drugs, we used a proposed weighted average of the top eleven Part B drugs to update those drug prices to 2011. As the top eleven drugs represented 99.7 percent of total separately billable Part B drug payments at the time of the proposed rule, we indicated that the overall weighted average was representative of the remaining 0.3 percent of drugs. (*See* Table 10 in the ESRD PPS proposed rule (74 FR 49943) for the price updates used.) We have refined our data and the top eleven drugs that now represent 99.8 percent of total separately billable Part B drug payments.

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

Comment: Commenters expressed concern about the lack of an update for ASP-priced drugs and biologicals and suggested that we use the Producer Price Index for Drugs (PPI) to inflate Part B drug prices.

Response: We agree with the commenters about the need for an update in ASP prices for Part B drugs and to use the PPI for the update. For that reason, we took the latest available ASP pricing data, which represented the second quarter of 2010, and updated these prices using the PPI for drugs. This update resulted in a 3.9 percent increase to the top eleven separately billable Part B Drugs from 2010 to 2011. Similar to the proposed rule, since the top eleven drugs account for over 99 percent of total spending, for the final rule we used a weighted average growth of the top eleven drugs (4.6 percent) for the remaining Part B drugs. Table 20 below shows the price increases, from 2007 to 2011, of the separately billable Part B drugs.

Table 20: Price Increases from 2007 to 2011 of Separately Billable Part B Drugs

Drugs and biologicals	Price Updates
EPO	7.0%
Paricalcitol	-3.2%
Sodium_ferric_glut	-0.2%
Iron_sucrose	2.6%
Levocarnitine	-22.5%
Doxercalciferol	16.6%
Calcitriol	-26.3%
Vancomycin	-3.1%
Alteplase	16.9%
Aranesp	-9.0%
Daptomycin	30.1%
Other injectables	4.6%

d. Laboratory Tests

We proposed to update payments for laboratory tests paid through the laboratory fee schedule to 2011 using projected CPI–U increases and any legislative adjustments that would be applied to this fee schedule (74 FR 49943). Using this approach, we proposed (74 FR 49943) a growth update of 5.1 percent from 2007 to 2011.

We did not receive any public comments regarding our proposal. Since the CPI–U increase, with any legislative adjustments, is the statutory updated required for laboratory testing, we are finalizing this approach. However, we have updated the growth percentage using more recent forecasts of the CPI–U data. For this final rule, the growth from 2007 to 2011 is 3.9 percent.

e. DME Supplies and Equipment

Since payments for supplies and equipments for Method II patients are subject to a monthly capitation payment that has not increased, we proposed that the CY 2007 amount represents the 2011 amounts (74 FR 49943).

We did not receive any public comments regarding our proposal. Therefore, for the reasons above, we are finalizing the proposed approach for updating the amount for DME supplies and equipment.

f. Supplies and Other Services

This category primarily includes the $0.50 administration fee for separately billable Part B drugs. Since this fee has not increased, as there is no update for such fees, we proposed no price update (74 FR 49943).

We did not receive any public comments regarding our proposal. Given that the administration fee has not increased, we are finalizing the proposed approach for supplies and other services.

g. Former Part D Drugs

We proposed that former Part D drugs would be updated by the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections and referred to the following link for further information on the National Health Expenditure Projections: *http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp#TopOfPage.* Using the National Health Expenditure Projections, we proposed a growth of 12.2 percent from 2007 to 2011 (74 FR 49943). We proposed this approach because we did not have enough data to establish a trend for Part D prices and we use this price growth in the overall Part D projections. Therefore, we believed it was an adequate proxy for updating prices for former Part D drugs.

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

Comments: A few commenters suggested the use of the PPI to update the Part D drugs.

Response: We continue to feel that the growth rates for overall prescription drug prices that are used in the National Health Expenditure Projections are the best proxy, as they are consistent with the price growth proxy used in Part D spending projections. However, due to new National Health Expenditure Projections, the final growth for Part D drugs is 12.9 percent. This growth factor would be applied to those Part D drugs that are to be included in the ESRD PPS bundle as of January 1, 2011. We note that oral-only Part D drugs will not be included until after the transition, as discussed in section II.A.3. of this final rule.

Once we determined updated CY 2011 payments for each component of the items and services discussed above, we proposed to add the components together to determine each ESRD facility's total payments under the current payment system in CY 2011. These estimated total 2011 MAPs divided by the total 2007 Medicare HD-equivalent sessions yielded the proposed unadjusted per treatment base rate for renal dialysis services in CY 2011 of $261.58 (74 FR 49944).

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

Comments: We received comments that we should account for increases in enrollment and utilization in determining the base rate.

Response: We do not typically make utilization increase assumptions in setting budget neutrality for PPS payment systems. In addition, the statute requires us to use the utilization for the lowest of 2007, 2008 and 2009. Enrollment growth assumptions would not affect a per treatment rate calculation, as it would increase total spending and total treatments.

However, due to changes in the components of the final ESRD PPS bundle described in section II.A. of this final rule, the final updated unadjusted per treatment base rate for renal dialysis services in CY 2011 is $251.60. We note that the reduction is primarily due to the delay in implementing oral-only Part D drugs under the ESRD PPS, as we have removed these MAPs from the unadjusted base rate computation. Other changes related to the composition of

the final ESRD bundle and hence the reduction in the unadjusted per treatment base rate are discussed in section II.A. of this final rule.

We are finalizing $251.60 as the starting point for further adjustments in determining the final ESRD PPS per treatment base rate. The 2011 unadjusted average payment per treatment of $251.60 was then used in the payment model to estimate final total payments under the ESRD PPS in CY 2011. These final CY 2011 ESRD PPS estimated payments are based on treatment data from the CY 2007 claims file.

3. Standardization Adjustment

CY 2011 payments under the proposed ESRD PPS were initially estimated without a budget-neutrality adjustment, using the unadjusted CY 2011 average payment per treatment amount of $261.58 (74 FR 49944). We calculated the proposed PPS payments using treatment counts from the 2007 claims file. The wage index and all applicable proposed patient-level and facility-level adjustments were applied to the unadjusted CY 2011 average payment per treatment to determine the estimated payment amount under the proposed ESRD PPS for each treatment and ESRD facility. We noted that to simulate payments, we used the latest available final CY 2009 ESRD wage indexes, with no floor (74 FR 49944) because it was the latest available wage index data at the time, and we had proposed to apply no floor to the PPS payments beginning January 1, 2011. In the proposed rule, we discussed how we standardized payments (74 FR 49942) and calculated the standardization factor (74 FR 49944) for the ESRD PPS.

Payments were standardized to account for the overall effects of the proposed ESRD PPS case-mix patient and facility adjustment factors and wage indexes. We must standardize payments in order to ensure that total projected PPS payments are equal to the payments under the current basic case-mix adjusted composite payment system. The proposed standardization factor was calculated to be 21.73 percent. As a result, the proposed CY 2011 unadjusted per treatment base rate of $261.58 was reduced by 21.73 percent to $204.74 (74 FR 49944).

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

Comment: We received numerous comments disagreeing with the significant reduction in the per treatment base rate caused by standardization. The commenters indicated that the per treatment base rate is too low to account for their high staffing and medical costs. The commenters suggested fewer adjustments yielding a smaller standardization adjustment and a high per treatment base rate.

Response: In an effort to respond to the concerns expressed about the amount of the base rate, as discussed in section II.F.3. of this final rule, we have removed a number of patient adjustments and co-morbidity categories. Following the methodology from the proposed rule, we have recomputed the standardization adjustment using the final ESRD PPS adjustments. The final standardization factor was calculated by dividing total estimated payments in 2011 under the current payments system by estimated payments under the final ESRD PPS in 2011. We have used the same method as in the proposed rule and since we received no comments on the standardization calculation, we are finalizing this approach and § 413.220(b)(3) as proposed. The final standardization adjustment is .9407 or a reduction of 5.93 percent from the unadjusted per treatment base rate. As a result, the CY 2011 standardized per treatment base rate is $236.68.

Based upon our review of the public comments and for the reasons described above, we are finalizing § 413.220(b)(3). However, we have corrected the cross reference to reflect the patient-level and facility-level adjustment sections (§ 413.231 through § 413.235).

4. Calculation of the Budget-Neutrality Adjustments

a. Outlier Adjustment

Section 1881(b)(14)(D)(ii) of the Act provides that the ESRD PPS shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management. We proposed that outlier payments be applied in a budget neutral manner, as doing so would ensure that estimated total payments under the proposed ESRD PPS equals 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented (74 FR 49944).

To ensure that the proposed outlier policy (74 FR 49944) under the ESRD PPS is budget neutral, we proposed to reduce the base rate by the proposed outlier percentage, or 1.0 percent. Specifically, we proposed to reduce the base rate from $204.74 to $202.69. We did this to account for the 1.0 percent of aggregate ESRD PPS payments estimated to be made as outlier payments. We then re-estimated the prospective payment amounts with the new reduced base rate of $202.69, allowing 1.0 percent of payments to be outliers. The outlier amount was computed for all treatments and the total outlier payment amount across all treatments was added to the prospective payment amount for all treatments.

We did not receive any public comments regarding our proposal to reduce the base rate to account for the outlier percentage and, therefore, we are finalizing 413.220(b)(4) as proposed. Specific comments about the outlier policy are discussed in section II.H. of this final rule. However, using the final standardized base rate of $236.68, we reduced this amount by 1.0 percent to account for outlier payments. This reduction resulted in a revised base rate of $234.31.

b. 98 Percent Budget-Neutrality Adjustment

Section 1881(b)(14)(A)(ii) of the Act requires that the ESRD PPS payment system be 98 percent budget neutral. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS had not been implemented. Therefore, we proposed to reduce the 2011 standardized base rate, which was already adjusted for 1.0 percent outlier payments, by an additional 2.0 percent, from $202.69, to yield a proposed base rate of $198.64 (74 FR 49944).

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

Comment: We received numerous comments indicating that the proposed per treatment base rate of $198.64 is too low to account for the costs of dialysis.

Response: As we indicated in the previous section, due to changes made to the final ESRD PPS payment model (specifically, the patient-level and facility-level adjustment factors described in sections II.F.3. and II.F.4, respectively, of this final rule), the final standardization adjustment is considerably lower that the proposed adjustment. For this reason, the final standardized base rate used as the starting point for the budget-neutrality adjustments is over $31 higher than the proposed amount.

Comment: Several commenters requested that the outlier percentage be

withheld after the 98 percent budget-neutrality adjustment.

Response: The budget-neutrality adjustments are multiplicative, and as a result, the order of the reductions has no effect on the final adjusted base rate. The adjustments for the outlier payments and the 98 percent budget-neutrality requirement are needed to ensure that total payments under the PPS are equal to 98 percent of payments under the current basic case-mix adjusted composite payment system.

In consideration of the comments received and for the reasons discussed above, we are finalizing § 413.220(b)(5). However, we have deleted the cross-references to the ESRD PPS regulatory citations. Instead, we have revised the language to clarify that CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under Title XVIII of the Act if the ESRD PPS described in section 1881(b)(14) of the Act were not implemented. We made this change because we believe the revised language is more straightforward and clear.

To summarize, the final base rate per treatment with an outlier adjustment and budget-neutrality is calculated to be $229.63. This amount includes a 5.93-percent reduction from $251.60 to account for standardization to the projected CY 2011 current system payment per treatment, a 1.0 percent reduction to account for outlier payments, and a 2.0 percent reduction for the required 98 percent budget-neutrality. We note that if the reader were to multiply the outlier adjusted base rate of $234.31 by .98 for the budget-neutrality requirement, they would calculate $229.62. However we did not round the figures in the calculation of each step and arrived at $229.63.

5. Calculation of the Transition Budget-Neutrality Adjustment

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

Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition. An ESRD facility that elects to be excluded from the transition receives payments for renal dialysis services provided on or after January 1, 2011 based on 100 percent of the payment rate under the ESRD PPS, rather than a blended payment based in part on the payment rate with regard to the current basic case-mix adjusted composite payment system and in part on the payment rate under the ESRD PPS. The proposed implementation of the transition is discussed in detail in the proposed rule (74 FR 50003). Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments for renal dialysis services provided by ESRD facilities during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition.

In the proposed rule (74 FR 49944 through 49947), we discussed that the transition budget-neutrality adjustment would be comprised of two parts. First, we proposed to make a payment adjustment under the basic case-mix adjusted composite payment system portion of the blended rate during the transition to account for the per treatment costs of drugs that are currently paid under Part D. Second, we proposed to compute a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition equal the estimated total amount of payments that would otherwise occur without such a transition (3.0 percent reduction).

In the proposed rule, we described in detail our rationale for the transition budget-neutrality adjustment and alternatives considered (74 FR 49944). We invited comments on the calculation and application of the proposed two-part transition budget-neutrality adjustment factor. The comments we received on this proposal and our responses are set forth below.

Comment: We received numerous comments about the proposed transition budget-neutrality adjustment. Many commenters focused on the transition budget-neutrality adjustment related to payment for Part D oral drugs. The commenters indicated that the proposed $14 adjustment is too low and does not reflect all of the ESRD patients covered under the ESRD PPS.

Response: As discussed in section II.A.3. of this final rule, although oral-only Part D drugs meet the definition of renal dialysis services and are included in the ESRD PPS bundle, we are not implementing these drugs under the PPS until after the transition. That section also addresses our rationale for the Part D component of the base rate and the data used for that analysis. As a result, we removed the amounts for those drugs from the base rate. However, oral drugs or other forms of ESRD-related Part B injectable drugs are in the ESRD PPS bundle and will be implemented January 1, 2011.

In addition, as discussed in section II.E. of this final rule, based on the comments, we reviewed our methodology to determine if there were ways to compute the Part D per treatment amount that would more accurately reflect payments for Part D ESRD-related drugs by ESRD beneficiaries. As a result of this review, for this final rule we revised the method of computing the Part D per treatment amount to divide by the number of Part D enrolled ESRD beneficiaries rather than total ESRD beneficiaries. As a result of these changes, the final transition budget-neutrality adjustment related to Part D drugs has been recomputed to be $.49. If we had not changed our methodology to divide by the number of Part D enrolled ESRD beneficiaries and had instead divided by the number of Part B enrolled ESRD beneficiaries, we would have calculated the Part D per treatment amount to be $.33. While we recognize the $.49 does not cover all the ESRD patients under the PPS, the statue limits us to payments made under Title XVIII of the Act.

Comment: Numerous commenters questioned CMS's legal authority to impose a transition budget-neutrality adjustment. They expressed concern about the proposed 3.0 percent reduction going beyond the 98 percent budget neutrality requirement in 2011. Commenters also expressed concern about the size of the transition budget-neutrality adjustment related to the cost of the transition. The commenters indicated that the adjustment was too high and may not reflect ESRD facility decisions regarding the transition, and expressed concern about our proposed method of determining which facilities would choose to opt out of the transition. Several commenters believed that the 3.0 percent reduction during the years 2012 and 2013 will go beyond the 98 percent budget-neutrality requirement. Commenters expressed concern that we should consider 2012 and 2013 payments in calculating this part of the transition budget-neutrality adjustment.

Response: We believe section 1881(b)(14)E)(iii) of the Act requires us to implement the transition budget-neutrality adjustment. We do not believe the proposed 3.0 reduction goes

beyond the 98 percent budget neutrality requirement; as it is necessary to ensure that total payments under the PPS do not exceed the 98 percent requirement. Since we assume that facilities will act in their best financial interest and opt to transition if it is beneficial, it is likely that total payments would exceed what is allowed. As we discussed in the proposed rule (74 FR 49946), we proposed to apply this adjustment to both the ESRD PPS and the blended payment so as not to affect provider decisions in opting out of the transition.

We recognize that the transition budget-neutrality adjustment may not reflect actual choices made by ESRD facilities regarding opting out of the ESRD PPS transition. We are requiring that ESRD facilities notify their FI/MACs by November 1, 2010 of their decision to opt out of the ESRD PPS transition. We are unable to wait until then to establish the transition budget-neutrality adjustment which is necessary to meet statutory budget-neutrality requirement.

As a result, we based the final transition budget-neutrality adjustment on our best projections of how ESRD facilities will fare under the ESRD PPS compared to the basic case-mix adjusted composite payment system. With regard to conducting the analysis using 2012 and 2013 projections, we note that the transition budget-neutrality adjustment will be updated each year of the transition to reflect the appropriate blend of PPS and composite rate payments. We agree that it is not possible for us to predict accurately which facilities will opt out of the ESRD PPS transition. Given that the transition budget neutrality adjustment applies in each year of the transition, we are considering whether to prospectively correct for over or understatement of the number of facilities that choose to opt out of the transition when we update the adjustment for 2012. We would address this issue in rulemaking for the CY 2012 ESRD PPS.

We conducted a preliminary analysis for the final rule, to simulate payments for 2012 and 2013 in order to assess whether considering these years in the calculation of the transition budget-neutrality adjustment is warranted due to the change in the blend of payments for those years. We determined that it makes very little difference in the adjustment calculation.

In consideration of the public comments and for the reasons described above, we are finalizing § 413.220(b)(6).

In § 413.239(d), we proposed to apply the transition budget neutrality adjustment during the first three years of the transition. As this characterization of the period during which the transition budget neutrality adjustment applies, we are revising proposed § 413.239(d) to clarify that there is a 4-year transition period.

In summary, for the final rule, due to revised estimates of simulated payments under the current basic case-mix adjusted payment system and under the ESRD PPS payment system by facility, we estimate that 43 percent of ESRD facilities will choose to be excluded from the transition and that 57 percent of ESRD facilities will choose to be paid the blended rate during the transition. Consequently, we estimate that during the first year of the transition, total payments to all ESRD facilities would exceed the estimated payments under the ESRD PPS in the absence of the transition.

Thus, in order to maintain the 98 percent budget-neutrality required by section 1881(b(14)(E)(iii) of the Act during the initial year of the transition period, we are finalizing the reduction of all payments to ESRD facilities in CY 2011 by a factor that is equal to 1 minus the ratio of the estimated payments under the ESRD PPS were there no transition (that is, 98 percent of total estimated payments that would have been made under the current basic case-mix adjusted payment system) to the total estimated payments under the transition, or 3.1 percent.

For 2011, application of this factor would result in a 3.1 percent reduction in all payments to ESRD facilities, that is, we intend to apply this adjustment to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS. We are finalizing this approach because, as we stated in the proposed rule (74 FR 49946), we believe that it would evenly distribute the effect of the transition budget-neutrality adjustment and it would not affect ESRD facilities' incentives with respect to whether to opt out of the transition.

F. Regression Model Used To Develop Final Payment Adjustment Factors

1. Regression Analysis

In the proposed rule, we described the two-equation methodology used to develop the proposed adjustment factors that would be applied to the base rate to calculate each patient's case-mix adjusted payment per treatment (74 FR 49947 through 49949). The two-equation approach used to develop the proposed ESRD PPS included a facility–based regression model for composite rate service, and a patient-level regression model for separately billable services. The composite rate and separately billable components of the model described in the proposed rule, used CY 2004–2006 Medicare cost report and claims data to develop the specific adjusters associated with the variables included in the payment model (74 FR 49947).

For purposes of developing the payment adjusters included in this final rule, we have updated the proposed two-equation methodology using CY 2006–2008 Medicare cost report and claims data. These are the latest available cost reports and claims given the time necessary for the preparation of this final rule. We have also reduced the number of co-morbidities and revised the definitions of co-morbidities for which payment adjusters apply; modified the separately billable regression model so that it reflects information for a patient-month rather than patient-year; added facility training status as a control variable; and eliminated sex and race as payment variables.

The addition of facility training status as a control variable and modification to the separately billable regression so that it reflects information for a patient-month rather than patient-year are described below. The basis for the reduction in the number of co-morbidities used to develop the case-mix adjusters and elimination of sex and race as payment variables are discussed in section II.F.3. of this final rule. For this final rule, the measures of resource use, specified as the dependent variables for developing the payment model in each of the two equations, are also explained below.

a. Dependent Variables

i. Average Cost per Treatment for Composite Rate Services

As described in the proposed rule (74 FR 49947) and for purposes of this final rule, we measured resource use for the maintenance dialysis services included in the current bundle of composite rate services, using ESRD facility data obtained from the Medicare cost reports for hospital-based ESRD providers and independent ESRD facilities. The average composite rate cost per treatment for each ESRD facility was calculated by dividing the total reported allowable costs for composite rate services for CYs 2006, 2007, and 2008 (Worksheet B, column 11, rows 7–16 on CMS 265–94; Worksheet I–2, column 11, rows 2–11 on CMS 2552–96) by the total number of dialysis treatments and Worksheet C, column 1, rows 1–10 on CMS 265–94; Worksheet I–4, column 1, rows 1–10 on CMS 2552–96). CAPD and CCPD patient weeks were multiplied by

3 to obtain the number of HD-equivalent treatments. We point out that our computation of the total composite rate costs included in this per treatment calculation includes costs incurred for training expenses, as well as all costs incurred by ESRD facilities for home dialysis patients.

The resulting composite rate cost per treatment was adjusted to eliminate the effects of varying wage levels among the areas in which ESRD facilities are located using the proposed ESRD PPS CY 2011 wage index published July 13, 2010, in connection with the proposed CY 2011 physician fee schedule (PFS)(75 FR 40673), and the estimated labor-related share of costs from the composite rate market basket. This was done so that the relationship of the studied variables on dialysis facility costs would not be confounded by differences in wage levels. The description of that labor-related share was contained in the Secretary's 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.*

The proportion of composite rate costs determined to be labor-related (53.711 percent of each ESRD facility's composite rate cost per treatment) was divided by the ESRD wage index to control for area wage differences. No floor or ceiling was imposed on the wage index values used to deflate the composite rate costs per treatment in order to give the full effect to the removal of actual differences in area wage levels from the data. We applied a natural log transformation to the wage-deflated composite rate costs per treatment to better satisfy the statistical assumptions of the regression model, and to be consistent with existing methods of adjusting for case-mix, in which a multiplicative payment adjuster is applied for each case-mix variable.

As with other health care cost data, there was skewness in the cost distribution for composite rate services in which a relatively small fraction of observations account for a disproportionate fraction of costs. Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria, were excluded from further analysis. (For an explanation of the statistical outer fence methodology used to identify unusually high and low composite rate costs per treatment, see pages 45 through 48 of UM–KECC's February 2008 report.)

ii. Average Medicare Allowable Payment (MAP) for Separately Billable Services

For purposes of the final rule, resource use for separately billable ESRD-related services was measured at the patient level using the payment data on the Medicare claims for CYs 2006–2008. This time period corresponded to the most recent three years of Medicare cost report data that were available to measure resource use for composite rate services. Measures of resource use included the following separately billable services: injectable drugs billed by ESRD facilities, including ESAs; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by ESRD facilities; other services billed by ESRD facilities, including support services for Method II home patients; medical equipment and supplies for Method II home patients billed by durable medical equipment suppliers.

In the proposed rule, we stated that complete data for CYs 2006–2008 for Part D claims were not available in sufficient time for the development of the proposed case-mix adjusters (74 FR 49947). Our decision not to implement oral-only drugs in the ESRD PPS until after the transition period ends January 1, 2014, as explained in section II.A.3. in this final rule, means that only oral drugs with an injectable version (that is, drugs other than oral-only drugs) would be relevant for inclusion in the separately billable regression model. Total payments for these drugs in 2007 and 2008 averaged about $12.8 million each year, an amount which on a per treatment basis would have a minimal impact on the magnitude of the case-mix adjustments.

In addition, there is a technical issue of how payments for prescription drugs taken at home over a period of time should be linked to specific patient HD-equivalent treatments, so that the regression results for patient utilization of separately billable services would not be distorted. Because of the time necessary to prepare for this final rule, we deferred resolution of this issue. Given that oral drugs and biologicals included in the payment bundle represent a very small proportion of the total annual total expenditures for the renal dialysis services included in the ESRD PPS ($8.8 billion in 2007), we believe that not including these drugs in the regression model used to develop the case-mix adjusters at this time is of little consequence.

We will need to revisit this issue prior to the expansion of the ESRD PPS to include all oral ESRD-related drugs and biologicals beginning in January 2014, because expenditures for oral-only ESRD-related drugs are significantly higher ($445 million in 2007), compared to those for the oral and other forms of injectable drugs. Including drug expenditures of this magnitude in the regressions used to develop the case-mix adjusters could impact the size of the adjustment factors in the ESRD PPS and will need to be evaluated. Accordingly, the regression model set forth in this final rule does not reflect the inclusion of oral or other forms of injectable ESRD-related drugs. Although these drugs have been excluded from the regression model, we point out that payments for these drugs have been included in the calculation of the ESRD base rate to which the case-mix adjusters will be applied.

We obtained Medicare claims data for separately billable services for CYs 2006–2008 for patient-months in which outpatient dialysis was provided and Medicare was the primary payer. Measures of resource use were based on MAPs, which were calculated using the payment data on the claims.

Medicare payments were inflated by a factor of 1.25 for services that have a 20 percent patient co-insurance (for example, ESRD-related injectable drugs), to yield the MAP. For laboratory tests that have no patient co-insurance obligation, the Medicare payment is identical to the MAP. The MAP amounts do not include the annual Part B payment deductible which may apply to separately billable services because we were unable to determine whether the deductible amount was incurred in connection with another Part B service. We point out that the Part B payment deductible can apply in connection with any Part B service, not just outpatient dialysis. As required under section 1881(b)(14)(B) of the Act, vaccines are excluded from the ESRD PPS and, therefore, were excluded from the computation of separately billable drugs.

Comment: One commenter questioned why CMS repriced injectable drugs, but not other payments included in the analysis. The commenter noted that the repricing was done to the first quarter of 2008 and pointed out that the ASP value for EPO for this period was the lowest value for the drug in four years. The commenter stated that the effect of selecting this quarter was to reprice several injectable drugs downward, dampen variations in payments, and lower the value of the case-mix adjustments.

Response: In the proposed rule, we repriced the payments for injectable drugs for CYs 2004–2006 to the first quarter of 2008. This was accomplished by using a ratio which was obtained by dividing the Medicare payment rate in the first quarter of 2008 by the Medicare rate in 2004, 2005, and 2006. The ratios used to adjust the MAPs for the 11 specified injectable drugs were shown in Table 11 in the proposed rule (74 FR 49948). The basis for the repricing of the top 11 injectable drugs in the proposed rule was due to the shift in the drug pricing methodology in 2006, from Average Wholesale Price to ASP+6 percent. The first quarter of 2008 was selected as the end quarter for the repricing because it represented the latest available quarter for which we had pricing information, consistent with the lead time necessary for the preparation of the proposed rule.

There was no attempt to select a quarter which would lead to reduced prices and reduced case-mix adjustments. For this final rule, we believe there is no need to reprice injectable drugs due to a change in the pricing methodology, because CY 2006, 2007, and 2008 drug prices consistently reflect the ASP+6 percent method.

The adjusted MAP values were standardized to reflect the number of Medicare outpatient dialysis treatments reported on the claims. This approach is consistent with the unit of payment under the current composite payment system. For patients who received PD during the month, the number of PD days reported on the claims was multiplied by 3/7 to obtain the number of HD-equivalent treatments. For example, 7 PD days were converted to 3 treatments since hemodialysis is typically performed 3 times per week. Monthly treatments reported on the claims were capped so as not to exceed the number of days in the month treatments were furnished, as treatments in excess of this number were considered clinically implausible.

Comment: Several commenters pointed out that our exclusion of claims in which the average utilization of EPO per treatment exceeded 30,000 units based on clinical implausibility was inconsistent with CMS's ESA Claims Monitoring Policy.

Response: We agree with the commenters and have revised the thresholds to conform with the medically unbelievable edit thresholds (MUE) for EPO and ARANESP® applicable to each year. Payments for EPO and ARANESP® in excess of the MUE thresholds of 500,000 units for EPO in 2006 and 2007, and 400,000 units in 2008 were excluded from the claims. Similarly, payments for ARANESP® in excess of the MUE thresholds of 1500 mcg in 2006 and 2007, and 1200 mcg in 2008 were also excluded from the claims. The ratio of the adjusted MAP values for separately billable services divided by the total number of treatments was used to calculate the average adjusted MAP per treatment.

As with the analysis of composite rate services described in section II.D. of this final rule, we similarly used the statistical outer fence methodology to exclude unusually high separately billed values. Claims with total separately billed amounts greater than $2,545.65 were excluded from the analysis of 2006 through 2008 data, used to develop the separately billed portion of the ESRD PPS payment model for patients age 18 and older. For the analysis used to develop the separately billed portion of the ESRD PPS payment model for pediatric patients for purposes of the pediatric payment adjustment, the application of this methodology resulted in no exclusions.

b. Independent Variables

In the proposed rule, we explained that two major types of independent or predictor variables were included in the composite rate and separately billable regression equations—case-mix payment variables and control variables (74 FR 49948 through 49949). Case-mix payment variables were included as factors that may be used to adjust payments in either the composite rate or in the separately billable equation. Control variables, which generally represent characteristics of ESRD facilities such as size, type of ownership, facility type (whether hospital-based or independent), etc., were specifically included to obtain more accurate estimates of the payment impact of the potential payment variables in each equation. Control variables were excluded from consideration as actual payment adjusters because they represent facility characteristics rather than patient characteristics. In the absence of using control variables in each regression equation, the relationship between the payment variables and measures of resource use may be biased.

i. Control Variables

In the proposed rule, we described seven control variables that were included in the regression analysis (74 FR 49948). They were: (1) Renal dialysis facility type (hospital-based versus independent facility); (2) facility size (<3,000 for less than three years, 3,000–5,000, 5,000–10,000, and > 10,000 dialysis treatments); (3) type of ownership (independent, large dialysis organization, regional chain, unknown); (4) whether the ESRD facility received a composite rate payment exception between November 1993 and July 2001; (5) adequacy of dialysis, based on the percentage of patients having a urea reduction ratio (URR) < 65 percent; (6) rural versus urban location; and (7) calendar year. For the proposed rule, calendar years 2004, 2005, and 2006 were included as a control variable in analyses that pooled three years of data. In order to avoid excluding dialysis facilities that treated PD patients from the analysis with control variables, for these facilities, if no URR was available for any patients in the facility, we used the average percentage of patients with a URR greater than 65 percent.

For this final rule, we have added an eighth control variable, training treatments, in which the proportion of training treatments furnished by each dialysis facility is specified. This was done in order to remove any confounding cost effects of training on other independent variables included in the payment model, particularly the onset of dialysis within 4-months variable. In addition, for the calendar year control variable, we have used CYs 2006, 2007, and 2008 in analyses that pooled 3 years of data.

ii. Case-Mix Adjustment Variables

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix, but gives the Secretary broad discretion with regard to the selection of patient-specific measures which would comprise the case-mix adjusters. In the proposed rule, we stated that as part of our case-mix analysis, we identified the same patient demographic variables used in connection with the basic case-mix adjusters under the current composite payment system: age (five groups, excluding patients less than age 18), BSA, and low BMI (values less than 18.5 kg/m^2) (74 FR 49949)). BSA was calculated as a function of height (H, in centimeters) and weight (W, in kilograms) using the following formula:

$$BSA = 0.007184 \times H^{(0.725)} \times W^{(0.425)}$$

BMI values below 18.5 kg/m^2 were used to identify patients who were underweight. BSA and low BMI are currently used as part of the basic case-mix adjustment for the composite payment system.

The same set of independent variables was included in both the composite rate and separately billable regression equations. To define the independent

variables for each equation, however, it was necessary to link patient and facility-level data. For example, measures for patient characteristics (for example, female gender) were included as potential payment variables in the facility-level composite rate equation, while measures for facility characteristics (for example, hospital-based or independent facility) were included as control variables in the patient level separately billable equation. For the composite rate equation, we defined case-mix measures using data for all Medicare dialysis patients treated in each facility. Specifically, we determined the percentage of a facility's patients having each patient characteristic. For example, patient sex was measured as the percentage of patients that were female. For the equation of the separately billable MAPs, we defined measures for facility characteristics using data for all facilities that treated each Medicare dialysis patient.

These patient and facility control variables were weighted to give greater emphasis to patient and facility observations that accounted for more of the care that was delivered, based on the number of dialysis treatments. For example, in defining facility-level case-mix measures, the characteristics of patients who were treated at the dialysis facility for twelve full months (for example, with 13 treatments each month), were given twelve times as much weight as the characteristics of patients who were treated at the facility for only 1 month (that is, with 13 treatments). Similarly, to define patient-level measures for the control variables, the characteristics of the facility that treated the patient for nine full months were given three times as much weight as the characteristics of the facility that treated the patient for the remaining three full months.

The resulting case-mix variables were examined as potential payment variables in the composite rate equation (for example, percent female and average BSA among patients in each facility). This was the same approach used to define the basic case-mix measures under the composite payment system. The resulting facility variables were included as control variables in the separately billable equation (for example, percent of a patient's treatment furnished in a hospital-based facility).

We have not departed from the use of facility control and patient-specific variables as described above in developing the case-mix adjusters set forth in this final rule. In the sections that follow, in response to public comments and for the reasons outlined below, we describe how we reevaluated and revised the proposed independent variables for use as potential case-mix adjusters in the ESRD PPS to determine their relationship to composite rate costs and separately billable payments.

Before we explain how the final set of case-mix adjustment variables was determined, we must first explain the difference between an annual model and a monthly model in connection with the separately billable regression equation component of the two equation model used to develop the case-mix adjustments. There are subtle but important differences in the interpretation of what variation in costs is being captured by the case-mix multipliers depending upon whether an annual model or monthly model is used. This has particular relevance in connection with the multipliers for co-morbidities.

2. Choosing Between a Separately Billable Model Based on Patient-Year or Patient-Month Data

The composite rate cost component of the two-equation model is based on Medicare cost reports that are submitted annually. The separately billable payment portion of the two-equation model is based on claims submitted monthly by ESRD facilities. Accordingly, the composite rate model is based on data that are observed annually, while the separately billable model is based on data that are observed monthly. In order to create consistency between the two models, the various versions of the separately billed models which we have analyzed have been based on annualized data.

For a chronic condition, the measurement of the co-morbidity at the annual or monthly level does not vary, because the patient either always has the condition or never has it. Aside from first time diagnoses, there is no distinction in how the co-morbidity is coded on an annual or monthly level, that is, patients will either have a zero or one for the variable. However, most patients with acute conditions (as will be shown later), are measured as present in the current month of treatment or previous 3 months, only have the condition for part of the year. Therefore, the coding of the co-morbidity variable for an acute condition will differ substantially on the annual versus monthly basis. On an annual basis, the value often lies between zero and one, representing the fraction of treatments in the year which occurred in months with the co-morbidity present (currently or within the three prior months). On a monthly basis, the value for the co-morbidity variable will be either zero or one, depending on whether the diagnosis is present in that month or the three preceding months.

We believe this distinction is important. The values of the case-mix adjustments for the acute co-morbidity variables in an annual model compared to a monthly model, create subtle but significant differences in the interpretation of what variation in costs the multipliers capture. Statistically, an omitted variable bias occurs when variables that predict the outcome (cost) are not included in the model, but are correlated with some of the variables that are included. As more variables predictive of costs are dropped from the model, the magnitude of the bias tends to increase. In this context, the proper interpretation of the multipliers is that they capture the costs directly associated with the co-morbidity being measured, plus part of the costs related to the omitted factors correlated with the condition.

In a payment model, this could be seen as either a positive or a negative characteristic. On the positive side, the omitted variables bias allows the model to partially adjust for unmeasured factors that influence costs, but are not reflected in the payment system. However, this bias undercuts the face validity of the case-mix multipliers because part of what they are capturing is unknown. Further, the larger multipliers would increase the incentive to report relatively minor cases of the co-morbidity that may not even be associated with whatever unmeasured conditions the multiplier reflects.

With respect to using an annual versus monthly unit of analysis in the separately billable model, the case-mix multipliers for acute co-morbidities in the annual model are likely to be subject to a greater degree of omitted variables bias because of the longer time span. In the annual specification, the question being answered is "Is a patient with this acute co-morbidity more costly to treat throughout the year?" Those higher costs could be directly attributable to the co-morbidity and occur in those months in which the co-morbidity was present. However, they could also represent costs directly attributable to the co-morbidity that occur outside the three month time interval in which the co-morbidity was coded as present (for example, if there is some impact on costs beyond three months), or costs attributable to any other correlated omitted conditions that occur at any time of the year.

Therefore, for those patients with the acute conditions coded for only part of the year, the case-mix adjuster in an

annual model can reflect costs occurring outside the time frame during which the co-morbidity was actually present. In other words, having the acute condition present for part of the year might be a marker for having other costly conditions at any time of the year.

In a monthly model, the case-mix multiplier can still reflect costs associated with correlated, omitted variables, but only if those costs occur in the same months the co-morbidity is coded as present. Any costs occurring outside the months in which the co-morbidity is coded as present, regardless of whether those costs are directly related to the co-morbidity, or arise from correlated, omitted conditions, will not be reflected in the multiplier because the co-morbidity is coded as zero in those months.

We want to focus on specific conditions that are associated with more costly resource intensive dialysis, not other unspecified conditions that may be an indicator for more costly care at any time of the year. We also want to minimize omitted variables bias as much as possible, but particularly for omitted conditions that can occur at any time of the year. Accordingly, in connection with this final rule, we have adopted the patient-month separately billable model. The case-mix adjusters reflected in the proposed rule were based on the annual unit of analysis for separately billable services (Table 14 at 74 FR 49954).

As shown in Table A of the Appendix in this final rule, the case-mix adjusters for acute conditions are substantially smaller in the patient-month model in comparison to the annual model. This indicates that the multipliers in the annual model are capturing costs that occur outside the time window during which the condition was coded as present. As will be explained later in section II.F.3. of this final rule, on co-morbidities, we have dropped certain co-morbidities after considering comments received and for the reasons highlighted below, with more of an emphasis on acute as opposed to chronic conditions, and modified the definitions of others. As conditions are dropped from the model, the tendency is for omitted variables bias to become more pronounced in the patient-year model. In the patient-month model, the case-mix adjustments are less affected by the elimination of co-morbidities as independent variables.

In selecting a patient-month separately billable model, we believe that the case-mix adjustments more closely reflect costs associated with the specific co-morbidity being measured, and occurring in the specific months in which the co-morbidity was present. We believe that this approach will more closely align the costs of furnishing dialysis with patient-specific conditions requiring more resource intensive care in a timely manner. Because composite rate cost data are only available on an annual basis through the Medicare cost reports, the option of switching to a monthly model for the composite rate component of the two equation regression model used to develop the case-mix adjusters is not possible. Therefore, the case-mix adjustments set forth in this final rule were developed using an annual model for the composite rate portion of the regression model and a patient-month model for the separately billable portion.

3. Patient-Level Adjustments

We proposed to include patient age, patient sex, body surface area (BSA), body mass index (BMI), onset of dialysis and certain co-morbidities as patient-level adjusters (74 FR 49949). Over one hundred commenters representing patients, health care professions and their professional organizations, ESRD facilities and ESRD organizations, renal organizations, and pharmaceutical companies commented on the patient-level adjusters.

The comments we received relating to the specific adjusters and our responses to those specific comments are discussed in their respective sections below.

Comment: Some commenters indicated that weight, size and age have little impact on overall costs of providing dialysis. One commenter did not believe that our analysis of the proposed adjustments reflected actual payments that facilities would receive. Another commenter suggested that the proposed adjustments would increase patients' co-payment obligations. Several commenters were concerned that the patient-level adjustments would lead to facilities "cherry picking" patients with better defined case-mix adjustments and turn away others whose reimbursement would not cover costs.

Response: As discussed in the proposed rule, multiple regression analysis was used to develop the proposed payment adjustment factors. The results of the proposed two-equation model (composite rate and separately billable items) using the latest data that was available at that time, demonstrated that age, sex, BSA, BMI, co-morbidities and onset of dialysis were indicators of higher cost patients (74 FR 49947). The discussion on the current analysis and findings is in section II.F.3. of this final rule. We appreciate the concerns raised about ESRD facilities "cherry picking" patients. We plan to monitor the effects of the payment system, which are discussed in section II.K. of this final rule and will be discussed in the future, and could make adjustments to the ESRD PPS in the future. We expect that ESRD facilities will not "cherry pick" patients under the ESRD PPS.

We believe that the same incentives and concerns could exist under the current composite rate payment system, as well. In other words, if ESRD facilities will select more lucrative patients under the ESRD PPS, they could also do so currently under the basic case-mix adjusted composite payment system. We also believe that in the absence of such adjustments, high cost patients could be turned away, thereby "cherry picking" only the least costly patients. Providing patient-level adjustments to the ESRD PPS base rate should result in adequate payment for the higher resource utilization and therefore higher cost patients.

Comment: Some commenters suggested that we decrease the number of case-mix adjustments to include only those affecting cost. Others stated that multiple adjustments will decrease the overall base payment rate taking funding away from the cost of providing care to the majority of patients. Some commenters suggested that money from the case-mix adjustments should be added to the base rate to provide the same reimbursement for all patients.

Response: As discussed in the proposed rule (74 FR 49938), our analysis demonstrated that the proposed patient-level adjustments did affect cost and those that did not were rejected. However, we did consider the concerns and comments about the adjustments and have eliminated some of them. These adjustments are discussed in the respective sections below. We discuss the methodology for computing the ESRD base rate in section II.E. of this final rule.

Comment: One commenter suggested that we provide all facilities with an electronic calculator to ensure consistency among providers. Several commenters believed that CROWNWeb would be used for documentation to be eligible for the patient-level adjustments. One commenter disputed our belief that nephrologists complete the Medical Evidence Form 2728 (Form 2728) indicating that the form is more likely completed by someone not medically trained. Therefore, this commenter believed the data on the form could be inaccurate, missing or incompletely filled out.

This observation was reiterated by another commenter who suggested that a study be conducted prior to the ESRD PPS 2011 implementation to determine who should complete the Form 2728. The commenter suggested that the study also include the experience and training of personnel completing the Form 2728 as well as a random selection of Form 2728. The commenter further suggested that the Form 2728 be compared with patient/family interviews, physician interviews, and medical record review. One commenter suggested that we continue to study and research additional variables that demonstrate a good correlation between resource consumption and patient characteristics.

Response: We appreciate the commenter's concerns regarding consistency among providers and agree that it is important. However, we do not believe that providing a tool such as an electronic calculator will ensure consistency as ESRD providers will be required to identify the appropriate patient-level adjustments for their individual patients. In addition, it is the responsibility of each ESRD facility to ensure that all information on patient claims submitted is accurate under any Medicare payment system. Contrary to the commenter's belief, CROWN is not the source for documenting eligibility for the patient-level adjustments. For the purposes of payment, the requisite information would be obtained from the claim or from sources that are discussed in the specific patient-level adjustments below.

We are concerned about the assertion made by the commenters about the completion of the Form 2728. We maintain that it is the ESRD facilities' responsibility to ensure that the information provided to Medicare is accurate. While there is no requirement that the nephrologist complete the form, instructions on the Form 2728 specify that the form "[b]e signed by the physician supervising the patient's kidney treatment [sic]." The instructions also specify that stamp signatures are not acceptable. In other words, the nephrologist may not complete the entire form but his or her signature serves to attest that the information is accurate. Therefore, we do not believe that performing a study to determine the qualifications of the person completing the form is warranted. However, we do believe that ESRD facilities are responsible for ensuring that appropriate staff who provide care, include documentation as appropriate. We agree with the commenter that we should continue to study and research the correlation between resource consumption and patient characteristics and we plan to do so.

After considering these comments and other comments below, we are finalizing age, BSA, BMI, certain co-morbidities and onset of dialysis as the patient-level case-mix adjustments in this final rule. Our rationale for including these factors, as well as the reasons for excluding patient factors for patient sex and race or ethnicity, are discussed below. We are revising § 413.235 to reflect the patient-level, case-mix adjustments to be implemented effective January 1, 2011.

a. Patient Age

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's age. In the proposed rule we pointed out that the basic case-mix adjusted composite payment system currently in effect includes payment adjustments for age based on five age groups (74 FR 49949), based on analyses that showed a strong relationship between composite rate costs and patient age. Table 12 from the proposed rule (74 FR 49950) contained the payment multipliers for each of these groups, along with a special multiplier that applies to pediatric dialysis patients. The proposed ESRD PPS adjustment factors for age reflected the U-shaped relationship of age with the CY 2007 MAP per treatment, a relationship similar to that observed in developing the current basic case-mix adjusted composite payment system.

The regression analyses performed in connection with the development of the ESRD PPS payment adjustments for this final rule indicate that age continues to be a strong predictor of variation in composite rate costs and separately billed payments, although the magnitude of the adjusters for the two oldest age categories has been attenuated as a result of other changes in the payment model (for example, elimination of sex and race/ethnicity as payment variables, revisions in the co-morbidities used for payment, modification of the low-volume threshold, etc.). Therefore, we are implementing payment adjustment factors for the same five age groups as proposed, calculated in accordance with the two equation regression methodology described elsewhere in this final rule. The final payment adjustment factors for age are shown in Table 21.

Table 21 – Patient Age

Variable	Multiplier
Ages 18-44	1.171
Ages 45-59	1.013
Ages 60-69	1.000
Ages 70-79	1.011
Ages 80+	1.016

We received several comments on our proposed use of age as a payment variable in the proposed ESRD PPS.

Comment: Several commenters stated that age is an objective and easily collected variable, demonstrably related to cost, and that continuing to collect age data would not be burdensome or require systems changes.

Response: We agree with the commenters. The use of a payment variable that is objective, easily collected, and related to patient-specific differences in the cost of dialysis strongly support its use as a case-mix adjuster in the ESRD PPS.

Comment: Several commenters suggested that we combine age with gender and ethnicity. Another commenter recommended that we match age with an adjuster for home dialysis training.

Response: The reason that age is included in the ESRD PPS is because analyses demonstrate that age is a significant independent predictor of variation in composite rate costs and separately billable payments. For reasons explained elsewhere later in this section, we have not adopted patient sex and race/ethnicity as payment adjusters in connection with the ESRD PPS set forth in this final. For information on our development of a special add-on to the otherwise applicable prospective payment rate for the costs of home dialysis training, *see* section II.A.7. of this final rule.

Comment: Several commenters suggested that we use an age adjuster for patients of "advanced age and/or frailty". One commenter recommended age specification of pediatric patients, claiming that both groups require specialized care resulting in higher costs for ESRD facilities.

Response: Both the proposed rule (74 FR 4995) and this final rule incorporate an age group for patients age 80+. Further disaggregation of the proposed age groups did not result in more statistically homogeneous age groups for the application of case-mix adjustments based on age. Therefore, we have not modified the proposed age classification categories. Nor have we identified a separate variable for patient frailty, as this would be very difficult to quantify objectively and measure with currently available sources of claims data. With respect to age classification groups for pediatric patients, we point out that we have adopted pediatric payment adjustments for two age groups (<13, and 13–17), and explain the basis for the selection of these two age categories in section II.G. of this final rule.

Comment: Two commenters representing ESRD facilities opposed the use of age as a basis for case-mix adjustment, claiming that they did not see any merit in its use.

Response: We strongly disagree with the commenters. The analyses in support of the payment adjustments for age used in connection with the basic case-mix adjusted composite payment system, the proposed ESRD PPS (74 FR 49949 through 49950), and the ESRD PPS described in this final rule, show that age is an important predictor of facility differences in ESRD composite rate costs, and patient-specific differences in separately billed payments. Therefore, we are incorporating age as a case-mix payment variable in the final ESRD PPS, and have specified the use of age as a patient-level adjustment in § 413.235(a).

b. Patient Sex

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a number of variables and may include "other appropriate factors." Consequently, for the proposed rule (74 FR 49950), we analyzed patient sex as part of the regression analysis and found that patient sex was a strong predictor of variation in payments for ESRD patients. In addition, we indicated that we believed patient sex is an objective measure and that data on patient sex are readily available.

Based on our analysis, we found that females were 13.2 percent more costly on a per treatment basis than males, primarily due to differences in use of ESAs. Therefore, we proposed an adjustment of 13.2 percent for female patients (74 FR 49951). We solicited public comments on this proposed adjustment, in addition to raising the possibility of unintended consequences of providing a payment adjustment for female patients that may lead to admission practices favoring female patients.

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

Comment: Most commenters supported adding patient sex as a case-mix adjustment. One commenter recommended that CMS monitor ESRD facility admission practices with regard to female patients. Two commenters indicated that they did not believe patient sex affects the cost of dialysis.

Response: As discussed in the proposed rule, the regression analysis showed that patient sex (female) was a strong predictor of variation in ESRD payments and the cost of dialysis. However, we are not convinced that a patient sex adjustment is necessary to ensure beneficiary access to ESRD services. That is, we believe that there may be sex-neutral factors that have not been identified in the ESRD PPS modeling that would explain the increased cost associated with providing renal dialysis services to members of a certain sex.

We intend to work to identify underlying patient-specific conditions that may result in increased treatment costs and also how a patient sex adjustment might be applied. To the extent that these factors are identified, they could be incorporated into the ESRD PPS model as patient-level adjustments. We will also continue to monitor and evaluate the impact of patient sex on cost to determine consistency in findings and identify other variables that may be responsible for producing cost variations.

Comment: Many commenters were opposed to or expressed concerns about the inclusion of patient sex as a case-mix adjuster. Some commenters opposed patient sex as a variable outright, while others indicated that the addition of patient sex adjustment could result in limited access to care for male patients, if providers engaged in "cherry-picking" behavior. Other commenters felt the impact would be debatable in view of a study that had been done 5 years ago indicating that men rather than women were the most costly beneficiaries in the dialysis setting and, therefore, would we see another shift in costs during the next 5 years.

Response: Beneficiary access to ESRD services and medications was an important factor we considered with regard to using a patient sex adjustment. At this point, we are not convinced that a patient sex or gender adjustment is necessary to ensure beneficiary access to appropriate ESRD services and medications. As we discussed above, the issue of patient sex influencing the cost of ESRD drugs and services will continue to be monitored with the possibility of including an adjustment for patient sex at some future date.

Therefore, in this final rule, we are not finalizing our proposal to include patient sex as a patient-level case-mix adjustment. We have revised § 413.235(a) to reflect the exclusion of patient sex (female) as a patient-level adjustment.

c. Body Surface Area and Body Mass Index

Section 1881(b)(14)(D)(i) of the Act requires that the bundled ESRD PPS must include a payment adjustment based on case-mix that may take into account patient weight, BMI, and other appropriate factors. Consequently, we evaluated height and weight because the combination of these two characteristics allows us to analyze two measures of body size: BSA and BMI. In the proposed rule, we analyzed both BSA and low BMI (< 18.5 kg/m^2) as independent variables in the regression

analysis and found that both body size measures are strong predictors of variation in payments for ESRD patients. In addition, both BSA and BMI are objective measures and the necessary data, that is, height and weight, to compute them are readily available from patient claims. In the proposed rule, we discussed our rationale for developing the adjustment factors for BSA and BMI in detail (74 FR 49951).

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

Comment: Some commenters agreed that CMS should continue to use only the existing case-mix adjustments which include age, BSA and BMI, because these adjustments are familiar to facilities and eligible patients can be identified using information that is currently available to ESRD facilities.

Response: We disagree with the commenters that we should only use the existing case-mix adjustments. As we discussed in the proposed rule (74 FR 49947), the results of our analysis demonstrated that in addition to the existing case-mix adjustments, other variables such as co-morbidities, were predictive of patient differences in cost. In this final rule, our analysis continues to show that BMI and BSA are strong predictors of variation in costs and payments for ESRD patients. Their use as payment variables ensure that ESRD facilities receive appropriate compensation for the costs associated with their specific patient population.

Comment: Two commenters believed that it was untrue that small-sized patients require less medication and fewer laboratory tests than larger-sized patients. The commenters believed that the "one size fits all" approach for drugs and laboratory tests based on the size of the dialysis patient may lead to discrimination against smaller patients and those patients with fewer applicable case-mix adjustments may find it difficult to gain admission to a dialysis center or possibly be undertreated with medications. One commenter suggested that the proposed rule created the false impression that dialysis is prescribed in a dosing format like drugs with well known pharmacokinetics that must be prescribed on patients parameters of BSA and BMI.

Response: As we discussed in the proposed rule, we individually analyzed both BSA and BMI (as two measures of body size) as part of the regression analysis, and found that both body size measures were significant predictors of variation in composite rate costs and separately billed payments for ESRD patients. Our analysis for this final rule demonstrates the same relationship. We do not believe that our analysis and findings imply a "one size fits all" approach. Because we recognized that there are other variables that explain the variation in costs for ESRD patients, we included other factors such as age, co-morbidity and onset of dialysis. We explain these variables in great detail in the proposed rule and later in this section. Because of these findings, we have included these variables as patient-level adjustments, as well as BSA and BMI.

Comment: One commenter questioned the methodology used to address the BMI fluctuation between a post dialysis weight on the last treatment and the post dialysis weight on the prior treatment. The commenter wanted to know if there would be an adjusted payment reflecting the two differing post dialyses weights or would the physician prescribed dry weight (weight without the excess fluid that builds up between dialysis treatments) be applied as the qualifier for the case-mix adjustment, because the post dialysis weight may drift enough to trigger a cost-adjustment. The commenter expressed concern that by using the physician prescribed dry weight, the treatment facilities and physicians would be rewarded for adjusting dry weights to reflect more profitable case-mix adjustments.

Response: As described in the Medicare Claims Processing Manual, Chapter 8, Section 50.3, facilities are required to report the weight of the patient after the last dialysis session of the month. However, the commenter raises an interesting point. We will need to consider the use of dry versus wet weight in future rulemaking.

In this final rule, the case-mix patient-level adjustment for BSA (per $0.1m^2$) is 1.020 and for low BMI (BMI <18.5) is 1.025 effective for renal dialysis services provided on or after January 1, 2011. We are also finalizing the inclusion of the factors for BSA and BMI in § 413.235(a).

d. Onset of Dialysis (New Patient Adjustment)

Section 1881(b)(14)(D)(i) of the Act, as added by MIPPA, requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's length of time on dialysis. Consequently, we analyzed the length of time beneficiaries have been receiving dialysis. We noted in the proposed rule (74 FR 49952), that the regression analysis demonstrated that patients who are in their first 4 months of dialysis have higher costs. We also looked at the amount of separately billable payments relative to the number of months the patients had been on dialysis. After reviewing the separately billable payment amounts for patients ranging from one month to twelve months since the onset of dialysis, we found that there was a drop in the separately billable payment amounts after the first 4 months of dialysis. Therefore, we proposed to define the onset of dialysis beginning with the starting date reported on Form 2728 through the first 4 months a patient is receiving dialysis (74 FR 49952).

We also proposed that the onset of dialysis adjustment be applied to both in-facility and home dialysis patients. We acknowledged that there may be patients whose first 4 months of dialysis occur when they are not yet eligible for the Medicare ESRD benefit. In these circumstances, we proposed that no onset of dialysis adjustment would be made. In other words, the onset of dialysis adjustment would be made only in the first 4 months of dialysis where the individual is also eligible for the ESRD benefit (74 FR 49952).

We received over 70 comments from nephrologists, ESRD facilities, nurses, ESRD organizations, health care professionals, patients, professional organizations, and hospitals. Most commenters supported the inclusion of an onset of dialysis patient-level adjustment factor. Some commenters were, however, opposed to the inclusion of home dialysis training as part of the onset of dialysis adjustment factor and recommended that the training be removed from the onset of dialysis adjustment. The commenters suggested that CMS create a separate training adjustment instead. Home training is discussed in detail in section II.A.7. of this final rule.

Comment: A few commenters recommended that the onset of dialysis adjustment not be implemented because the commenters believed it would be duplicative of other adjusters such as hospitalization and race that the commenters believed more accurately predicted treatment costs. Another commenter recommended that CMS eliminate the onset of dialysis adjustment in favor of other adjustments which focused on the root causes of higher costs during the first 4 months of dialysis.

Response: We do not agree with the commenters who stated that the onset of dialysis adjustment is duplicative of other adjustments in predicting treatment costs. The adjustment for the onset of dialysis reflects higher costs seen during the first 4 months a patient receives dialysis and is independent of the effects of other adjustment factors

(such as hospitalization), included in the regression analysis. There is however a risk that a hospitalization adjustment would create an inappropriate financial incentive for ESRD patients to be hospitalized for the purpose of receiving a payment adjustment. We discuss the issue of using race as an adjustment factor in section II.F.3. of this final rule.

We agree with the commenters who noted that patients in the first 4 months of receiving dialysis may be frail and unstable. We believe that the onset of dialysis case-mix adjustment recognizes the higher costs associated with newly diagnosed patients and reflects the care required to stabilize their conditions. As discussed above, in the proposed rule our analysis showed that patients who are in their first 4 months of receiving dialysis have higher costs. Subsequent to the proposed rule, we performed additional analyses.

In our analysis for this final rule, our findings confirmed that higher costs were attributed to the first 4 months of dialysis in both the composite rate model and in the separately billable model. We believe that at the current time, the onset of dialysis adjustment is a good predictor of higher costs during the first 4 months of receiving dialysis and, therefore, in this final rule we are retaining the onset of dialysis payment adjustment.

Comment: Several commenters strongly urged adoption of the onset of dialysis adjuster because of the effort required to obtain consents, waivers, and complete forms and all other compliance documents required under the Conditions for Coverage for new ESRD patients from nursing homes.

Response: As discussed in the proposed rule, we believe that the higher costs associated with patients during the first 4 months of receiving dialysis may be due to: the need to stabilize patients' conditions; administrative and labor costs associated with patients new to dialysis; or initial costs to train patients (74 FR 49952). The analysis conducted for this final rule continues to indicate higher composite rate costs and separately billable payments associated with patients new to dialysis. As the commenter indicates, some of the increased administrative costs associated with providing dialysis in the first 4 months that a beneficiary begins dialysis treatment may be attributed to the costs associated with obtaining medical or other records from other providers and suppliers of services.

Therefore, we are retaining the onset of dialysis adjustment under the final ESRD PPS. We note that the onset of dialysis adjustment is applicable only for those patients 18 years or older, during the first 4 months of the onset of dialysis and would not apply to any patient who might receive renal dialysis services by an ESRD facility for subsequent treatments.

Comment: One commenter claimed that there are higher costs due to the need to increase hemoglobin levels; hospitalizations in the first months of diagnosis for cardiovascular disease and catheter-induced infections; and staff time needed for patient assessment and care planning required by the new conditions for coverage. Other commenters also supported this assertion stating that it was "well documented that staff and drug costs with new patients and the conditions of participation outline the intense responsibilities during this period."

Response: We thank the commenters for their support of the onset of dialysis adjustment. We acknowledge that our analysis in the proposed rule and this final rule showed higher composite costs and payment for separately billable items during the first 4 months of dialysis. As we noted in the proposed rule, the higher costs for new patients in the first 4 months of receiving dialysis, may be due to stabilization of a patient's condition; administrative and labor costs associated with the patient being new to dialysis; or initial costs of training patients and their caregivers to perform home dialysis (74 FR 49952). Therefore, the intent of the onset of dialysis adjustment was to account for the higher costs through the first 4 months a patient is receiving dialysis in response to the need for separately billable items such as ESAs.

Due to our further analysis of onset of dialysis for this final rule, our findings confirm an increase in costs for the composite rate portion of the two-equation model for patients in their first 4 months of dialysis. The analysis also demonstrates an increase in measured costs based on the separately billable portion of the model, particularly for ESA utilization. Because of the absence of patient-level data on resource use for composite rate services, and the relatively small number of individuals who historically received home dialysis training during the first 4 months of dialysis (which limits the potential of facility-level analysis to examine resource utilization for home training), we are unable at this time to determine the extent of overstatement of composite rate costs if we apply both the onset of dialysis adjustment and the training adjustment discussed in section II.A.7. of this final rule. In order to avoid potentially overstating payments to ESRD facilities under the ESRD PPS for costs related to new dialysis patients and training during the first 4 months of dialysis, the training add-on adjustment will not apply for patients receiving the onset of dialysis adjustment. We note that home dialysis training is not included in the onset of dialysis adjustment and is a separate payment adjustment which we discuss in section II.A.7. of this final rule.

Comment: One commenter disagreed with the onset of dialysis adjuster indicating that there was little data proving that higher labor costs was associated with the onset of dialysis. The commenter stated that costs associated with the initial months of dialysis do not prevent access to dialysis care and, therefore, if the intent of case-mix adjustments is to erase disincentives to treat costly patients, the adjustment is not necessary.

Response: Contrary to the commenters' views, our analysis demonstrates that the first 4 months of receiving dialysis was a predictor of higher resource utilization. As discussed in previous responses, our subsequent analysis for this final rule confirmed our findings as discussed in the proposed rule (74 FR 49952). Our updated analysis for this final rule shows a drop in the amount of separately billable payments after 4 months on dialysis, which was the basis for our establishing a 4-month time period for the onset of dialysis adjustment.

The intent of a case-mix adjustment is to provide payment that reflects the resources associated with patients, whose needs are greater than patients without certain characteristics or conditions. The onset of dialysis adjustment is intended to provide payment that reflects the higher composite rate costs and higher separately billable payments associated with patients during the first 4 months of dialysis.

Comment: One commenter alleged that dialysis services are provided at great expense to the taxpayer with "very little benefit to the individual" and questioned if this adjustment was "good policy."

Response: We do not agree with this commenter. We believe that the onset of dialysis adjustment reflects the average higher costs associated with patients during the first 4 months of dialysis. We believe that the ESRD PPS will support the care needed by Medicare beneficiaries receiving dialysis treatment while controlling costs.

Comment: One commenter questioned whether the onset of dialysis adjuster was underestimated because of the 90-

day delay in Medicare entitlement for the ESRD benefit under Medicare and suggested that the period be 180 days. Other commenters suggested that the eligibility requirement be reduced to allow ESRD facilities to receive the adjustment for more than one month. One commenter suggested that the 90-day waiting period be reduced and the payment be increased. The commenter acknowledged that statutory change would be required to make these changes.

Response: We do not agree that the onset of dialysis adjustment is underestimated. We analyzed ESRD facility claims beginning with the dialysis onset date on the Form 2728 and found an increase in separately billable payments in the first 4 months. We also found increased composite rate costs. We believe that our analysis adequately and accurately reflects the higher costs associated with the first 4 months of dialysis among patients eligible for Medicare.

We believe the commenters are referring to the need for legislative changes to reduce the 90-day waiting period for entitlement to benefits under Part A and eligibility to enroll under Part B required by section 226A of the Act and an increase in payment to ESRD facilities. We agree that a legislative change would be required to change the 90-day waiting period, however, such changes are beyond the scope of this final rule.

Comment: One commenter noted that new patients are costly to care for, but indicated that many of the patient "problems" are not ESRD-related. The same commenter believed that the onset of dialysis adjustment will give ESRD facilities an incentive to care for new patients.

Response: Our analysis demonstrated that patients in the first 4 months of dialysis have higher composite rate costs and separately billable payments. To the extent that ESRD patients may have other non-ESRD–related issues or conditions, we do not believe that our analysis would have captured this. Therefore, in this final rule, we do not believe that we captured non-ESRD-related costs.

We agree with the commenter that the onset of dialysis adjustment will have a positive effect in access to care for patients during the first 4 months of receiving dialysis.

Comment: Several commenters indicated that the proposed onset of dialysis adjustment was too high and that the duration for the eligibility requirement for ESRD facilities to receive payment was too long. A few commenters noted that the high onset of dialysis adjustment would result in beneficiaries assuming responsibility for large co-payments. Some of these commenters provided recommendations on changing the time frame for the onset of dialysis, as well as the amount of the adjustment.

Some commenters suggested the adjustment should be a 90-day initial adjustment with the difference re-allocated for a home dialysis adjustment. Another commenter noted that if the onset of dialysis adjuster is intended to protect small dialysis providers who cannot easily spread risk, than the weighting should be recalculated to ensure accuracy as the proposed weight of 1.47 appears quite high. Others believed the adjustment should be reduced to 15 or 30 percent using the remaining percentage for a home dialysis adjustment.

Response: The multiplier amounts for the onset of dialysis adjustment, as well as all other adjustments, are the result of the regression models for composite rate and separately billable services. In the proposed rule, we analyzed Medicare claims for 2004–2006, which indicated greater resource utilization for separately billable items among patients treated during the first 4 months of dialysis. An analysis of cost reports for the same period indicated higher costs for composite rate services associated with the first 4 months of dialysis. Based on our subsequent analysis for this final rule, (which used cost reports and Medicare claims for the years 2006–2008), the onset of dialysis adjustment under the ESRD PPS for ESRD items and services provided on or after January 1, 2011 is 1.510.

We note that our analyses also suggest there are effects of co-morbidities on resource utilization for separately billable items that are independent of the onset of dialysis. We performed further analysis of the co-morbidity diagnostic categories for this final rule, in combination with the onset of dialysis. We found that while costs were higher on average for dialysis patients with co-morbidities during the first 4 months of dialysis, the effect of compounding a co-morbidity adjustment along with the onset of dialysis adjustment would, on average, result in overstatement for separately billable services. Therefore, ESRD facilities will not receive a co-morbidity adjustment for dialysis patients during the first 4 months of dialysis.

We plan to continue to study the onset of dialysis adjustment because we believe that it is important for us to be cognizant of the impacts of additional adjustments made to ESRD facilities, the ESRD base rate, as well as effects on patient co-insurance liabilities.

Comment: One commenter strongly opposed the onset of dialysis adjustment citing a number of reasons such as: (1) Most of the higher costs occurring in the first 4 months of dialysis are explained by hospitalization, race, and age; (2) most beneficiaries in the first 120 days do not receive home training; (3) those under 65 are not covered by Medicare for the first 90 days unless they begin training for home dialysis.

The commenter asserted that this would then have the effect of increasing the number of patients who become entitled to Medicare earlier. The commenter further stated that the characterization of the onset of dialysis adjustment as independent of the other ESRD patient-level adjustments will overestimate the onset of dialysis adjustment's value. The commenter suggested that the onset of dialysis adjustment be examined in tandem with other parts of the proposed rule to formulate a fair and accurate facility payment. The commenter further suggested that if reliable data such as labor costs are elevated (as asserted by CMS) at the beginning of dialysis, are found to not exist, the onset of dialysis adjuster should not be included in the ESRD PPS. The commenter further noted that CMS's reliance on cost reports is misplaced because the cost reports are not limited to Medicare, thereby skewing the sample with non-Medicare patients. The commenter asserted that patients with commercial primary insurance are over-represented among new dialysis patients. Other commenters believed the onset of dialysis adjustment would lead to patients under 65 years of age, to begin home dialysis therapy in the first 90 days in order to trigger early Medicare entitlement for the purpose of higher payment.

Response: In our analysis we found that there was an association of higher composite rate costs and separately billable costs even when controlling for race and age. The onset of dialysis adjustment reflects higher costs for patients eligible for Medicare during the first 4 months of dialysis.

With regard to concerns about the inclusion of patients not covered under the Medicare ESRD benefit, patients who were not entitled to the ESRD benefit under Medicare during this period were not used in our analysis for determining the onset of dialysis adjustment because they would not be eligible for the adjustment. As we discussed in a previous response, the onset of dialysis adjustment we are

finalizing under the ESRD PPS will not be applied in combination with either the co-morbidity adjustment or the home training payment add-on adjustment.

We do not agree with the commenter who expressed concern that the onset of dialysis adjustment would trigger an earlier Medicare entitlement. We will be monitoring the onset of dialysis adjustment, specifically, to determine if there is an increase in the number of individuals who become entitled to Medicare prior to the 90-day waiting period as a result of receiving home dialysis training.

We are aware of the prevalence of patients who receive home dialysis during the first 4 months of dialysis. As many commenters have noted, few patients receive home or self dialysis training during the first 4 months of dialysis. We would not expect to see more patients receiving home or self dialysis training in the first 4 months of dialysis in order for ESRD facilities to receive the onset of dialysis payment adjustment. We expect that ESRD facilities, nephrologists and other health care providers will provide care in accordance with the established plan of care and would not require home or self dialysis for the purpose of a payment adjustment.

With regard to the comment concerning our misplaced reliance of cost reports, cost reports capture ESRD data and provide the only comprehensive national data source to measure ESRD resource use of composite rate services, and reflect costs for Medicare patients. Therefore, we believe cost reports provide the best available data.

Comment: One commenter expressed concern that many facilities will no longer accept patients for no fees (free) for the first 90 days since overall payments will be decreased.

Response: We do not understand the association between the onset of dialysis adjustment and the facility's decision to not accept patients for free. However, we believe the decision of an ESRD facility to accept or not accept patients without payment is beyond the scope of this final rule.

Comment: One large dialysis organization noted that an adjuster "of this magnitude invites gaming or cherry picking." The commenter expressed concern that ESRD providers could or do routinely provide dialysis services for the first 4 months of dialysis, and then transferred the patient to another ESRD facility.

Response: We are concerned about ESRD facilities "cherry picking" patients for the purpose of receiving the onset of dialysis adjustment. We believe that in the absence of any case-mix adjustments which provide for additional payments for patients with higher resource utilization and associated higher costs, ESRD facilities may refuse to provide dialysis services to higher cost patients over less costly patients.

We are also concerned that ESRD patients may be inappropriately placed on home dialysis who either do not want home treatments or who require more frequent monitoring for medical, social and other reasons, in order to decrease the eligibility period for the purpose of receiving the onset of dialysis adjustment.

The ESRD patient's plan of care must reflect the patient's needs. If a patient is unwilling or unable to self-dialyze at home, insisting that the patient go on home dialysis would be a violation of the patient plan of care as described in § 494.90. An ESRD patient who cannot/would not comply with a home dialysis plan of care is likely to have poor clinical outcomes and may require additional care, both of which negate any cost benefits for ESRD facilities of home dialysis. The ESRD Conditions for Coverage can be found at 42 CFR Part 494. We expect that ESRD facilities will provide an appropriate plan of care and continued monitoring will identify ESRD facilities that do not.

Comment: Several commenters believed the onset of dialysis adjuster should apply to all patients and not solely Medicare beneficiaries, as all dialysis patients receive more care at the beginning of dialysis. A few commenters complained that patients under 65 only have 30 days of increased payment as facilities would need to wait for these patients to be covered by Medicare before they can receive payment.

Response: The onset of dialysis adjustment will only apply to ESRD patients who are entitled to receive the ESRD benefit under Medicare. As explained in a previous response, data for patients who were not eligible for Medicare during this period were not used in the analysis for determining the onset of dialysis adjustment. ESRD facilities would only receive the onset of dialysis adjustment for patients that are covered under the ESRD Medicare benefit. Therefore, the onset of dialysis adjustment would not apply to individuals receiving dialysis care paid for by other third party payers during the first 90 days. We note that ESRD facilities would receive the onset of dialysis adjustment for the 4-month adjustment period for its new patients who are already entitled to Medicare at the time of the onset of dialysis.

Comment: A few commenters noted that the onset of dialysis adjuster had "limited administrative complexity or burden" and therefore, approved the onset of dialysis adjuster.

Response: Information on the Form 2728 and stored in our systems will be used to determine if a patient is within the first 4 months of dialysis. Therefore, ESRD facilities will not have any additional reporting requirements or burden associated with the onset of dialysis adjustment.

Comment: While one commenter was in favor of including home training in the onset of dialysis adjuster because the commenter believed it could help increase the number of patients on home dialysis, most commenters opposed inclusion of home dialysis training costs in the onset of dialysis adjustment. Many of the commenters were opposed to the inclusion of home dialysis training indicated that training ESRD patients for home dialysis does not occur in the first 4 months of dialysis because individuals are more likely to receive the initial treatments in a facility. Other commenters believed that expecting newly diagnosed ESRD patients to assume responsibility for home dialysis while they are adjusting to an overwhelming diagnosis would be inappropriate. Commenters also stated that new patients are often medically unstable, psychologically compromised by anxiety and depression, and unable to make home dialysis decisions.

Several commenters noted that training or retraining for home dialysis may be needed for modality changes after the initial 4 months of dialysis and therefore, the training portion of the onset adjustment should be removed. These commenters all recommended that training be adjusted separately regardless of when training begins.

One commenter noted that ESRD facilities that do not provide home dialysis training would receive the same enhanced reimbursement as the facilities that do provide the home training. The same commenter further believed that inclusion of home training in the onset of dialysis adjustment would penalize facilities with active growing ESRD programs. One commenter noted that the increased payment from this adjustment "defrayed some increased expenses with indigent patients and as most patients elect home dialysis after 120 days there is little incentive to initiate training." One commenter believed that even a significant increase in payment will not encourage home treatments.

Response: The data analysis conducted for this final rule supports the commenters' views that most ESRD

patients are not trained for home dialysis in their first 4 months of dialysis. In our analysis, there were too few training patients in their first 4 months of dialysis to assess the composite rate costs associated with patients training for home dialysis compared to those related to the onset of dialysis.

With regard to payment for both training and the onset of dialysis adjustments, as we discussed in a previous response, we believe that the costs associated with the onset of dialysis adjustment and the training add-on adjustment overlap (that is, costs for services could be accounted for in both adjustments). Therefore, to avoid duplicative payment, ESRD facilities will not receive the home dialysis training adjustment while they are receiving the onset of dialysis adjustment for a patient. We will continue to study the relationship between costs related to the onset of dialysis and home training for future refinement of the ESRD PPS.

The payment multipliers are based on the regression analysis that compared costs and payments among Medicare ESRD patients. It would not be appropriate for Medicare to make duplicative payments to fund care for indigent or other patients.

Therefore, after considering the public comments and for the reasons stated above, we are finalizing the onset of dialysis adjustment. ESRD facilities will receive the onset of dialysis adjustment for renal dialysis services provided on or after January 1, 2011. We are finalizing an adjustment of 1.510 for in-facility and home dialysis patients eligible for the Medicare ESRD benefit for the first 4 months of the initial onset of dialysis. We are finalizing the definition of the onset of dialysis as the date reported on the Form 2728 that dialysis begins through the first 4 months a patient is receiving dialysis. The onset of dialysis adjustment will only apply for the period of time in the first 4 months of dialysis that occurs while the patient is covered under the ESRD benefit. In other words, the onset of dialysis adjustment will not apply after the initial 4 months of dialysis. We are finalizing that ESRD facilities that are eligible for and receive the onset of dialysis adjustment for a patient may not receive a co-morbidity adjustment, nor will they receive the home training add-on adjustment for that patient during the first 4 months of dialysis. We are finalizing § 413.225(a) to include onset of dialysis (new patient) as a patient-level adjustment.

e. Co-morbidities

Section 1881(b)(14)(D)(i) of the Act requires that the bundled ESRD PPS include a payment adjustment based on case-mix that may take into account patient co-morbidities. In the proposed rule, we analyzed co-morbidities as part of the regression analysis and found that certain co-morbidities are predictors of variation in costs for ESRD patients (74 FR 49952). We noted that the potential co-morbidity adjustments are intended to recognize the increased costs by providing additional payments for certain conditions that occur concurrently with the need for dialysis. We explained that we used stepwise regression analysis for the current basic case-mix adjusted composite payment system to identify case-mix factors that explained statistically significant variation in ESRD facility costs. We summarized our findings as a result of our analysis (74 FR 49952).

As discussed in the proposed rule, we retained UM–KECC to assist us in developing a case-mix adjustment for the ESRD PPS (74 FR 49947). One of the tasks was the identification of specific diagnoses within co-morbidity categories. We explained the methodology we used to capture changes in patient conditions and patient co-morbidities. We explained that we began with a long list of patient characteristics based on diagnostic categories developed for the Medicare Advantage Program and categories developed for the co-morbidities on the Form 2728.

We also explained that we used co-morbidity diagnoses reported in multiple types of Medicare claims (inpatient dialysis and other outpatient, skilled nursing facility, physician/supplier, hospice, and home health). We acknowledged that because some diagnoses reported on laboratory claims may represent a condition being excluded by the test, diagnoses reported on laboratory claims were not used. We solicited recommendations on the type of claims that reflect the co-morbidities for beneficiaries receiving renal dialysis services that could be used in future analyses (74 FR 49953).

Comment: We received a few comments questioning our use of claims rather than relying on Form 2728 to identify co-morbidities of ESRD patients. Some commenters questioned the use of other sources such as emergency room claims to determine co-morbid conditions for ESRD patients.

Response: We believe that the predominant use of hospital and physician claims, as well as other types of claims (such as skilled nursing facilities, home health and hospice claims) to identify co-morbidities, provided for a more comprehensive picture of co-morbidities that ESRD patients may have during the course of their dialysis. The Form 2728 accurately provides the co-morbid conditions at the time the ESRD diagnosis was made and, therefore, does not reflect any other medical condition(s) that may have come about subsequent to that time. We note that the level of co-morbidity reporting on the Form 2728 is quite low. The ICD–9–CM diagnostic codes for patients' co-morbid medical conditions should be reported in compliance with coding requirements on the ESRD 72x claim, as well as the official ICD–9–CM Coding guidelines, which can be found at: *http://www.cdc.gov/nchs/icd.htm,* regardless of whether a payment adjustment could be associated with the diagnosis. Entering complete and accurate codes enables CMS to better evaluate our payment systems and provide updates as necessary.

In the proposed rule, we discussed how we would ensure that each proposed case-mix adjuster would have a statistically significant relationship to cost in order to ensure that the magnitude of the relationship is economically meaningful. We also explained that we evaluated a refined list of case-mix co-morbidities comprised of 1,022 ICD–9–CM diagnosis codes for persistence of effect and cost. The co-morbidity categories we proposed were: Cardiac arrest; pericarditis; substance abuse; positive HIV status and AIDS; gastrointestinal tract bleeding; cancer since 1999 (excludes non-melanoma skin cancer); septicemia/shock; opportunistic infections (pneumonias); aspiration and specified bacterial pneumonias; pneumococcal pneumonia, empyema, lung abscess; monoclonial gammopathy; myelodysplastic syndrome; leukemia; hereditary hemolytic anemias and sickle cell anemia; lymphoma; Hepatitis B; and multiple myeloma (74 FR 49953).

We also discussed the use of the stepwise regression model in analyzing co-morbidity data for case-mix adjustments (74 FR 49953). We explained that the eleven proposed co-morbidity variables had statistically significant relationships to cost. However the magnitude of the co-morbidity effects varied substantially. We found that short-term acute conditions (for example, infections, gastrointestinal bleeds, and pericarditis) would result in a temporary ESRD payment adjustment. We found that long-term chronic conditions would result in a permanent increase of an ESRD payment adjustment. We believe

the long-term chronic conditions may tend to have a more persistent effect on cost (74 FR 49953).

We explained how we applied the composite rate and separately billable services using the modeling approach (74 FR 49952). We discussed the rationale for proposing to include cancer, for example, as a co-morbidity eligible for a patient-level adjustment if the cancer has a direct effect on the cost of ESRD treatment. We also explained why HIV/AIDS was included as our proposed co-morbidity case-mix adjustment although it has since been eliminated from the current basic case-mix adjusted composite payment system. We acknowledged that including HIV/AIDS as a co-morbid adjuster would have benefits that would need to be balanced with stringent confidentiality concerns (74 FR 49954). In our proposed rule, we also solicited public comments on suggested conditions or diseases that CMS should consider for future refinements.

We received comments from approximately one hundred commenters on the proposed inclusion of co-morbidities as a patient-level case-mix adjustment. In general, most commenters were opposed to the inclusion of co-morbidities, or specified co-morbidities that they would like to see included. Many commenters offered suggestions on certain diagnoses to include as an adjustment, as well as those that should be eliminated. A few commenters expressed support for the proposed co-morbidities, stating that these adjusters would provide a more accurate payment for complex patients. Specific comments and responses are discussed below.

Comment: A few commenters offered to work with CMS to identify co-morbidities that: Influence the cost of dialysis care; are based on verifiable data; and can be implemented and administered in a practical manner. They also urged CMS to develop methods to enhance access to information for conditions that predict hospitalization.

Response: We reviewed public comments on co-morbidities and considered each for this final rule. In general, we believe that the commenters were suggesting future collaborative efforts to identify co-morbidities that influence the cost of dialysis care. We thank these commenters and we anticipate continuing to work with ESRD facilities, patients, physicians, organizations, and other stakeholders to refine the ESRD PPS.

Comment: One commenter suggested that we use facility size as a co-morbidity adjustment.

Response: As we discussed in the proposed rule, a co-morbidity is a specific patient condition that is secondary to the patient's principal diagnosis that necessitates dialysis, yet has a direct effect on dialysis (74 FR 49952). Therefore, contrary to the commenter's suggestion, a facility's size does not meet the definition of a co-morbidity.

Comment: Some commenters asserted that CMS excluded the co-morbidities that affect dialysis treatment, such as: Hyperglycemia; hypoglycemia; peripheral vascular disease (PVD) manifested as gangrene requiring wound care or special therapy; amputations and peripheral artery disease (which they believed were the major cause of morbidity, hospitalization, antibiotic expense and poor outcomes); recent re-entry of transplant patients with re-introduction, continuation, and tapering of transplant medication; hypertension; hypotension; angina with chest pain; post-operative affecting heparin dose; sepsis with antibiotics; routine Coumadin with diagnosis unrelated to ESRD; recurrent transfusions for hematologic problems and site access issues. A few commenters indicated that patients returning after hospitalizations incur extra cost and changes in outcome. One commenter alleged that ESRD facilities need to address nutritional and volume issues after hospitalizations that require extra time and attention.

Response: We thank the commenters for their many suggestions. The inclusion or exclusion of a diagnostic category was based on the regression model. As we explained in the proposed rule, we found that certain co-morbidities are predictors of variation in costs for ESRD patients. We also explained that these co-morbidities have a direct effect on dialysis. We discussed the process used in identifying the universe of ICD–9–CM codes that were initially used in the analysis and how we derived the proposed eleven diagnostic categories.

We do not agree with the commenters' conclusion that we had excluded co-morbidities that affect treatment because, in fact, we did analyze co-morbidities that affect ESRD patients and contribute to increased payments. In our proposed rule, we explained that to ensure that each potential case-mix adjuster had a relationship to cost that was statistically significant and to ensure that the magnitude of the relationship was economically meaningful, low magnitude association with cost, as well as co-morbidities with ambiguous definitions were excluded. Several patient co-morbidities were analyzed having statistical significance and low magnitude association with cost in the preliminary models. Also, co-morbidities with high prevalence such as diabetes and vascular disease were excluded from the proposed diagnostic categories (74 FR 49952).

Based on various issues and concerns raised in public comments regarding the proposed co-morbidity categories recognized for a payment adjustment, we further evaluated the co-morbidity categories with regard to: (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, diagnostic testing patterns, or liberalizing the diagnostic criteria. We utilize these criteria (referred to "criteria") in subsequent discussions below.

We reiterate that it is important for ESRD facilities to report all patient co-morbidities accurately, regardless of whether or not these codes are or are not eligible for an ESRD PPS adjustment. The ICD–9–CM diagnosis codes should be reported in compliance with coding requirements on the ESRD 72x claim as well as the official ICD–9–CM Coding Guidelines.

Comment: Several commenters cited the higher cost of treating patients with Hepatitis B because of facility costs associated with complying with the isolation requirements under the ESRD Conditions for Coverage. Commenters stated that facility costs include providing isolation rooms, protective garments such as gowns and gloves, and special cleaning protocols. Another commenter did not believe the Hepatitis B adjustment amount covered the actual costs for full isolation, special gowning, and the limitations on staff while also caring for additional patients. The same commenter recommended either eliminating the Hepatitis B adjuster or substantially increasing the amount.

Response: Our model demonstrated that Hepatitis B is a stable predictor of separately billable costs. We also recognize that there are costs associated with the ESRD Conditions for Coverage requirements. We utilized the criteria as described above in evaluating the inclusion of Hepatitis B for a payment adjustment. We believe that while there are accurate definitions of Hepatitis B, in our analysis for the proposed and the final rule, we did not access whether a shorter term (acute) or a longer term (chronic) payment adjustment would be most appropriate. This information may depend on the conditions reported on the claims in our determination of whether Hepatitis B is classified as an

acute or chronic co-morbidity adjustment. Further research could also be helpful to determine if the cost of providing care to ESRD beneficiaries with Hepatitis B approximates or exceeds the costs associated with the coefficient. Because we recognize that we need additional research on Hepatitis B, we did not proceed with the remainder of the evaluation. Therefore, in this final rule, we are eliminating Hepatitis B as a co-morbidity diagnostic category adjustment to the ESRD PPS base rate.

Comment: Some commenters opposed the inclusion of cardiac arrest as a patient-level adjustment. One questioned if someone with end-stage cardiac disease would be less complicated to care for in the absence of cardiac arrest. Another commenter asked how long a history of cardiac arrest could be valid in order to receive the cardiac arrest adjustment. Some commenters objected to the cardiac arrest adjustment, citing reasons such as: The nephrologist would need to know about the cardiac arrest and communicate this to staff; HIPPA (patient privacy) may restrict sharing of such information; cardiac arrest is more costly to hospitals but not to ESRD facilities; and difficulty in obtaining cardiac arrest information by the ESRD facility. One commenter recommended eliminating this adjustment because they believed a cardiac event did not significantly affect the amount of time required to provide care for an ESRD patient unless the cardiac arrest was very recent and the patient was unstable. Another commenter tentatively supported inclusion of cardiac arrest as a patient-level adjuster, pending clarification of the testing and documentation required to substantiate the initial and ongoing diagnosis.

Response: We believe the commenters have expressed valid concerns. We applied the criteria as discussed above to cardiac arrest. We believe the first criterium is met because there is a potential for misclassifying a medical episode as a cardiac arrest (for example, considering a patient with transient unresponsiveness during dialysis to have had a cardiac arrest). Other medical episodes and situations can be mistakenly classified as a cardiac arrest, when in fact they are not an actual cardiac arrest. As a result, there is the potential for ESRD facilities to influence the prevalence of cardiac arrest as a co-morbidity recognized for a payment adjustment (criteria number 3). Because we believe there is a lack of consistency in what constitutes a cardiac arrest diagnosis and because commenters generally did not support the inclusion of cardiac arrest as a co-morbidity adjustment, we are not finalizing cardiac arrest as a co-morbidity diagnostic category recognized for a co-morbidity payment adjustment under the ESRD PPS in this final rule.

Comment: Several commenters were in favor of the payment adjustment for infections because commenters believed that treating infections adds cost and intensity of care. A few commenters suggested that an additional outlier payment should be given for each patient month in which a patient is treated for either infections or symptoms of infection to reflect the additional costs of laboratory work, greater use of antibiotics and higher ESA needs. The commenters believed that this met the legislative intent for outliers.

Response: We assume the commenters believed that Congress intended outlier payments to address infections and therefore suggested that an outlier payment be made for each patient month in which symptoms of infection existed or an infection was treated. We do not agree with the commenters because we do not believe that Congress intended for any particular co-morbidity to be eligible for outlier payments. Rather, under the outlier policy described in section II.H. of this final rule, an outlier payment will be made to share the cost of renal dialysis services beyond a fixed dollar loss amount. To the extent that the use of outlier services (that is, drugs and laboratory tests) as a result of an infection exceeds the fixed dollar loss amount, Medicare will make an outlier payment.

As we discussed in the proposed rule, we used a stepwise regression analysis model in analyzing co-morbidity data for case-mix adjustments. The relationship between patient characteristics was related to the reported facility costs. A patient-level model was used to identify potential payment adjusters for separately billable services. We identified co-morbidities that had statistically significant relationships to cost. Based on our analyses, we proposed adjustments for eleven co-morbidity categories. In other words, because our analyses found a correlation between the diagnostic categories (including infections) and higher costs, we proposed to provide a payment adjustment to be applied to the proposed ESRD PPS base rate. For co-morbidities found to be short term, we proposed that the condition must have existed within the past 3 months and affected treatment. In the proposed rule, infections were classified as a short-term co-morbidity eligible for a payment adjustment to the ESRD proposed base rate (74 FR 49953 and 49954). However, we are not including all infections as co-morbidities recognized for separate payment in the final ESRD PPS as we discuss in greater detail below.

Comment: Other commenters opposed the inclusion of infections citing the facilities' success in decreasing infections. Several commenters expressed concern that higher payment (such as the infection adjustment) may be provided for conditions such as bacteremia (related to dialysis catheter) or pneumonia (related to lower vaccination rate) that could be attributed to poor care.

MedPAC expressed concern that paying more for septicemia, for example, could give ESRD facilities an incentive not to provide the necessary care to minimize infections, and could reverse the effectiveness of Medicare's quality improvement efforts for promoting arterio-venous fistulas. (Septicemia was included in the proposed infections co-morbidity category recognized for a proposed payment adjustment.) MedPAC further opined that suboptimal care should not be rewarded.

A few commenters suggested that an adjuster for sepsis/septicemia should be excluded because the commenters believe that it is not a consistent factor in the cost of dialysis care and that paying for infections and hospitalizations serves as a disincentive for reducing catheter use. One commenter believed that if infections remain as an adjustment, peritonitis for patients on PD should be added.

One commenter noted that in addition to the vague meaning of septicemia, the adjustment largely reflects high use of Epoetin® from the acute illness and inflammation. The commenter further stated that variation in Epoetin® dose accounted for almost all cost variation among dialysis patients, thereby driving the associations in the statistical models.

Response: Our analysis for the proposed rule demonstrated that certain diagnostic categories showed effects on cost either long-term or short-term (74 FR 49953). Infections showed higher cost effects for 3 months after the date of diagnosis. Our analysis for this final rule indicated the same findings. We are, however, convinced by the concerns expressed by commenters who opposed the inclusion of infections as a co-morbidity diagnostic category recognized for a payment adjustment to the ESRD PPS base rate.

The intent of a case-mix adjustment is not to award higher payments to ESRD facilities for medical conditions that could be avoided through ESRD facility

practices. To do so, would have the effect of inadvertently rewarding poor quality care. We acknowledge that there may be a greater risk for certain types of infections that we proposed for payment adjustment, including septicemia known to result from vascular access infections.

We evaluated pneumonia, septicemia, and other pneumonia/opportunistic infections using the three criteria described earlier in this section. It is our understanding that vascular access infections are often the result of organisms that cause bacteremia/septicemia conditions in ESRD patients. Prevention of these infectious conditions is a fundamental tenet of dialysis care. Septicemia is a clinical syndrome consisting of a number of non-specific symptoms and signs. In the context of a suspected or known infection, the diagnosis of sepsis is considered when some or all of the defining signs and symptoms are present depending on the severity of those signs and symptoms. The inherent ambiguity of this definition makes the diagnosis subjective. Lack of an objective standard in the diagnosis of septicemia creates the opportunity for providers to increase their payments by changing the sensitivity of the diagnostic criteria for this condition.

Furthermore, we are concerned the inclusion of septicemia as part of the infection co-morbidity category could create perverse financial incentives not to follow this fundamental tenet. This is an area where further research may inform us that subsequent modification of the case-mix adjustment is needed. As additional information becomes available for further analysis, it may be possible to develop an adjustment for septicemia while not negating facility efforts to minimize vascular access infections. Therefore, in this final rule, we are not finalizing septicemia as part of the infection co-morbidity diagnostic category.

We also are not finalizing other pneumonias/opportunistic infections as part of the infection co-morbidity category. We believe that other pneumonias/opportunistic infections meet all of the criteria. Therefore, their inclusion as a co-morbidity payment adjustment category could, as commenters have noted, negate the positive gains made in controlling infections. In the analysis conducted for this final rule, we analyzed the pneumonias/opportunistic infections separately from other infections and did not find the same degree of association with higher costs associated with higher separately billable items and services, as was seen with bacterial pneumonia. For this reason, we do not believe these infection diagnoses warrant a co-morbidity adjustment.

We note that the elimination of "other pneumonias" has a limited effect on the magnitude of the adjustment for patients with bacterial pneumonia and only slightly reduces the number of pneumonias that would be used to determine eligibility for the adjustment. Therefore, for this final rule, we excluded the diagnoses for primary plague pneumonia, unspecified pneumonia, primary coccidiodomycosis unspecified, and rare non-bacterial opportunistic infections.

We believe that bacterial pneumonia does not meet the 3 criteria and, therefore, should be included as a co-morbidity adjustment. Once the other infections were removed, we reran the regression analysis. The regression analysis showed that bacterial pneumonia have a strong validity as a cause of ESA resistance and, therefore, increased ESA requirement for 4 months. Therefore, we are finalizing bacterial pneumonia as the infection co-morbidity diagnostic category eligible for a payment adjustment under the ESRD PPS. The list of bacterial pneumonia ICD–9–CM codes that will be recognized for a payment adjustment to the ESRD PPS base rate appears in Table E of the Appendix. We note that as discussed earlier in this section, an ESRD facility will not receive co-morbidity adjustments during the 4-month onset of dialysis time period.

We will require a documented radiographic diagnosis in the patient's clinical or medical record, in order for an ESRD facility to be eligible for the co-morbidity payment adjustment for the bacterial pneumonia infection category. We will discuss the documentation requirements in future administrative issuances. After the implementation of the ESRD PPS, we will monitor the reporting of bacterial pneumonia on ESRD claims and compare the prevalence of bacterial pneumonia with their prevalence over the past several years.

Comment: A few commenters believed that patients with gastrointestinal bleeding should be eligible for a fixed outlier payment due to ESA and transfusion expense, because this meets the legislative intent of high cost outliers.

Response: We do not agree with the commenters who believed that there should be an additional outlier payment for patients with gastrointestinal bleeding due to ESA and transfusion expense because we believe that the co-morbidity adjustment is more appropriate than applying the outlier policy. We discuss the outlier policy in detail in section II.E.4. of this final rule.

The regression analysis for this final rule demonstrated that certain diagnostic categories showed higher costs over either the long term or the short term. Gastrointestinal bleeding showed higher cost effects for three months after the date of diagnosis (that is, the month of the diagnosis and three months after). As we indicated above, based on various issues raised in public comments regarding the proposed co-morbidity payment adjustment categories, we further evaluated the proposed categories, including the gastrointestinal tract bleeding diagnostic category, based on three criteria. The gastrointestinal tract bleeding co-morbidity category met all of the three criteria, however, as we discussed above, we believe that by limiting gastrointestinal bleeding to gastrointestinal bleeding with hemorrhage, we have satisfied the established criteria by creating accurate clinical definitions and mitigating the potential for adverse incentives regarding care for ESRD facilities to influence the prevalence we are finalizing it as a co-morbidity diagnostic category because our analysis for this final rule also indicated significant validity of gastrointestinal tract bleeding as a cause for increased ESA utilization and, therefore, higher separately billable costs.

However, because we are concerned that the gastrointestinal tract bleeding diagnostic category we proposed is overly broad (as determined by criteria number 1) and could be "gamed" (as noted by the commenter), we have limited in this final rule the diagnoses to gastrointestinal tract bleeding with hemorrhage and have limited the ICD–9–CM codes for luminal ulcers with associated hemorrhage which would be eligible for the payment adjustment. In addition, in order to receive a co-morbidity payment adjustment for this co-morbidity category there must be documentation of an associated hemorrhage with a gastrointestinal tract bleed. We will monitor ESRD claims after the implementation of the ESRD PPS is implemented to see if the prevalence has changed over the past several years.

Comment: Most commenters opposed the inclusion of HIV/AIDS and alcohol or substance dependence as patient-level adjustments. Many cited State confidentiality laws protecting patients' privacy against discrimination, as well as difficulty in obtaining this information for the purposes of documenting the presence of HIV/AIDS and substance abuse.

One commenter questioned how a substance abuse diagnosis would be made if not disclosed by the patient. The same commenter indicated that the inclusion of these codes would be inappropriate, as it would stigmatize patients and require facilities to violate State law in order to meet the requirements to be eligible for the payment adjustment. The commenters therefore believed that if they did not comply with the requirements, they would be inappropriately forced to forego payment. Several commenters stated that substance abuse is highly subjective diagnoses and prone to "gaming" and, therefore, should be eliminated as payment adjustments.

A few commenters believed that a diagnosis of HIV should be a patient level adjuster due to the increased cost of care. However, the commenter questioned how the information would be obtained in order to qualify as an adjustment. Other commenters indicated that HIV/AIDS and substance abuse diagnoses could not be reported without the patient's permission. Other commenters stated that often the ESRD facilities would not be aware of the diagnoses. One commenter opined that providers do not alter their overall treatment practices because of HIV/AIDS suggesting that HIV/AIDS actually may be a surrogate for other costly patient characteristics such as being hypo-responsive to ESA, increased hospitalization, or race. The same commenter suggested that if HIV/AIDS remains a payment adjustment, it should be as a facility-level adjuster.

Response: We concur with the commenters that requiring ESRD facilities to place a diagnosis of HIV/AIDS or a diagnosis of alcohol/drug dependence on the claim may be contradictory to State and other privacy requirements. We acknowledged in the proposed rule that we recognized the difficulties encountered by ESRD facilities that must comply with State privacy requirements (74 FR 49953 and 49954). As a result, the diagnostic categories may be misreported. We do not understand the commenter's suggestion that HIV/AIDS should be a facility adjustment rather than a patient-level adjustment.

Because of the concerns expressed by commenters about State privacy requirements, we are not finalizing HIV/AIDS and Alcohol/Drug Dependence as co-morbidity diagnostic groups and, therefore, HIV/AIDS and Alcohol/Drug Dependence will not be recognized as co-morbidity diagnostic groups for purposes of the co-morbidity payment adjustment under the ESRD PPS.

Comment: Several commenters expressed concerns about patients in nursing homes or long term care (LTC) facilities. One commenter believed the adjustment for alcohol and drug dependency was adequate to compensate for the effort required to determine dependency needs and that alcohol and drug dependency were frequent problems in nursing homes. One commenter indicated that many of the new admissions in nursing homes were for infection. The commenter did not indicate whether to include or exclude the infection adjustment as a payment adjustment until further clarification was provided by CMS regarding testing and documentation requirements. Another commenter claimed that the cost for treating nursing home dialysis patients is higher than community-dwelling patients, because nursing home dialysis patients had higher acuity due to the extent of their co-morbidities; the need for one-on-one caregiver assistance; and higher staffing costs.

Some commenters complained that many of the co-morbidities seen in nursing homes, such as hypertension, diabetes, coronary artery disease, peripheral vascular disease, Alzheimer's, senile dementia, and other mental impairments and ventilator dependence were not considered as being eligible for a payment adjustment. One commenter indicated that the administrative burden for a provider with a disproportionate number of nursing home dialysis patients, because of the limited time they were under the care of the ESRD provider, as well as high turnover. The commenter also suggested that the request for medical records to obtain nursing home patient information should be added to the co-morbidity condition information being tracked on the Form 2728 to help determine patient acuity and cost to treat. Other commenters believed that functional limitations such as inability to walk should be factors included in determining payment adjustments.

Response: The purpose of the co-morbidity adjustments is to provide added payment for those co-morbid diseases that result in higher dialysis costs. Therefore, to the extent that a patient residing in a nursing facility has one of the designated co-morbidity diagnostic categories, the ESRD facility would receive an adjustment to the ESRD PPS base rate.

The only information on functional limitations available to us is from Form 2728 (inability to ambulate or transfer). Our analyses used in developing the proposed rule did explore functional variables, when they were reported, and found no statistically significant relationship to cost for such functional variables. We believe, however, that functional limitations are important measures and will consider these in the future if more complete data become available and show a significant relationship to costs.

We disagree with the commenter requesting changes on Form 2728 to allow it to be used to determine changes in patients' acuity and the resulting cost to treat them. We do not believe that adjustments on a form which is used for the purpose of establishing the ESRD diagnosis should be the basis for determining on-going case-mix adjustments because the Form 2728 would not reflect changes in patient's conditions. In other words, the Form 2728 is a snapshot at the time of the onset of ESRD (capturing, for example, any co-morbidity that exists at the onset of dialysis) and not an ongoing reflection of that individual (capturing, for example, any co-morbidity that might occur during the span of dialysis).

Comment: Some commenters stated that they often do not know about patient's temporary conditions, such as pneumonia, gastrointestinal (GI) bleeding, and pericarditis and, therefore, would not be able to indicate their presence on ESRD claims for the purpose of a payment adjustment.

Response: We believe it is important for ESRD facilities to be aware of patients' conditions. For example, § 494.80(a)(1) indicates that a patient's comprehensive assessment must include evaluation of current health status and medical condition, including co-morbid conditions. For the purpose of receiving a payment adjustment, the appropriate ICD–9–CM codes are required to be present on the claim, and documentation in the patients' medical record supporting the diagnosis is also required.

We discussed in previous responses that bacterial pneumonias and gastrointestinal tract bleeding with hemorrhage as short-term, acute co-morbidity diagnostic categories that would be recognized for the co-morbidity payment adjustment under the ESRD PPS. In addition, our analysis for this final rule supports the inclusion of pericarditis as a co-morbidity diagnostic category because ESRD patients with pericarditis have increased ESA utilization. Therefore, we believe pericarditis would be a predictor of higher costs in ESRD patients with this condition.

We evaluated the pericarditis co-morbidity diagnostic category using the criteria discussed earlier. Because there are distinct clinical definitions for

pericarditis (and diagnostic criteria) and we do not believe that pericarditis has the potential for adverse incentives or the potential to be directly influenced by ESRD facilities (in that an ESRD facility could not influence the development or prevalence of pericarditis), we are finalizing pericarditis as a co-morbidity diagnostic category recognized for the co-morbidity payment adjustment under the ESRD PPS.

We will require ESRD facilities to provide documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment, utilizing specific criteria. We will address these documentation requirements in sub-regulatory guidance. As we have responded to previous comments, we will be monitoring the prevalence of any co-morbidity diagnoses recognized for the co-morbidity payment adjustment under the ESRD PPS as compared to the prevalence of these categories over the past several years. In this manner, we will be able to identify any changes in the prevalence of any of the co-morbidity diagnoses recognized for purposes of the co-morbidity payment adjustment as compared to previous trends.

Comment: We received a wide variety of comments suggesting an array of co-morbidities that commenters believed should or should not be included as being eligible for the co-morbidity payment adjustment. Most commenters opposed the inclusion of the proposed co-morbidity categories, either in totality or in part.

Of the commenters who supported the inclusion of the proposed co-morbidity categories, most supported the chronic co-morbidity categories such as cancers,

Hepatitis B, hereditary hemolytic anemias/sickle cell anemia, monoclonal gammopathy, and myelodysplastic syndrome. Some commenters offered suggestions regarding co-morbidities they believed should have been included in the ESRD PPS such as senility and Alzheimers; methylcyline resistance staphlococcus aureus (MRSA); staphylococcus septicemias; and diabetes. Other commenters opposed the inclusion of cardiac arrest, pericarditis, septicemia, bacterial pneumonia, gastrointestinal bleeding, sickle cell anemia, cancer, myelodysplastic syndrome and monoclonal gammopathy. Some commenters indicated that they were unaware of patients' prior medical histories, such as a history of cancer.

Response: As we explained in the proposed rule, we found that certain co-morbidities are predictors of variation in resources for ESRD patients. We discussed the process we used to identify the ICD–9–CM codes that we initially used in the analysis and how we derived the proposed eleven diagnostic categories. We also explained why certain conditions such as diabetes and vascular disease were excluded from the proposed diagnostic categories (74 FR 49952).

With regard to the cancer co-morbidity diagnostic category, we recognize that a co-morbidity payment adjustment would be applied for patients that may differ greatly in the clinical severity of their cancer diagnosis.

For example, we believe that for patients successfully treated in the past for their cancer, there may be few or no implications for the dialysis care currently being received in an ESRD facility. In contrast, we believe patients undergoing treatment for cancer may require a higher intensity of care (that is, higher use of separately billable services) and, therefore, have higher costs.

We believe that the proposed payment adjustment for the cancer co-morbidity category may have overstated costs for some patients whose dialysis treatment is no longer affected by their history of cancer and may have understated the costs of patients whose current cancer diagnosis and treatment affect their dialysis treatment because, at the current time, we are unable to differentiate the cost impact between the two groups. Therefore, we are not finalizing cancer as a co-morbidity diagnostic category recognized for the co-morbidity payment adjustment under the ESRD PPS.

Future research may identify the cost of providing dialysis care to patients receiving active cancer treatment and potentially could be used to determine a co-morbidity payment adjustment that would more accurately reflect the ESRD resources being used. We believe that differentiating a history of a cancer diagnosis from an active cancer diagnosis, could provide information on how the type of cancer or whether the cancer is being treated affects the cost of dialysis care.

Using the three criteria referenced above, we evaluated the proposed co-morbidity diagnostic categories for chronic, long-term conditions of hereditary hemolytic anemia, myelodysplastic syndromes, and monoclonal gammopathy. Due to the consistent effect (that is, not limited to a short period of time) of the hereditary hemolytic anemias (including sickle cell anemia) on higher EPO useage and therefore, higher separately billable costs, we are finalizing this as a co-morbidity diagnostic category eligible for a payment adjustment to the ESRD PPS. We also believe that myelodysplastic anemia and monoclonal gammopathy should be finalized as co-morbidity diagnostic categories because both of these co-morbidity diagnostic categories have shown an association with higher ESA usage and, therefore, higher separately billable costs. However, we have excluded multiple myeloma, a form of cancer included in the monoclonal gammopathy diagnostic co-morbidity category, because multiple myeloma is a form of cancer and, as we noted above, additional research is needed on the effect of cancer on dialysis costs.

Accordingly, we are finalizing six co-morbidity diagnostic categories and the associated payment adjustment multipliers, which are as shown in Table 22, recognized for the co-morbidity payment adjustment under the ESRD PPS for renal dialysis services provided on or after January 1, 2011. We also are finalizing the diagnostic codes for each of the six diagnostic categories found in Table E in the Appendix. For the co-morbidity payment adjustment to apply, an ESRD facility must document in the patient's medical or clinical records the presence of one of the diagnosis codes eligible for the co-morbidity payment adjustment under the ESRD PPS. We will provide specific instructions for such documentation in the future.

Table 22. Co-Morbidity Diagnostic Categories Recognized for a Payment Adjustment Under the ESRD PPS

Diagnostic Category	Multiplier
Pericarditis (acute)	1.114
Bacterial Pneumonia (acute)	1.135
Gastrointestinal Tract Bleeding with Hemorrhage (acute)	1.183
Hemolytic Anemia with Sickle Cell Anemia (chronic)	1.072
Myelodysplastic Syndrome (chronic)	1.099
Monoclonal Gammopathy (chronic)	1.024

The ICD–9–CM diagnostic codes should be reported in compliance with coding requirements on the ESRD 72x claim, as well as the official ICD–9–CM Coding guidelines. Accurate reporting of co-morbid diagnoses will enable CMS to evaluate the need to update the co-morbidities that would be recognized for the co-morbidity payment adjustment under the ESRD PPS.

Comment: One commenter believed that facilities should receive higher payments for certain "problematic" patients to balance losses on average patients with few adjustments.

Response: We believe that the commenter is referring to financial losses that ESRD facilities may experience under the ESRD PPS treating patients with few characteristics that would be recognized for a payment adjustment. We do not agree with the commenter that ESRD facilities will experience losses on the average patient to whom few payment adjustments would apply and that this would be balanced by higher payments for certain "problematic" (that is, patients for whom the facility receives multiple payment adjustments) patients. The ESRD PPS base rate reflects the cost of the average patient.

Our analysis has identified certain co-morbidity diagnostic categories that have shown higher use of separately billable renal dialysis items and services, which are recognized for a payment adjustment under the ESRD PPS. The co-morbidity payment adjustments are based on evidence from the regression model that the presence or absence of certain co-morbid conditions are related to costs. Therefore, the payment model should neither favor nor disfavor patients with co-morbidity adjustments relative to those who do not qualify for such adjustments; rather the payment adjustment should reflect the higher costs associated with providing renal dialysis services.

As we discussed above, we will need to conduct further research to identify additional co-morbidity categories and diagnoses that could be recognized for the co-morbidity payment adjustment. For these reasons, for this final rule, we have reduced the number of co-morbidity diagnostic categories from eleven to six and among these categories, we are finalizing three acute, short-term diagnostic categories (pericarditis, pneumonia, and gastrointestinal bleeding) and three chronic diagnostic categories (hereditary hemolytic anemia, myelodysplastic syndrome, and monoclonal gammopathy).

Under the final ESRD PPS, the three acute co-morbidity adjustments will be paid for the month the diagnosis is reported on ESRD facility claims and for the next three months. The chronic co-morbidity adjustments will continue to apply to all claims submitted.

Comment: One commenter questioned how the Form 2728 would be updated once it has been completed. Another commenter expressed concern about the time period for applying the co-morbidity adjuster, particularly for gastrointestinal bleeding.

Response: The purpose of the Form 2728 is to attest to the initial ESRD diagnosis. Included in that attestation are additional demographic and clinical information that are present at the time of the initial ESRD diagnosis. As we indicated earlier, the Form 2728 is a snapshot of the ESRD patient's status at the onset of dialysis. Therefore, we would not use information on the Form 2728 to determine the presence of a co-morbid condition for payment adjustment under the ESRD PPS. Instead, co-morbidity payment adjustments under the ESRD PPS will be based upon the diagnosis codes reported by ESRD facilities on their Medicare claims. We plan to use those reported diagnoses for future refinements to the co-morbidity categories and diagnoses.

Comment: Several commenters indicated that they were unable to replicate the proposed co-morbidity adjustments. One commenter claimed that we had overestimated the number of co-morbidities, resulting in an overestimation of reimbursement. Several commenters provided their own analyses (using data resources available to them, such as their own medical records, electronic medical records, hospital discharge summaries, paper charts, health care professional notes, and discussions with professional staff) and were unable to replicate our findings. The commenters indicated that in each of their analyses, their calculated adjustment was lower than the adjustments in the proposed rule. The commenters acknowledged that they do not have access to the vast data resources regarding patient conditions and, therefore, CMS can more accurately determine the adjustments. The commenters questioned CMS' projections of the financial consequences on ESRD facilities due to the proposed "overstated" adjustment factors.

Response: We regret the inability of commenters to replicate our findings. As the commenters acknowledged, claims data are not available due to confidentiality requirements and, therefore, commenters are unable to replicate our findings. We believe that the inability of the commenters to replicate CMS' findings may contribute to the commenters' belief that we have over- or under estimated reimbursement amounts. Historically, there has not been a financial incentive for ESRD facilities to document the presence of co-morbidities. We believe that by including co-morbidity adjustments under the ESRD PPS, ESRD facilities

will implement more active processes for gathering diagnostic information, which will facilitate care planning. We appreciate that commenters were able to identify co-morbidities for their patients for their analyses as it confirms our belief that co-morbidity information is available to ESRD facilities.

Comment: One commenter claimed that six of the proposed co-morbidities were unstable. The commenter indicated that when comparing the co-morbidity adjusters in the proposed rule with the adjusters published by UM–KECC in 2008, six of the adjusters (HIV/AIDS, Hepatitis B, bacterial/other pneumonias/opportunistic infections, hereditary hemolytic/sickle cell anemias, cancer and monoclonal gammopathy) were highly "unstable" and not reliable predictors of cost and, therefore, they should be eliminated as payment adjustments.

Response: Three of the six co-morbidities referred to by the commenter as unstable are not being used to adjust payments in this final rule (HIV/AIDS, Hepatitis B, and cancer). Their exclusion as co-morbidity adjusters was based on other factors which are described above in the response to other comments.

For the three remaining co-morbidities mentioned by the commenter (bacterial/other pneumonias/opportunistic infections, hereditary hemolytic/sickle cell anemias, and monoclonal gammopathy), similar measures are included as payment adjusters for the final rule. These measures, which have undergone several refinements since the proposed rule, are bacterial pneumonia, hereditary hemolytic/sickle cell anemias, and monoclonal gammopathy. In conjunction with the exclusion of cancer as a co-morbidity adjuster, the monoclonal gammopathy category has been narrowed by the exclusion of multiple myeloma (a malignancy). As with the bacterial pneumonia category being used for the final rule that excludes other pneumonias and opportunistic infections, making this category more homogeneous may also serve to enhance its stability. Similarly, sickle cell trait is no longer sufficient for the patient to be classified into the heredity hemolytic anemia/sickle cell anemia category, which should also serve to focus this classification on relatively severe cases most likely to impact dialysis facilities.

For each of these co-morbidity measures, the adjustments in the final rule are for separately billable services only, where the estimated payment multipliers were found to be relatively stable both in the analyses for the final rule and in previous analyses of similar measures that were used for the proposed rule and for the 2008 UM–KECC report. It should be noted that for some co-morbidities, there has been less stability in the estimated payment multipliers based on facility level models for composite rate services. Partly for this reason, the co-morbidity adjusters in this final rule are based on separately billable services only, and are not based on composite rate services. Generally, the payment adjusters are those deemed to best satisfy multiple criteria for inclusion (for example, objective measurability, limited variability in severity, not likely to result from poor quality care, consistent relationship to costs in multiple years of data, and non-trivial impact on costs).

Comment: One commenter asserted that the co-morbidities were not predictive of dialysis costs because they involved medical conditions that are not relevant to dialysis treatment, especially when significant time has elapsed between the condition and the onset of dialysis. Another commenter believed the purpose of case-mix adjusters was valid, but questioned how well the adjustments reflect resource consumption. Another commenter complained that the co-morbidity adjustments do not identify differences in patient utilization of drugs and other resources. One commenter believed the proposed co-morbidity categories did not align with actual resource utilization for dialysis treatment. The commenter believed that CMS was inconsistent in assigning co-morbidity adjustments used for the regression analysis which casts doubt on the predictive value of adjusters produced.

Response: We do not agree with the commenter who believed the co-morbidities were not predictive of dialysis costs because they involved medical conditions not relevant to dialysis treatment. We believe that the co-morbidity adjustments reflect resource consumption and utilization because they reflect higher separately billable payments made for ESRD-related drugs and biological and laboratory tests for patients with certain co-morbid diagnoses. Our analysis has demonstrated that the co-morbidity adjustments have predictive value as evidenced by the overall predictive power of the model. We articulated in the proposed rule how we determined co-morbidities. We began by discussing the process initiated in the CY 2005 PPS proposed rule, whereby we proposed a limited number of patient characteristics including a large number of specific co-morbidities. We explained the methodology we used in selecting the co-morbidities as well as why certain ones were excluded (74 FR 49952). We then explained the rationale used for the CY 2005 final rule (including why we did not include co-morbidities), which implemented the current case-mix adjusted composite payment system (74 FR 49953).

In the proposed rule (74 FR 49953), we explained that the relationship between patient characteristics and cost for composite rate services was estimated using a facility level regression model. We stated that the average patient characteristics were related to the reported facility costs. We further stated that a patient level model was used to identify potential payment adjusters for separately billable services. While the modeling approach used separate equations for the composite rate and separately billable services to select patient characteristics as payment variables, we combined the estimated payment multipliers for composite rate and separately billable services. The payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers (74 FR 49953), where the weights are the shares of total costs attributable to composite rate and separately billable services. As the cost reports are not patient specific, we believe that we addressed costs using the best methodology with the data available.

The range used in the analysis in the proposed rule was based on the years during which our contractor began and continued analyzing ESRD data. For some categories, which we identified as acute, there was a clear break in the data at the 4-month interval, with the presence of the co-morbidity more than 3 months prior to the current month resulting in a substantially weaker relationship to current costs. For others, which we identified as chronic conditions, we could not identify a clear break. For this final rule, the analysis of the co-morbidity diagnostic categories looked at 2006, 2007, and 2008 claims for acute conditions and claims since 2000 for a 6-year span for the chronic conditions. We used 2006, 2007, and 2008 claims for the separately billable analyses.

While the proposed rule used a patient year separately billable model to create consistency between the composite rate and the separately billable models, for this final rule, we used a patient-month level separately billable model for the acute short-term diagnostic category, as the coding of the variable will differ substantially on the annual versus monthly basis because patients only have the condition for part of the year. Measurement for a chronic

condition at the annual or monthly level generally does not vary because the patient either has the condition or does not. The change to the monthly observation tended to reduce the multipliers, especially the short-term acute co-morbidity diagnostic categories. Statistically, this reduction in multipliers for acute conditions is likely to have occurred because patients coded as having the acute condition for part of the year may also have had higher costs at other times of the year. Therefore, the multiplier in an annual model can reflect not just the costs during the months in which an acute condition was present. Because we wanted the short-term multipliers to reflect short-term increases in costs, we believe that changing to a monthly model is appropriate. The net effect in the changes to the separately billable model is smaller adjustments for the acute, short-term diagnostic categories. By using the patient-month separately billable model, the multipliers would more closely reflect costs associated with the specific co-morbidity being measured and occurring in the specific months in which the co-morbidity was present.

The composite rate model continues to be based on data only observed annually. In the proposed rule, the only short-term co-morbidity adjustment in the composite rate model was for bacterial pneumonias/other pneumonias and opportunistic infections. For the final rule, we dropped a measure of bacterial pneumonia from the composite rate model. The exclusion of this co-morbidity adjustment from the composite rate model involves the same reasoning that was used in changing the unit of analysis for the separately billable model from the patient year to the patient-month. We found, for example, that the bacterial pneumonia multiplier in the composite rate model was relatively sensitive to the presence of other co-morbidities in the model, including those that were used in the composite rate model for the proposed rule. As a result, a relatively large portion of this adjustment is likely to capture the effects of other unmeasured factors that increase facility costs. Unlike the separately billable model, however, the same option is not available to change the unit of analysis for modeling composite rate costs, because the cost data are only available at the facility level.

Another concern with applying the bacterial pneumonia adjustment from the composite rate model was that the magnitude of the effect was relatively unstable from year to year in the analysis for the final rule. Therefore, in this final rule, the composite rate model was not applied.

Comment: One commenter suggested that we calculate co-morbidity adjustments not from data from other settings, but on data readily available to ESRD facilities. Other commenters claimed that use of hospital and emergency department records to determine co-morbidities overstated adjusters because these claims include acute illnesses. Commenters suggested that CMS delineate chronic outpatient co-morbidities, resulting in higher reimbursement, and discount the unadjusted mean bundled payment.

Response: We presume that the commenter is referring to sources, such as hospital and physician claims, that were used in conjunction with the ESRD claims. In the proposed rule, we explained our rationale for using the Form 2728, the ESRD cost reports, and claims from various health care providers (74 FR 49952 through 49954). We indicated that we had encouraged ESRD facilities in the past to report co-morbidities on the ESRD claims (74 FR 49953) for purposes of establishing future payment refinements. However, as sufficient co-morbidity diagnoses were not reported on ESRD facility claims, we used other sources of data for the regression analyses.

We believe that given the co-morbidity adjustments under the ESRD PPS, ESRD facilities will take a more active role in gathering information in order to receive a payment adjustment. If so, it may be possible to use diagnostic information reported on claims for future refinements to the ESRD PPS.

With regard to the comment concerning chronic co-morbidities, we believe that the commenter is alleging that chronic co-morbidities rather than acute co-morbidities should be considered for payment adjustment. We do not share this view. As we explained in detail above, we believe the methodology used in determining acute and chronic co-morbidities recognized for the co-morbidity payment adjustment captures those conditions that require more composite rate and separately billable services.

Comment: One commenter expressed concern that many of the proposed co-morbidity adjusters were neither reliable nor robust and, therefore, the commenter recommended the exclusion of the proposed 11 co-morbidity categories. The commenter claimed that the regression methodology that CMS proposed results in overestimation of the adjuster values. The commenter further stated that unless clinical evidence exists to support the independence of the variables in the model, as they pertain to ESRD services furnished and such services' cost distribution, the co-morbidities should be excluded.

One commenter stated that it was not clear how the co-morbidities were identified in the regression analysis or in assigning patients. The commenter also stated there was no reference, analysis, or statistical evaluation of the period of time in the past, for which the co-morbidity condition is relevant. The commenter concluded that flagging patients for each adjuster could be different if co-morbidity codes were searched on claims at different time periods. The same commenter stated that in the proposed rule, we did not provide an explanation about how we determined that an "old" diagnosis no longer affected treatment and, therefore, did not qualify as an adjuster, nor did we discuss how we had historically evaluated which co-morbidity condition was relevant.

Response: As we discussed in the proposed rule (74 FR 49952), we proposed case-mix adjusters in the CY 2005 PFS proposed rule. We explained in the proposed rule that for some diagnoses, such as cancer, we looked at any occurrence since 1999. We also explained that in the proposed rule we used 2007 claims (74 FR 49954). For this final rule, co-morbidities referred to as "acute" were identified in the current month of the analysis or previous 3 months of claims. Co-morbidities referred to as "chronic" were identified in claims since 2000.

For some categories, which we identified as acute, there was a clear break in the data at the four-month interval, with presence of the co-morbidity more than three-months prior to the current month resulting in a substantially weaker relationship to current costs. For others, which we identified as chronic conditions, we could not identify a clear break.

For this final rule, the analysis of the co-morbidity diagnostic categories involved 2006, 2007, and 2008 claims for acute conditions and claims since 2000 for a six-year span for the chronic conditions, although the actual Medicare history will vary based on when a patient became entitled under Medicare. Because some patients have shorter Medicare histories, the claims may miss some diagnoses that were actually present, resulting in an underestimate of their clinical prevalence.

We used 2006, 2007, and 2008 claims for the separately billable analyses. Estimating the regression models year by year (rather than for the full 3-year

period) showed that the same co-morbidities tended to predict costs in each year, which suggested the adjusters were reliable and robust. In our analysis for this final rule, we once again identified a clear break in the higher utilization of separately billable items and services after 4 months for the acute conditions and no break for the chronic conditions.

In the proposed rule, we used a patient year separately billable model to create consistency between the composite rate and the separately billable models. For this final rule, we used a patient-month level separately billable model for the acute short-term diagnostic category. The coding of the variable will differ substantially on the annual versus monthly basis because patients only have the condition for part of the year. Measurement for a chronic condition at the annual or monthly level generally does not vary, because the patient either has the condition or does not. The change to the monthly observation tended to reduce the multipliers, especially the short-term acute co-morbidity diagnostic categories.

Statistically, this reduction in multipliers for acute conditions is likely to have occurred because patients coded as having the acute condition for part of the year, may also have had higher costs at other times of the year. Therefore, the multiplier in an annual model can reflect not just costs during the months in which an acute condition was present. Because we wanted the short-term multipliers to reflect short-term increases in costs, we believe that changing to a monthly model is appropriate. The net effect in the changes to the separately billable model is smaller adjustments for the acute, short-term diagnostic categories. The composite rate model remains as data only observed annually because the cost reports which are used are completed on an annual basis. By using the patient-month separately billable model, we believe that the multipliers would more closely reflect costs associated with the specific co-morbidity being measured and occur in the specific months in which the co-morbidity was present.

As for the assertion by commenters that there was a lack of independence of predictors, we found that there were no strong correlations between the presence of different co-morbidities. Regression analysis identifies the independent contribution of different variables on the outcome of interest. If multiple variables were highly correlated, the regression analysis would be unlikely to show that each of the variables had a statistically significant, independent effect on the outcome.

Comment: One commenter opposed the inclusion of the proposed co-morbidities out of the belief that ESRD facilities' lack access to reliable data, which would prevent facilities from tracking and reporting co-morbidities in a manner that is adequate to support reimbursement. The commenter argued that the disparity in the findings using data available to ESRD facilities was not surprising and referenced an article published in the Journal of the American Society of Nephrology. The commenter alleged that in the article, the CMS contractor, UM–KECC, had conceded that additional data not currently available to CMS is required to improve the predictive power of its case-mix model. The commenter further alleged that what data exists is incomplete or inaccurate with respect to occurrence, frequency, and severity. The commenter also stated that in the article, UM–KECC acknowledged that some co-morbidities were difficult to collect and the prevalence varies with the "look-back" period. The commenter further noted that in the article, UM–KECC stated that reporting on the claims would create a new administrative burden and that adjusting payments for co-morbidities could create inappropriate incentives.

Response: Although UM–KECC acknowledged that the article does refer to limitations that exist in the available data, they believe that the available data are sufficient to estimate some of the important predictors of costs. UM–KECC has indicated that it does not doubt that additional data would improve the predictive power of the models, but acknowledges that such data are not available. UM–KECC noted the prevalence varied most with look-back period for those co-morbidities that were used as acute conditions. For those conditions, older diagnoses had substantially weaker relationships to costs and therefore, were not proposed as case mix adjusters.

Given the low level of reporting of co-morbid conditions on current ESRD claims, UM–KECC agrees that obtaining and reporting the information could create some new burden, but hopes that encouraging facilities to increase awareness of co-morbid conditions will facilitate improvements in the care planning process. Given that in-center dialysis patients typically are in the facility three times weekly and see a nephrologist about four times per month, we believe the additional burden will be relatively minor.

Comment: Some commenters claimed that we overstated the prevalence of the co-morbidity diagnoses because their findings did not demonstrate the same prevalence for the adjusters we identified. One commenter noted their findings about prevalence were lower than the prevalence that we reported in the proposed rule, with the magnitude of the difference very large for hepatitis B, septicemia, cancer HIV/AIDS, hemolytic or sickle cell anemia, monoclonal gammopathy, myelodysplastic syndrome, and pericarditis. One commenter reported a higher prevalence for cardiac arrest, pneumonia/other opportunistic infections, alcohol-drug dependence, and gastrointestinal bleeding, but noted that in each case the difference was less than 2 percent.

One commenter stated they were only able to replicate the prevalence rate for cardiac conditions. The commenters acknowledged that they used their own data sources, which they recognize are not as comprehensive as the data available to CMS.

Response: We appreciate that commenters were able to identify co-morbidities for their patients for their analyses, as it confirms our belief that co-morbidity information is available to ESRD facilities.

As we discussed above in response to commenters' inability to replicate our findings, historically there has not been a financial incentive for ESRD facilities to document the presence of co-morbidities because there was no payment associated with a co-morbidity. We believe that given the co-morbidity adjustments under the ESRD PPS, ESRD facilities will take a more active role in gathering and reporting co-morbid diagnostic information.

However, frequencies of co-morbidities found in the Medicare claims files may still differ from those found in the historical records of ESRD facilities, because each ESRD facility may not have the same number or percentage of patients with the same co-morbidities as other ESRD facilities or they may differ from the national average. The reported diagnosis information provided by ESRD facilities will serve as the basis for subsequent revisions to and improvements in the case-mix adjustments.

Comment: One commenter believed that without access to all the claims data that was used to ascertain the adjusters, ESRD facilities will under-report them, resulting in systematic underpayment.

Response: We believe that the commenter means that if ESRD facilities do not have access to other claim sources (such as hospital claims), they may under-report co-morbidities. We acknowledge that ESRD facilities will

need to be proactive in obtaining co-morbidity information from other health care providers.

We will require ESRD facilities to report the appropriate ICD–9–CM code for the co-morbid condition recognized for purposes of the co-morbidity payment adjustment under the ESRD PPS, if the ESRD facility wishes to receive the adjustment. However, as we discussed and explained above, we are finalizing a smaller number of co-morbidity diagnostic categories in this final rule. The number of co-morbidity diagnostic categories we are finalizing for purposes of the co-morbidity payment adjustment has been reduced from eleven to six.

We also are providing in Table E in the Appendix, the list of ICD–9–CM codes that would be recognized for purposes of the co-morbidity payment adjustment. The number of specific diagnostic ICD–9–CM codes eligible for the co-morbidity payment adjustment has been reduced from hundreds to eighty-eight. We believe these reductions will mitigate many of the concerns expressed by commenters.

As we discussed in a previous response, § 494.80 in the ESRD Conditions for Coverage, specifies that a patient's comprehensive assessment must include an evaluation of current health status and medical condition, including co-morbidities. We acknowledge that the Conditions for Coverage do not require that co-morbidities be documented on the ESRD claim using ICD–9–CM codes. However, for the purpose of receiving a co-morbidity payment adjustment for an eligible co-morbidity, ESRD facilities will be required to document the ICD–9–CM code on the ESRD claim with documentation to support the ICD–9–CM code maintained in the patient's medical or clinical chart. We will discuss the documentation requirements further in the future in administrative issuances.

Comment: One commenter expressed concern that our reliance on cost reports is misplaced and claimed that there is nothing to support a presumption that facility cost report data can be linked with patient-level variance in the cost of care. The same commenter claimed that company practices, such as staffing practices, volume discounting, and group purchasing, may have a greater impact on facility costs than a transitory combination of patient characteristics and conditions that may not be tied to the cost reporting period.

Response: We do not share the commenter's view that the use of cost reports is misplaced. We acknowledge that ESRD facility cost reports cannot be linked with individual patient level variance in the cost of care. In the proposed rule, we indicated that the relationship between patient characteristics and cost for composite rate services was estimated using a facility-level regression model to relate the average patient characteristics to the reported facility costs. We further stated that a patient level model was used to identify potential payment adjusters for separately billable services. While the modeling approach used separate equations for the composite rate and separately billable services to select patient characteristics as payment variables, we combined the estimated payment multipliers for composite rate and separately billable services. The payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers (74 FR 49953).

To assess the relationship between patient characteristics and costs for composite rate services, we are currently limited by the absence of patient-level cost data. Instead, this analysis must be done by relating differences in patient characteristics across facilities with differences in average facility costs for composite rate services, using cost report data. For example, if each 10 percent increase in the prevalence of a co-morbidity within an ESRD facility's population is associated with one percent higher cost per treatment (across all treatments the ESRD facility provides), that characteristic would have a multiplier of 1.10. This is the same approach that was used to develop the basic case-mix adjustment for the composite rate.

We recognize there are limitations to this approach for co-morbidities that are relatively uncommon, where estimates of the increment in cost for a particular condition are generally based on very small differences in the prevalence of the condition across facilities. Therefore, unlike the payment model in the proposed rule, the current payment model does not reflect co-morbidity adjustments for composite rate costs.

Most cost reports cover a calendar year. In cases where the cost report does not coincide with the calendar year, weighted averages of success cost reports were calculated to link the cost reporting period more closely to the period over which patient characteristics were measured. For example, if a facility's reporting period is October 1 through September 30, its 2006 costs would be a weighted average of its report covering October 1, 2005 through September 30, 2006 and its report covering October 2006 through September 30, 2007, with three quarters of the weight placed on the earliest report (which included three quarters of the 2006 calendar year).

Comment: One commenter indicated that we did not take into account certain diseases that require more care and costs. The commenter believed we failed to take into account the variations in caring for individual patients, and were penalizing facilities that provide more comprehensive care (thus eliminating patients' need to spend non-dialysis days in other health care settings). Examples that the commenter cited were diabetes management, hypertension management, anti-coagulant monitoring, and pre-transplant testing.

Response: We do not believe that we are penalizing ESRD facilities that provide comprehensive care to patients. For example, as discussed in section II.E.1. of this final rule, commenters indicated that ESRD facilities administer drugs and biological for purposes other than for renal dialysis-related conditions. Consequently, we provided for these services to continue to be paid as separately billable items. In section II.K. of this final rule, we discuss how we will provide for laboratory tests that are performed for non-ESRD-related conditions, to be paid as separately billable items.

With regard to the comment that we have not accounted for other conditions that require more care or costs, in the proposed and in this final rule, we have addressed the methodology of how we identified payment adjustments that capture higher resource utilization and, therefore, higher costs. We believe that the patient-level adjustments, the home training add-on adjustment and the outlier payment all address patients who require higher resource utilization. We will continue to analyze ESRD claims and costs after the implementation of the ESRD PPS and will discuss any refinements that may be needed in future rulemaking.

Comment: Most commenters cited administrative reasons for wanting to exclude the co-morbidity categories as patient-level adjusters, such as difficulties in obtaining hospital data; difficulties in determining beginning and end dates of co-morbidities such as gastrointestinal bleeding; the financial burden on the facilities due to the cost of training and hiring coders to document conditions properly with cost possibly exceeding payment increases; changes in systems to collect and update data continuously to capture adjusters and codify them on claims requiring additional staff; limited number of diagnoses that facilities use to justify dialysis treatment; complexity

overwhelming facilities; risk of reducing staff time from patient care to allow them to code diagnoses; incurring fees from other providers for copying medical records; difficulty in tracking co-morbidities; the need to create new documentation processes to capture necessary medical information and accurately code, entailing efforts by medical records personnel, clinical personnel, nurses, and physicians; and the need to add complex administrative resource intensive systems.

Several commenters claimed the co-morbidity adjustments would cause administrative burdens to small dialysis organizations. The same commenters indicated that the information would be hard to collect and assure accuracy except for hepatitis B. Others cited lack of reporting of co-morbidities due to patients' and caregivers with poor memories or cognitive abilities; multiple hospitalizations in multiple hospitals; and the need to obtain information from nephrologists.

One commenter believed the adjustments were too high and that there would be a financial risk to providers who will require increased resources to code correctly. One commenter claimed that the facilities facing severe financial losses would reduce costs and shift from the goal of seeking the best or highest standards of patient care towards those that are merely acceptable or adequate. Some commenters claimed that the co-morbidities have not historically been collected and should be eliminated because it is difficult, unreasonable, unrealistic and almost impossible to obtain the information that may affect the ability to provide care. Another commenter stated that the administrative and information technology burden for tracking co-morbidities outweighed the benefit.

A few commenters opined that the new payment system should revert back to the system prior to 2005, whereby all facilities received a lump sum payment for every dialysis treatment provided to all patients. Several commenters believed the system is too complex for patients and families to follow the calculations to determine their responsibility. Several commenters indicated that most providers accurately code all chronic ESRD problems and rely on hospital certified coders to code problems in the discharge summary. The same commenters were concerned that they will need to capture all new co-morbidities in the month that they occur with incomplete data thereby delaying claims processing resulting in lost reimbursement. A few commenters suggested that the adjusters be limited to those at the time of initiation of dialysis, because they claim there is no mechanism to update information when co-morbidities change. Others cited the lack of access to hospital and other records.

Response: We thank the commenters for sharing their concerns. We understand that the implementation of the ESRD PPS, including the requirement to document co-morbidity diagnostic categories to be eligible for adjustment to the ESRD PPS, will be new to some ESRD facilities. However, since the ESRD Conditions for Coverage were issued in 2008, ESRD facilities have been aware of their responsibility to assess and record co-morbid medical conditions in the medical records.

We believe that ESRD facilities will obtain diagnostic information through increased communication with their patients, their patients' nephrologists and their patients' families. When an ESRD patient misses a treatment, the ESRD facility should determine whether the patient has been hospitalized and, if so, what was the condition treated. To the extent the patient is unable to provide the information the ESRD facility would consult with the patient's nephrologists or family to seek additional information.

The reduction of the number of co-morbidity diagnostic categories should reduce the burden on ESRD facilities to identify co-morbidity diagnostic categories that would need to be entered on ESRD claims to be recognized for a payment adjustment. Given that we have reduced the number of co-morbidity adjustments and that in-center dialysis patients typically are in the ESRD facility three times per week, and that ESRD patients typically see a nephrologist about four times per month, we believe the burden of tracking co-morbidities will not be as onerous as the commenters fear.

Comment: Some commenters suggested that co-morbidity adjusters should only be those that are chronic in nature and do not change each month, and that we should consider operating costs in deciding which adjusters to use.

Response: The determination of which co-morbidity diagnostic category would be recognized for purposes of the co-morbidity payment adjustment is based on results of the analyses we described above. We identified and are finalizing three chronic and three acute co-morbidity diagnostic categories that would be recognized for the co-morbidity payment adjustment under the ESRD PPS.

Comment: Several commenters suggested that CMS be responsible for assessing when adjusters are necessary. The commenters noted that because CMS has access to all claims, CMS should incorporate the co-morbidities that it identifies into payment determinations without burdening providers. The commenters further suggested that if CMS assumed responsibility for determining which diagnosis were eligible for a payment adjustment, adjustments would not be subject to fraud and abuse.

Response: We believe that ESRD facilities should be aware of patients' co-morbidities and we assume are in the best position to determine such information and, therefore, should be responsible for identifying all co-morbidities on the ESRD claim whether or not they are eligible for a payment adjustment. Accordingly, we do not believe that we should be assuming responsibility for identifying patient co-morbidities for ESRD facilities. We do not believe that our assuming responsibility for identifying payment adjustments would, in itself, serve to eliminate fraud and abuse, because other health care providers would be documenting co-morbidities on their respective claims and we would be obtaining the co-morbidities from those claims. It is incumbent on all providers to put correct information on claims, whether or not there are payments associated with the information.

As we noted above, in order to receive a payment adjustment to the ESRD PPS base rate, ESRD facilities will be required to document on ESRD claims the co-morbidity using the appropriate ICD–9–CM code in accordance with ICD–9–CM coding guidelines.

Comment: One commenter expressed concern that ESRD organizations will determine which combination of co-morbidities would generate large payments. One commenter suggested that we consider the compound effect of multiple adjusters that may have a singular association, but may not warrant compounding when used for a single patient and treatment. Other commenters believe that the adjusters will result in facilities only treating the sickest patients with the most co-morbidities in order to increase revenue. Some commenters expressed their concerns about adjusters being manipulated resulting in up-coding in order to seek higher payment. Another commenter indicated that facilities would be motivated to have patients with as many adjustments as possible regardless of whether there were appropriate numbers and quality of trained staff or the ability to care for more complex patients.

Several commenters predicted that the fallout of including co-morbidities

as adjusters would result in "cherry picking" leading to a crisis in dialysis care. One commenter expressed concern that extra care may be the same for a patient with a single co-morbidity, as a patient with multiple ones. Another commenter indicated adjusters are based on past history and subject to interpretation and abuse. The commenter questioned whether ESRD facilities will try to maximize revenues by qualifying patients for greater reimbursement due to previous medical histories that have no impact on patients and do not add costs to their current treatment regimen.

Some commenters expressed concern that sicker patients with multiple co-morbidities may not find an ESRD facility to provide care. A few commenters believed patients with few or no co-morbid conditions may be unable to transfer to another facility because facilities will fill open slots with patients who have enough co-morbid conditions to cover the cost of providing dialysis to them. Other commenters acknowledged the potential of errors and manipulation with the co-morbidities, citing alcohol dependency as an example. One commenter suggested eliminating the adjusters, if ESRD facilities would be responsible for tracking them.

Response: We appreciate the concerns raised by commenters. We do not agree that the inclusion of co-morbidities as payment adjustments will lead to "cherry picking" of patients, because in the absence of case-mix adjustments reflecting patient cost, "cherry picking" the healthiest patients may well be a more serious problem. We believe that ESRD facilities will provide appropriate care under the ESRD PPS and we believe that our continued monitoring will identify the few ESRD facilities that do not.

We acknowledge that the number of co-morbidities that an individual has does not necessarily determine the need for additional care. As commenters have noted, there may be other factors, such as functional limitations, that result in the need for additional care. However, at this time, with the data available to us, we have identified six co-morbidity diagnostic categories which have shown higher costs due to higher separately billable costs. These co-morbidity diagnostic categories will be recognized for the co-morbidity payment adjustment under the ESRD PPS base. We will continue to look at other factors and other co-morbidities as ESRD facilities begin to enter co-morbidities on ESRD claims.

With regard to the commenters expressing concerns about dialysis organizations determining which combination of co-morbidities would generate large payments and "cherry picking" these patients, we performed further analysis of the co-morbidity diagnostic categories for this final rule. We found that although costs were somewhat higher for patients with multiple co-morbidities, the effect of compounding two or more co-morbidity adjustments would on average result in a higher payment adjustment than is warranted. However, because we are unable to determine the extent of this higher cost, we do not believe that providing an adjustment for more than one co-morbidity, is warranted at this time. In addition, the costs the co-morbidity adjustments are capturing are mostly related to separately billable services, primarily the use of EPO. We believe that providing multiple co-morbidity adjustments would overstate EPO utilization, especially in light of the medically unbelievable edits applied under the EPO Claims Monitoring Policy.

In order to avoid overly-high payments for co-morbidities, under the final ESRD PPS an ESRD facility may receive only one co-morbidity case-mix adjustment per co-morbidity category per claim, regardless of whether the patient has co-morbid conditions from different co-morbidity diagnostic categories. In the event that there is more than one co-morbidity diagnosis category that is applicable, we will apply the highest payment adjustment in order to reflect the slightly higher costs associated with patients with multiple co-morbidities.

In addition, our analysis has shown that it is very rare for an ESRD patient to have more than one of the final diagnostic categories recognized for a payment adjustment. Using the same comprehensive data sources we used to identify co-morbidity categories (including claims from hospital inpatient stays, outpatient encounters, physician, skilled nursing facilities, etc.), we determined that approximately 92 percent of patient-months have no co-morbidities reported; approximately 7.4 percent of patient-months had only one reported co-morbidity. Less than 0.45 percent of patient-months had two co-morbidities reported.

Therefore, in the rare event that a patient has more than one co-morbidity diagnostic category, the adjustment for the category with the highest adjustment factor would be applied. Where there are two chronic categories reported, a payment adjustment would be applied using only the chronic co-morbidity category with the highest adjustment. Since the acute co-morbidity categories all have higher values than the highest chronic co-morbidity category, in the event a patient with a chronic condition that is eligible for a payment adjustment acquires an acute condition that is also eligible for a payment adjustment, the payment adjustment would only apply for the acute condition. In the event that a patient has 2 or more acute co-morbidities eligible for a payment adjustment, the adjustment would only apply to the acute co-morbidity with the highest adjustment.

We wish to ensure that patients continue to have access to high quality dialysis care. It will be an important focus of our monitoring efforts to review multiple data sources on co-morbidities and determine if these trends change as a result of the ESRD PPS and the co-morbidity adjustments so that we can ensure continued access for patients. We will track data on co-morbidities to detect changes in prevalence or type of conditions coded. To the extent that an ESRD patient has higher resource needs, as a result of multiple co-morbid conditions, or some other complication, we expect that the outlier adjustment and blended transition payments, as set forth in this rule, would provide sufficient protection against extraordinarily high costs, particularly in the first year of the transition. We will consider future refinement of our co-morbidity adjustment policy based on data from ESRD claims and other sources from the period after implementation of the new payment system to ensure that patients continue to have access to high quality care.

As we noted in the onset of dialysis discussion earlier in this section of this final rule, our analysis for this final rule indicates an increase in costs for the composite rate portion of the two-equation model, which may reflect an increase in the level of resource utilization required to stabilize individuals who are new to dialysis. The analysis also demonstrates an increase in measured costs for the separately billable portion of the model, particularly for ESA utilization. While we found that costs were higher, on average, for dialysis patients with a co-morbidity during the first 4 months following the onset of dialysis, the effect of compounding a co-morbidity adjustment with the onset of dialysis adjustment would, on average, result in higher payment adjustment than is warranted for separately billable services. Therefore, the co-morbidity payment adjusters will not apply for facilities receiving the onset of dialysis payment adjustment.

With regard to the comment that adjusters are based on past history, we

are finalizing three chronic co-morbidity categories which are based on the patient's medical history and, which would be recognized for a continuous payment adjustment (except when there is an acute co-morbidity as described above); and, three acute co-morbidities that are based on the co-morbidity's presence in the current claim month and for three subsequent months.

With regard to commenters' concern about errors and manipulation of the reporting of co-morbidities, specific documentation of co-morbid conditions in patient medical/clinical records using specific guidelines will be required for this payment adjustment and we will address such details in future administrative issuances. We anticipate monitoring the use of co-morbidities. We will continue to assess the current as well as future co-morbidity diagnostic categories to ensure that all Medicare beneficiaries with ESRD have access to appropriate renal dialysis services.

Comment: One commenter cautioned that the number of co-morbidities would go up, stating the analogy of increased Epogen® use by the LDOs due to financial gains. The same commenter suggested that providers will encourage physicians to admit high-cost patients to other facilities and order expensive medications and tests at these facilities. One commenter expressed concern that the current claims processing system does not accommodate the potential number of adjustments needed.

Response: The current claims are able to accommodate the reporting of nine co-morbidities as secondary diagnoses. We will explain billing issues relating to co-morbidity adjustments in sub-regulatory guidance in the future.

As we indicated above, we expect ESRD facilities to furnish appropriate care to their patients under the ESRD PPS, but we will monitor the ESRD PPS to identify the ESRD facilities that may not. We believe the concerns raised by the commenters could also exist under the current basic case-mix adjusted composite payment system.

Comment: Some commenters explained that many adjustments do not have significant impact on the delivery of care. One commenter believed that the case-mix adjusters are for the purpose of protecting small providers against financial consequences of high-risk patients.

Response: We recognize that the presence of a co-morbidity does not always result in high costs. As explained in the discussion of the regression model in this final rule, adjustments to the ESRD PPS base rate are based on average costs. In other words, on average, patients with diagnoses in the co-morbidity diagnostic categories will have higher separately billable costs. The payment adjustment reflects this average. There may be patients with the co-morbidity who have less-than-average separately billable costs and others with higher costs. Because of this variability, some patient costs will be lower than the adjusted payment rate while others will be higher. In the absence of co-morbidity payment adjustments, differences between patient costs and payment are greater. The purpose of adjusting for co-morbidities and other patient characteristics is to reduce the average difference between actual patient cost and payment.

Comment: Several commenters expressed concern that the adjustments decrease the base rate. These commenters recommended a higher base rate with fewer adjustments. Some commenters stated that in order to recapture the payment lost to the base rate, ESRD facilities would have to ensure that some of their patients have the co-morbidities recognized for a payment adjustment to the ESRD PPS base rate. Several commenters suggested eliminating all adjustments and providing the same payment for all.

Response: The commenters are correct that the base rate has been reduced as a result of the co-morbidity diagnostic categories in order to maintain budget neutrality as discussed in section II.E.3. of this final rule. Failure to adjust for patient characteristics related to cost could result in reduced access to care for patients with characteristics generally known to be associated with cost.

Eliminating all adjusters and providing the same payment for all facilities is not an option, as section 1881(b)(14)(D)(i) of the Act specifies that the Secretary shall include a payment adjustment based on case-mix that may take into account patient weight, body mass index, co-morbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. We believe that providing for the case-mix and other adjustments we are including in this final rule to account for the higher costs for certain patients meets the intent of the statute.

Comment: One commenter believed that bundling oral drugs would impact management of common co-morbidities such as anemia, secondary hyperparathyroidism and metabolic bone disease.

Response: We discuss the oral drugs in section II.A.3. of this final rule. With regard to the co-morbidities that the commenter identified (anemia, secondary hyperparathyroidism, and metabolic bone disease), we are not finalizing these three diagnoses for purposes of the co-morbidity payment adjustment under the ESRD PPS. We explained in detail in the proposed rule and in this final the methodology that was utilized in identifying co-morbidities that would be recognized for a payment adjustment. Furthermore, anemia, secondary parathyroidism and metabolic disease are complications that occur in ESRD patients (that is, they are ESRD-related). If we apply the criteria that we discussed above, these conditions would meet two of the three criteria. That is, because these conditions are ESRD-related, there is a potential for adverse incentives regarding care (criteria number 2) and there is a potential for ESRD facilities to directly influence the prevalence of the co-morbidity either by altering dialysis care, diagnostic patterns, or liberalizing the diagnostic criteria. Therefore, they would not be considered as co-morbidities recognized for a payment adjustment.

Comment: One commenter expressed concern that facilities obtaining multiple co-morbid adjustments would result in patients paying more co-insurance and those lacking supplemental coverage facing financial hardship or even involuntary discharge for non-payment. One commenter suggested adding money for units that provide care to higher-acuity patients.

Response: As discussed in section II.K.l. of this final rule, beneficiary co-insurance liability is based upon the total payments made to an ESRD facility on behalf of the beneficiary. As we discussed earlier, ESRD facilities will only receive a payment adjustment for one co-morbidity and, therefore, beneficiaries will not be held financially accountable for a co-insurance based upon multiple co-morbidities.

With regard to the commenter who suggested adding money for units that provide care to higher acuity patients, we note that the patient-level adjustments are intended to provide additional payment for higher cost patients.

f. ICD–9–CM Coding

We proposed that in order to receive a co-morbidity payment adjustment, the appropriate ICD–9–CM code, using the official ICD–9–CM Coding Guidelines, would need to be entered on the claims (74 FR 49954). This includes codes from both the individual body system chapters (codes 001.0–999.2), as well as appropriate codes from the supplementary classification of factors

influencing health status and contact with health services chapter (VO1.0–V89.09). We acknowledge that many of these codes, such as those for a history of a disease would not be eligible for a co-morbidity adjustment. We noted that we would issue through sub-regulatory guidance, any changes in codes eligible for a co-morbidity payment adjustment in the event of any changes in coding in the future (74 FR 49954). For example, ICD–10–CM will be implemented for services occurring on or after October 1, 2013. (See 74 FR 3328–2238–3362 for information on the Implementation of ICD–10–CM). We are finalizing our determination that in order to receive a co-morbidity payment adjustment, the appropriate ICD–9–CM code, using the official ICD–9–CM Coding Guidelines, would need to be entered on the claims.

In the proposed rule (74 FR 50027), we explained the analyses that we performed to determine the extent that specific diagnoses within the eleven co-morbidity categories are on ESRD claims. We also explained our analysis of the ICD–9–CM diagnosis codes, as identified by UM–KECC, and we provided a complete list of the codes identified by UM–KECC. We also provided a list of codes associated with diseases/conditions that we proposed would be recognized for the purposes of an ESRD co-morbidity payment adjustment (74 FR 50069).

We also explained that we eliminated specific ICD–9–CM codes associated with specific diseases/conditions that we proposed would not be recognized for purposes of a co-morbidity payment adjustment, and we provided a listing of these ineligible codes (74 FR 49955).

Comment: Some commenters expressed concern that facilities will face a huge administrative burden to ensure accuracy of data in order to be eligible for the patient-level adjusters, which "could and likely will result in cutting corners in care delivery." Others expressed concern about the need to change systems or lack of data to support eligibility for adjusters. A few commenters suggested including only adjustments that do not require administrative time, have a real impact on care, and do not need to be changed or documented. Other commenters stated that they have access neither to ICD–9–CM codes nor to claims from other health care providers who do document ICD–9–CM codes. Some commenters lamented that the co-morbidity adjustments did not offset the cost to change systems, obtain staff, and document codes correctly. One commenter believes that the difficulty of documenting ICD–9–CM codes would indicate that the co-morbidities should be eliminated.

Response: We do not believe that changes in a payment structure that represent appropriately case-mix adjusted payments should be eliminated because of administrative changes that result. We also do not agree that patient-level adjusters should be comprised of only those that do not require staff to ensure accuracy or are easier to manage administratively. We agree with the comment that adjustments with "real impact on patient care and care planning should be principle factors for which information should be reported," as we believe that our analysis on correlating payment with the adjustments does support patient care and planning principles.

Comment: We received two comments indicating that the elimination of the heading for myelodysplastic syndrome resulted in no codes for this condition that would be eligible for the co-morbid payment adjustment.

Response: We thank the commenter for bringing this to our attention and for providing a list of codes that can be used. We acknowledge that we inadvertently omitted the specific ICD–9–CM codes for myelodysplastic syndrome in the proposed rule. We have indicated the specific ICD–9–CM codes for myelopdysplastic syndromes in Table E of the Appendix.

In the proposed rule (74 FR 49955 through 49962), we proposed a number of tables identifying specific ICD–9–CM codes which would not be recognized for purposes of the co-morbidity payment adjustment. We solicited comments on the ICD–9–CM codes which we proposed to not recognize. We did not receive any comments pertaining to the ICD–9–CM codes we proposed not to recognize for purposes of the co-morbidity adjustments. Therefore, in this final rule, we are eliminating the tables with ICD–9–CM codes for co-morbidities not affecting costs in outpatient ESRD facilities; NEC/NOS/Unspecified codes; benign tumors; and category headings.

In this final rule, we are finalizing in Table E of the Appendix, the ICD–9–CM codes for the six co-morbidity diagnostic categories which would be recognized for an adjustment to the ESRD PPS base rate. As we have reduced the final co-morbidity diagnostic categories to six and made changes to the diagnoses we are finalizing in this final rule, we have updated Table E to contain only the ICD–9–CM codes which will be recognized purpose of the co-morbidity payment adjustment under the ESRD PPS. We note that we have included the list of ICD–9–CM codes that were used by UM–KECC in the analysis of the co-morbidity diagnostic categories for this final rule. This list is in Table E in the Appendix of this final rule. We are also finalizing the inclusion of co-morbidities as patient-level adjustments in § 413.235(a).

As we discussed earlier, documentation supporting the eligible co-morbidity diagnosis on the ESRD claim will be required in the patient's medical record. We will be providing specific instructions about such documentation requirements in the future.

g. Race/Ethnicity

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's race and ethnicity (as well as other patient characteristics such as patient weight, body mass index, etc.). In the proposed rule, we presented analyses of potential case-mix adjustments based on race and ethnicity (74 FR 49962). We indicated that while the inclusion of race and ethnicity factors may improve the predictive value of the proposed ESRD PPS, we had concerns about whether the data were of sufficient quality upon which to base payment adjustments (74 FR 49966). The regression analysis we conducted for purposes of the proposed rule relied on two separate data sources for race and ethnicity status to assess the extent to which race and ethnicity would account for cost factors that are otherwise unexplained in the model. The first analysis was based on race and ethnicity data retrieved from the Renal Management Information System (REMIS) and the second analysis was based on data retrieved from the Medicare Enrollment Database (EDB). We note that in the proposed rule we inadvertently indicated that race and ethnicity data that were collected on the Form 2728 were retrieved from REMIS for purposes of conducting the analysis. We wish to clarify that these data were retrieved from the Standard Information Management System (SIMS). From this point forward we refer to data that were collected from the Form 2728 as SIMS data.

In the proposed rule, we presented a comparison between SIMS and EDB data of the potential for race and ethnicity to predict differences in composite rate costs among ESRD facilities, as well as differences in MAP for separately billable services at the patient level (74 FR 49962 through 499650). We identified several concerns with the quality of the SIMS and the

EDB data (74 FR 49966). With respect to the SIMS data, we noted that for data analysis purposes, it was necessary to default beneficiaries into the category of "Other" making it more difficult to assess the effect of race and ethnicity on costs and payments (74 FR 49966). With respect to the EDB data, we noted that race and ethnicity data was either unavailable or defaulted into the "Unknown" category (74 FR 49966). We also indicated that in accordance with MIPPA, we planned to explore opportunities for improving Medicare program data on race and ethnicity for purposes of addressing health care disparities (74 FR 49966).

Although we did not propose case-mix adjustments for race and ethnicity, we requested comments on the data issues presented, other potential data sources for race and ethnicity that we could consider, and specifically, the need for adjustments for race and ethnicity in the final ESRD PPS. The comments that we received on whether race or ethnicity adjustments may be warranted under the ESRD PPS and our responses are set forth below.

Comment: We received three types of comments-—some in support, some in opposition and some that requested that CMS delay the inclusion of race and ethnicity as payment adjusters until the accuracy of Medicare race and ethnicity data could be improved. Commenters presented a variety of views. Some commenters believed that we should implement race and ethnicity adjustments in the final rule as a mechanism of preserving access to care for patients in the high cost racial categories. Many commenters believed that an adjustment for race has the potential to improve payment accuracy and to meet clinical needs of African Americans and other minority dialysis patients. Some commenters asserted that the exclusion of an adjustment for race would produce significant social and racial inequalities. Commenters cited fundamental concerns with the implementation of race or ethnicity adjustments indicating that such policy would not be appropriate. The commenters expressed concerns pertaining to individual rights, equality, and stereotyping. Commenters also opposed the implementation of adjustment factors that were not clinically or biologically based. Several commenters expressed concern about basing payment on racial or ethnic status indicating that race or ethnicity adjustments may infringe on individual rights. Some commenters believed that we should not implement race or ethnicity payment adjustments, suggesting that such a policy could be viewed as discriminatory. One commenter believed that implementation of race or ethnicity adjustments would open CMS up to risk of claims of racial bias and legal challenge.

Finally, other commenters believed that we should continue to work to improve the accuracy of the data, study the extent to which race or ethnicity discrimination was occurring, and consider implementing race or ethnicity adjustments at a future date.

Response: To maximize Medicare payment accuracy, we considered targeting higher payments to facilities on behalf of patients of certain racial or ethnic groups that, as demonstrated in the regression analysis, have been shown to have higher resource needs. We note the regression analysis is discussed further in section II.F. of this final rule. However, given the concerns we noted in the proposed rule, we do not believe it is appropriate to provide a patient-level payment adjustment based on race or ethnicity at this time.

In particular, we are not convinced that race or ethnicity adjustments are necessary to ensure beneficiary access to ESRD services. That is, we believe that there may be race-neutral biological factors that have not yet been identified in the ESRD PPS modeling that could explain the increased cost associated with providing renal dialysis services to members of certain racial or ethnic groups. We intend to work to identify underlying patient-specific conditions that may result in increased treatment costs and also how a race/ethnicity adjuster might be applied. To the extent that these factors are identified, they could be incorporated into the ESRD PPS model as patient-level adjustments. We anticipate presenting our further analyses in future rulemaking.

Comment: Several commenters believed that a race adjustment may shift payment for a large portion of the population on behalf of one racial group, African Americans. Another commenter noted that some groups, such as African Americans, would "gain" with the adjuster, while other groups such as Asians and Hispanics would "lose".

Response: We believe the commenter is referring to the financial implications of a race adjuster. While a case-mix adjustment may result in higher payments to ESRD facilities that treat patients with the specified characteristic, the adjustment is intended to offset a demonstrated increased cost associated with treating patients with that characteristic. As described further in section II.E.3. of this final rule, all adjustment factors are accounted for in reductions to the base rate. As a result, all facilities will be impacted by the reduced base rate whereas only those facilities that treat patients who qualify for the adjustment factors would receive the higher payments associated with those factors. We intend to continue to study this issue and will present our findings in future rulemaking.

Comment: Some commenters opposed adjustments based on race or ethnicity, including patients who would be included as part of the class/group to which the adjustment would apply. One commenter who opposed implementation of race or ethnicity adjustments, raised concerns about being labeled or stereotyped based on race, especially when the label may adversely affect that individual's care. Other commenters argued that it would be wrong to reimburse dialysis based on a patient's identification with a particular ethnic group. The commenters believed that all dialysis patients, without regard to racial or ethnic status, deserve the best care that is provided equally to all.

One commenter who supported the inclusion of an ethnicity adjustment suggested that in clinical practice certain patient ethnic groups are more or less compliant as patients. The commenter further indicated that non-compliant patients require greater effort in counseling, monitoring and communication with physicians.

Response: ESRD facilities are required to provide care that is based on individual patient need without regard to race or ethnicity. It is not our intent for ESRD facilities to rely on collective identity whereby the characteristics of a group are attributed to every member of that group, rather than basing treatment decisions on individual patient characteristics. We believe that patients should be assessed and treated according to their individual need, not according to the stereotypical traits ascribed to or manifested by (many or most but not all members of) their group.

Comment: Several commenters opposed the implementation of race and ethnicity adjustments stating that these factors would not be clinically verifiable. Commenters expressed concern about whether race has been shown to be a clinically-driven, independent variable that predicts the cost of providing ESRD services. One commenter stated that race is not a biological concept, but rather, it is a social concept. The commenter asserted that basing public policy on the social concepts of race or ethnicity has been judged by the Supreme Court to deserve

condemnation. The commenter further asserted that there would need to be a biological basis for racial and ethnic classifications upon which payment adjustments would be made. The commenter stated that there is no biological basis for racial categories noting that a person's classification is commonly based on self-reported information.

Other commenters who supported race or ethnicity adjustments asserted that scientific literature supports the validity of self-reported data. In addition, a commenter stated that major epidemiological entities in the U.S. government such as the U.S. Census, CDC, NIH and OMB use self-reported race and self-reported race is used to make national policy decisions.

Response: We agree with the commenter that race and ethnicity are not biological factors. According to the OMB, racial and ethnic categories should not be interpreted as being biological or genetic in reference. Rather, the race and ethnicity variables are based purely on categorization. By definition, race and ethnicity are based on social and cultural characteristics and ancestry.

OMB considers self-reported race and ethnicity classification to be the most appropriate mechanism for establishing an individual's race or ethnicity. As OMB further indicated in its Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity, self-identification means that the race and ethnicity responses are based on self-perception and therefore, are subjective, but by definition, the responses are accurate (December 15, 2000, *http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf*).

While race and ethnicity are not biologically based, as described above, we intend to perform additional studies to determine whether there are underlying clinical or biological factors contributing to the increased cost of providing renal dialysis services to certain racial or ethnic groups. For this reason, we are not implementing a case-mix adjustment for race or ethnicity in this final rule. We intend to continue analyses that may identify the race-neutral factors that explain the higher costs concentrated in certain racial or ethnic groups. If associations between race or ethnicity and cost are present after addressing race-neutral factors that may be associated with increased treatment cost, we will consider development and implementation of race or ethnicity adjustments in future rulemaking. In the interim, we will continue to monitor for evidence of decreased access to renal dialysis services by racial or ethnic groups, following implementation of the ESRD PPS.

Comment: Several commenters expressed concern over decreasing the base rate and adjustment amounts for case-mix variables that are objective and clinically verifiable, to account for the factors of race and ethnicity, which are not objective and clinically verifiable. The commenters indicated that it would be better to provide a sufficient base rate to support better treatment delivery.

Response: As described above, we are not implementing in this final rule, case-mix adjustments under the ESRD PPS for race or ethnicity. As a result, there will be a lower standardization factor resulting in a higher base rate as described further in section II.E.3. of this final rule.

Comment: A patient asserted that if CMS were to consider a patient's perception of their racial or ethnic status as a basis for an adjustment, then CMS should also consider accounting for the patient's perception of their dialysis provider's performance based on how they feel, whether they are informed about the dialysis process, etc.

Response: We appreciate the commenter's suggestion to consider an adjustment based on patient's satisfaction with care received at the ESRD facility. We intend to take this suggestion under consideration in future rulemaking, as we develop QIP measures.

Comment: Many commenters cited studies demonstrating differences in cost and utilization of renal dialysis services, primarily medications, among racial and ethnic groups. These commenters asserted that research demonstrates that race is a predictor of health care cost and believe that race may explain cost variability in patients more effectively than other adjusters. These commenters stated that African American patients require more ESAs, vitamin D therapies, and calcimimetics for bone and mineral metabolism disorders than other racial and ethnic groups. Commenters also stated that African Americans have higher rates of venous catheter use than other groups. Several commenters cited studies illustrating differences in disease severity and clinical management for secondary hyperparathyroidism between African Americans and other races.

Several commenters provided alternative suggestions for race adjustments including a patient-level "black vs. non-black" adjustment or a facility-level race adjustment.

Response: We thank the commenters for their analysis of studies on race and we will take them into consideration.

Comment: Several commenters noted that case-mix adjusters help ensure equal access to care, especially for those with higher costs of care. Several not-for-profit small dialysis organizations (SDOs) did not believe that facilities would discriminate against African American patients in the absence of race or ethnicity adjustments by withholding adequate doses of ESAs.

Response: We agree with the commenters and intend to monitor access to care under the ESRD PPS and stand poised to take necessary measures to ensure equal access to care for all ESRD patients regardless of cost.

Comment: Commenters believed that the payment policy should not hinder access to care for minority populations. Many commenters provided their analyses of regional impacts, and compared them to CMS' impact analysis in the proposed rule.

Commenters were concerned that in instances where higher costs are associated with a racial group, such as costs for ESAs associated with hypo-responsive patients, and given that these costs would be bundled into the ESRD PPS and no longer separately paid, facilities with patients who are mostly in the high cost racial group will be negatively impacted.

Many commenters referred to CMS' impact files showing that facilities serving the African American population have the most significant reduction in payments. We received divergent comments with respect to where the most severe impact of not implementing race or ethnicity adjustments would be realized including those facilities in various regions of the country according to facility-type, urban and rural status.

Response: We expect facilities to treat ESRD patient regardless of their race or ethnicity. To a certain extent, variations in resource intensity and the associated cost of providing renal dialysis services to individual patients, are reflected in the patient-level adjustments within the ESRD PPS model. However, to protect ESRD facilities from unusually high costs attributed to individuals, we have finalized an outlier policy described in section II.H. of this final rule. In instances where costs of providing ESRD services exceed the projected amount plus a fixed dollar loss amount, we will pay a percentage of the difference.

Comment: One commenter asserted that scientific studies provide evidence that for-profit ESRD facilities engaged in gaming behavior that resulted in higher

cost to the Medicare ESRD program and compromised patient safety. Commenters claim that these studies illustrated that "* * * patients in for-profit facilities were EPO "sensitive" during the period of time that payments were being made per administration and they became EPO "resistent" when the reimbursement system changed." These commenters believed that a large portion of increased pharmaceutical costs related to African Americans are based on past over-utilization of anti-anemia drugs and that factoring out the overuse identified in scientific studies may result in a smaller cost difference among racial or ethnic groups.

One commenter asserted that for-profit providers will rely on race and ethnicity adjustments to circumvent the elimination of incentives currently in place related to drugs such as Epogen®.

Response: We thank the commenter for identifying these scientific studies. We plan to consider such information for further analysis of race or ethnicity adjustments in the future.

Comment: Several commenters questioned whether other factors in the model may be correlated with the increased cost associated with treating African American patients. One commenter stated that race and weight or BMI, may be correlated and points to a study that found a correlation between African Americans and higher than average weight and BMI. A commenter also noted that the manufacturer of EPO includes dosing instructions calling for an increase in dose as the patient's BMI increases. The commenter believes that one may infer that treating African American patients may be more costly simply based on their higher than average BMI and associated greater use of EPO.

Another commenter questioned whether adjusting for co-morbidities would address the variability between patients of different races. The commenter stated that there is not enough scientific evidence for CMS to account for every underlying cause of utilization differences among races. A commenter who conducted an independent analysis of the proposed rule asserted that based on their analysis, race is a better predictor of cost than the co-morbidities and onset of dialysis that were specified in the proposed rule.

Many commenters supported the concept of patient level adjustments that are based on a demonstrated variation in resource utilization. MedPAC reiterated this point in referring to our analysis in the proposed rule that demonstrated associations between race and ethnicity and composite rate costs and separately billable payments (74 FR 49966). MedPAC stated that if race and ethnicity predict providers' resource needs, then these factors should be included as adjusters. Alternatively, MedPAC suggested that we include clinical factors that are correlated with race and ethnicity that would make moot the effect of race and ethnicity on predictors' resource needs.

Response: We believe that a portion, but not all, of the incrementally higher dialysis costs among African American patients are accounted for by other patient characteristics in the model, such as body size and co-morbidities. Despite the remaining effect that race has on the model, we have decided not to implement race or ethnicity as case-mix adjustments in this final rule. As described above, we believe that there are specific underlying factors that contribute to higher costs among certain racial groups and intend to study this further. We will continue to assess payments made on behalf of patients under the ESRD PPS during the transition. The results of this additional study potentially could be incorporated into future refinements of the ESRD PPS.

Comment: Several commenters indicated that according to their own analyses, when the basic case-mix adjusters were implemented under the basic case-mix adjusted composite payment system, reimbursement for Chinese, Japanese and other Asians with smaller body size dropped. These commenters were concerned that a case-mix adjuster for race or ethnicity would extend this reimbursement inequality to laboratory tests and medications under the expanded bundle of services in the ESRD PPS, resulting in lower reimbursement for laboratory tests and medications on behalf of average Asian patients, than average White or African American patients. Commenters believed that the basic case-mix variables have little impact on providers' overall cost of care.

One commenter indicated that Asian patients do not have shorter dialysis times nor the associated decrease in the ESRD facility's staffing and salaries. This commenter asserted that Asian patients have the same needs regarding assessment, dietary education and monitoring, psychosocial issues, medications and laboratory tests. The commenter asserted that race and ethnicity adjustments would create a bias against patients of Asian descent and further decrease reimbursement for dialysis care that is already below the national average and create inequalities in reimbursement.

Response: Many of the services described by the commenter have been taken into account in developing the base rate amount. As described above, we are not implementing a case-mix adjustment for race or ethnicity under the ESRD PPS in this final rule. We intend to continue studying the underlying clinical conditions behind the increased cost that is linked to certain racial groups. We note that, as described in section II.F.3. of this final rule, we are finalizing our proposal to retain the adjusters for body size, BSA and low BMI, that are currently in place under the basic case-mix adjusted composite payment system in the final ESRD PPS.

Comment: One commenter was concerned about a decrease in reimbursement for medications noting that beneficiaries of certain races may be perceived as potentially costly, which could result in these patients being denied access to care. Another commenter believed that individuals who require the most resources may be at increased risk of not receiving adequate care for conditions such as anemia and bone and mineral disorders under the ESRD PPS.

Response: We are also concerned about beneficiaries being denied access to care based on racial or ethnic status and are concerned about any potential for a provider to make choices to provide treatment solely based on that provider's perception of an individual's racial or ethnic status. For this reason, and as discussed previously, we have decided to continue to study this issue and therefore, we will not implement race or ethnicity case-mix adjustments under the ESRD PPS at this time. We have been and will continue to monitor inappropriate care based upon race and ethnicity.

Comment: Several commenters believe that the inclusion of calcimimetics and phosphate binders in the ESRD PPS is likely to result in negative consequences disproportionately for African Americans.

Response: As discussed previously in section II.A.3. of this final rule, the implementation of the oral-only medications, including calcimimetics and phosphate binders, into the ESRD PPS will be delayed until January 1, 2014. Potential impacts of including these drugs under the ESRD PPS, including those on racial and ethnic groups, will be addressed through future rulemaking.

Comment: Several commenters asserted that considering each patient's differing makeup, there may be a built-in disparity in patient co-insurance

amounts for relatively the same care plan. Another commenter indicated that a race case-mix adjuster would increase individuals' co-insurance obligations regardless of whether the individual required increased amounts of medications such as ESAs.

Similarly, MedPAC indicated that including payment adjusters for beneficiaries' demographic and clinical characteristics would result in some beneficiaries having higher copayments than others. MedPAC intends to study this issue in the future.

Response: For the various reasons we have discussed above, we have decided to exclude the race and ethnicity case-mix adjustments from the ESRD PPS. Similarly, as described in section II.F.3. of this final rule, we have narrowed the list of patient co-morbidity case-mix adjusters which will decrease beneficiary co-insurance obligations. In doing so, we believe that co-insurance payment obligations will be more uniform among beneficiaries. We are targeting higher payments and the associated higher beneficiary co-insurance obligations to facilities that treat patients with verifiable conditions known to be associated with an increased treatment cost.

Comment: Several commenters indicated that they were unable to replicate UM–KECC's regression analysis that supported the proposed case-mix adjustments in the proposed rule. Commenters further noted that higher costs are not distributed evenly or randomly across the population but are concentrated in areas where demographics are dominated by one group. These commenters also found increased payment by racial group, primarily for medications for African Americans. In addition the commenters' analyses revealed that whites have higher costs compared to Native American, Hispanic and Asian patients.

Another commenter indicated that its analysis differed from the regression analysis set forth in the proposed rule. The commenter's findings suggested that the case-mix adjustment for African Americans would be approximately 11 percent and 3 percent for Whites.

Response: The results of the regression based case-mix adjustments for the race and ethnicity categories are summarized in the proposed rule (74 FR 49965). We believe that the reason for the differing results between our proposed rule analysis and that of the commenter relates to the data that was used. Specifically, we believe that the commenter's data was more limited in scope to the facility or chain with which the commenter was associated. As indicated above, we have decided to study this further and are not implementing race and ethnicity case-mix adjustments in this final rule.

Comment: One commenter indicated that minorities are disproportionately affected by chronic kidney disease (CKD) and believes that the solution lies in addressing the root cause of this problem by providing stage 4 CKD education, pre-dialysis anemia and access care and other means rather than race and ethnicity case-mix adjusters within the ESRD PPS.

Response: We appreciate the commenter's view on this matter and note that kidney disease patient education provisions authorized under section 152(b) of the MIPPA were implemented in the CY 2010 Medicare PFS final rule (74 FR 61894). We intend to evaluate the extent to which patient participation in the new kidney disease patient education benefit impacts the cost of dialysis and whether these patient outcomes would be relevant to the adoption of race or ethnicity adjustments.

Comment: Several commenters believed that the data sources identified in the proposed rule provided a significant amount of data to inform decisions regarding race and CMS currently has the means to implement a case-mix adjuster based on race. Commenters referred to CMS' efforts that have improved the quality of race data including beneficiary surveys, annual file updates from NUMIDENT, and work with the Indian Health Service that helps to identify American Indians and Alaska Natives. Other commenters were skeptical about the implementation of race or ethnicity adjustments and suggested that we conduct further analysis.

Response: As described in the proposed rule, we considered two distinct sources of race and ethnicity data upon which the race or ethnicity adjustments could be modeled. We believe this commenter is referring to the EDB data source. We agree that the accuracy of the EDB data has improved as a result of our supplementary data file matching procedures over the last 15 years such as the annual updates, surveys and coordination with the Indian Health Service (74 FR 49963). Despite these efforts, the core race and ethnicity data for the Medicare population that are sent to us by the Social Security Administration (SSA) on a daily basis from the master beneficiary record (MBR) are not currently collected in a format that is compliant with OMB standards for the collection of this data.

To summarize, OMB requires race and ethnicity data to be collected using a two-question format, with the ethnicity question preceding the race question. In addition, OMB also requires the following minimum set of race categories: (1) White, (2) Black or African American, (3) American Indian or Alaska Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. However, as described in the proposed rule, the SSA's collection instrument includes the following categories: (1) Asian, Asian-American or Pacific Islander; (2) Hispanic; (3) Black (Not Hispanic); (4) North American Indian or Alaska Native; or (5) White (Not Hispanic). Conversely, the SSA's collection instrument groups race and ethnicity into one question with instructions to "check one only." We are obligated to follow OMB standards.

We note that OMB's standards were last updated in the October 30, 1997 **Federal Register** Notice: Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (62 FR 58782). OMB also released Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity on December 15, 2000. That guidance is available at: *http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf.*

As a result, these data with EDB are known to be inaccurate. Only an improvement of the MBR's race and ethnicity data collection will provide a long-range solution to the problem. We do not believe that it would be appropriate to establish race or ethnicity adjustments that would be based on EDB data until additional improvements are made to ensure that EDB race and ethnicity data are collected in a manner that is consistent with OMB standards.

Comment: Several commenters suggested that CMS continue to improve the data. One commenter suggested methods set forth in various reports generated from public, private and academic entities. One commenter suggested that HHS issue guidelines for the uniform collection of data on race by health care organizations. Another commenter specified that CMS should consider conducting a mailing to persons with race coded as "other" or "unknown" and evaluate the effectiveness of using surnames to identify the race of enrollees.

One commenter believed that we may be able to develop coding modifiers to further verify the accuracy of the data provided. A commenter also believed that Medicare Advantage plans should be required to collect and report to CMS the race of all Medicare members. The commenter further suggests that the SSA should collect race information on

the SS–5 Form and through the enumeration at birth process using 1997 OMB standards for race.

Response: We appreciate the commenters' suggestions for improving race and ethnicity data. Improving the accuracy of race and ethnicity data by establishing consistent mechanisms by which race and ethnicity data are collected are essential for identifying and addressing health disparities. We are in the process of carrying out provisions of MIPPA and the Affordable Care Act (ACA) of 2010 that require the Secretary of Health and Human Services to evaluate race and ethnicity data and provide recommendations for improving the quality of the data.

We appreciate the commenter's suggestion that Medicare Advantage plans should collect and report the race of their enrollees. We will take this suggestion under consideration, but note that Medicare Advantage plan requirements are beyond the scope of this rule. Similarly, we clarify that it would be beyond our authority to impose requirements on the SSA.

Comment: Several commenters believed that race and ethnicity should not be case-mix adjusted asserting that the current data does not provide a rigorous statistical basis for reaching a reliable conclusion on the relevance of this characteristic.

Other commenters believed that the reliability of CMS' existing data sets (REMIS and EDB) is sufficient for purposes of implementing race and ethnicity case-mix adjusters. Several commenters referred to a presentation at the 2009 American Society of Nephrology meeting that revealed near perfect agreement between the Medicare EDB and REMIS for three major U.S. race groups (Caucasian, African American and Asian) suggesting that race could be used as a case-mix adjuster for these three race groups.

Another commenter believed that ESRD facilities may face operational difficulties in collecting race and ethnicity data, but believed that the 4-year phase-in period would allow providers to operationalize data collection. Other commenters stated that if deemed appropriate upon reconsideration, CMS should implement race and ethnicity adjustments. Several commenters stated that race and ethnicity adjustments would be more administratively manageable to report and would not require ongoing documentation especially for facilities that do not have sophisticated systems capabilities to track multiple patient-level adjusters.

Response: Based on subsequent analyses, we agree with the commenter that the agreement between data collected on the Form 2728, located in SIMS, as compared to data in EDB is very high for Blacks and Whites. However we continue to have concerns that about the level of accuracy for the remaining racial and ethnic groups. Specifically, analyses reveal that the agreement for Asians is considered substantial and low moderate for American Indians or Alaska Natives and Hispanics. As indicated previously, we intend to continue to evaluate race and ethnicity data and provide recommendations for improving the quality of the data and re-evaluate the extent to which it would be appropriate to adopt race or ethnicity adjustments. As described above, we intend to set forth our additional analyses and proposal for handling race or ethnicity adjustments in future rulemaking.

Comment: In comparing the two data analyses conducted by CMS, REMIS and EDB, one commenter believes that payment amounts would vary by as much as $21,000 on behalf of individuals whose race is defaulted to "Other." The commenter believes that this difference is unacceptable considering the volume of Medicare ESRD beneficiaries. Another commenter stated that the category "Other" produced wildly different results for adjusters in REMIS as compared to other databases.

Response: To the extent that we were to implement race or ethnicity payment adjustments in the future, we do not believe that it would be appropriate to provide an adjustment for "Other" as this category may fail to reflect the characteristics of the individual. Rather, we would rely on OMB's established list of racial categories including: (1) White, (2) Black or African American, (3) American Indian or Alaska Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. As mentioned previously we intend to consider the extent to which OMB's guidance for allocating individuals who select more than one racial category into a single category would be appropriate for payment adjustment purposes.

Comment: One commenter believed that we would need to further refine the race and ethnicity categories to avoid distortions that might result from lumping Native Hawaiians (the largest race/ethnic group) with Asians (one of the smallest race/ethnic groups).

Response: As indicated in the proposed rule (74 FR 49963) the EDB is populated with race and ethnicity data that come from the SSA. The SSA's race and ethnicity data are collected on the SS–5 form which groups Asian, Asian-American or Pacific Islander into a single category. We agree with the commenter that to the extent we were to rely on data obtained from the EDB, there would be an increased risk of distortion. We further believe that it would be essential to base any proposed race or ethnicity adjustments on data collected from a source that is supplied by data that is collected in a manner that is consistent with OMB standards.

Comment: One commenter asserted that Native Hawaiians have the highest average BMI and increased rates of obesity and diabetes. As such, the commenter believes that CMS should include a payment adjuster for ESRD patients in the state of Hawaii to reflect the higher costs involved in treating patients in that state.

Response: As described in section II.F.3. of this final rule, we are finalizing the BMI case-mix adjustment under the ESRD PPS. To the extent Native Hawaiians have higher than average BMI, the ESRD facilities that provide treatment to these individuals will be compensated for this factor. In addition, our impact analysis reveals that the ESRD PPS would adequately reimburse ESRD facilities located in Hawaii. Specifically, facilities located in Hawaii are expected to see a 4.2 percent increase in payment. Therefore, consistent with our decision to not implement race or ethnicity adjustments, we decline to adopt the commenter's suggestion.

Comment: One commenter suggested that we collect patient-level data for purposes of determining the extent to which race and ethnicity are independent predictors of cost associated with the treatment of ESRD. The commenter believed that implementation should only occur after CMS has an appropriate mechanism by which to collect the data. Another commenter questioned the extent to which the race and ethnicity variables used in the proposed rule were independent in relation to the other factors being used in the model. The commenter emphasized the importance of independence of the variables to assure accurate payments that are reflective of the differences in cost in treating certain patients. The commenter asserted that the discussion in the proposed rule pertaining to the findings from the different regression models suggests that the variables may not be independent. Thus, the model may result in overpayment to certain patients and underpayment to others.

Response: As we indicated in the proposed rule, the race and ethnicity case-mix adjustments were based on a regression analysis that used patient-level separately billable payments and

facility-level costs (74 FR 49962). Each of the proposed payment variables, including race and ethnicity were independent variables. However, we believe that the race and ethnicity adjustment factors may reflect factors that are not otherwise reflected in the model. We intend to study this further and include our findings in future rulemaking.

Comment: One commenter stated that many minority populations are of lower socioeconomic status and lack sufficient insurance coverage outside of Medicare. As such, the commenter indicated that race and ethnicity adjustments are even more important. Another commenter requested that we consider an adjustment for socioeconomic status to encourage dialysis providers to establish facilities in disadvantaged communities. The commenter suggested that a socioeconomic status adjustment may be a less problematic patient-level adjustment, as compared to other adjustments in the proposed ESRD PPS. For example, the commenter asserted that socioeconomic status cannot be gamed and would not raise privacy issues.

Response: We do not have access to socioeconomic status data within our Medicare databases. However, because Medicaid eligibility is based on an individual's income and resources, we consider it to be one measure of socioeconomic status and one for which we have data. We have started to explore the extent to which Medicaid status is associated with increased cost. To date, we have not found that Medicaid status is associated with increased cost but we intend to study this potential variable in future proposed rulemaking.

Comment: Several commenters believed that we should delay implementation of race and ethnicity case-mix adjusters and continue to investigate the degree to which such adjusters would be appropriate. Commenters asserted that the goal should be to close health disparity gaps first and then create an adjuster for any differences that remain. The commenters stated that to provide an adjustment without fully understanding the cause of the health disparity would create inappropriate incentives.

The commenters suggested that we work to improve the adequacy of data that could be used as the basis of future race or ethnicity adjustments. For example, commenters asserted that specifying the race adjuster eligibility criteria would improve data accuracy and decrease the risk of provider gaming. Commenters requested that we specify the timeframe for completing refinements that would allow for adjustment. In the meantime, commenters stated that we should continue to collect data based on the categories included on the Form 2728 that was implemented on June 1, 2005 and develop a placeholder that recognizes the impact of race on the cost of dialysis. Other commenters believed that we should implement an adjustment for race while working with the community to develop further appropriate case-mix adjusters in the future. Another commenter stated that the initial adjusters could be periodically revised as additional, proven sources of data become available.

Response: As described in the most recent IOM report in December 2009 (Standardization for Health Care Quality Improvement, Institute of Medicine, 2009), Kilbourne and colleagues identify three key phases in addressing disparities: Detecting, understanding and reducing. We are currently in the detecting phase of accurately identifying vulnerable racial and ethnic groups and developing valid measures. Part of this phase involves implementation of a reliable tool for collecting racial and ethnic data that will ensure the linking of data to quality measures. Once we have a more complete understanding of the determinants of health disparities, we will be positioned to consider the extent to which a payment intervention is appropriate. We do not believe that it would be appropriate to implement payment intervention until the earlier phases of detecting and understanding racial and ethnic health disparities have been completed.

As indicated previously, section 185 of MIPPA requires further study to identifying and addressing healthcare disparities in the Medicare program including those related to race or ethnicity. In addition, section 4302 of ACA requires ongoing analysis of race and ethnicity data to detect and monitor for trends in health disparities. In addition to these analyses, we intend to issue a Report to Congress recommending improvements to identifying health care disparities.

Comment: Several commenters believed that we should continue to explore race and ethnicity case-mix adjustments and develop a methodology to collect racial and ethnic data that is reliable for reimbursement purposes. MedPAC suggested that CMS use current OMB categories to collect race and ethnicity data. This data could be collected via Form 2728. Other commenters believed that Form 2728 has sufficiently provided the race and ethnicity data for USRDS utilization analyses for several years.

Other commenters were concerned about the potential for providers to misidentify racial and ethnic status to qualify for greater payments. The commenter suggested that we consider expanding racial and ethnic categories to minimize gaming and account for patients who associate with more than one racial category. Another commenter believed that instructions to patients to identify themselves with only one supplied race and ethnicity category on the form would mitigate data quality issues. Another commenter suggested that patients who elect to not select race or ethnicity categories should default to other or unknown and thus, become ineligible for the race or ethnicity adjustments.

Other commenters indicated that many facilities rely on clerical personnel to complete the Form 2728. The commenter was concerned that this practice may result in incorrect or missing data which would have an impact on reimbursement.

Response: To the extent we were to implement race or ethnicity adjustments in the future, we would rely on a collection instrument that is consistent with OMB standards. However, as discussed previously, we are not including a race or ethnicity adjustment in the ESRD PPS at this time. With the exception of the self-identification criteria, race and ethnicity data collected on the Form 2728 after May 31, 2005 is consistent with the OMB collection standards. As mentioned previously in section II.C. of this final rule, the final ESRD PPS model is based on 2006–2008 data. Therefore, race and ethnicity data collected on the Form 2728 during the timeframe and reflected in SIMS is consistent with OMB's race categorizations. We note that ESRD facility costs and payments on behalf of patients during 2006–2008 that have been incorporated into the ESRD PPS model would not have been limited to incident patients. That is to say, costs and payments on behalf of patients between 2006–2008 included patients for whom the Form 2728 was completed prior to June 1, 2005. As indicated in the proposed rule, the Form 2728 that was in use prior to June 1, 2005 did not reflect the current OMB standards for collecting racial and ethnic information (74 FR 49963).

With respect to addressing individuals who identify with more than one racial category, we note that OMB standards do not permit guiding an individual to select only one race. However, to account for individuals who select more than one racial

category, we believe that it may be possible to allocate these individuals into one race category. OMB has issued guidance to agencies for the allocation of multiple race responses for use in civil rights monitoring and enforcement. The March 9, 2000 OMB bulletin No. 00–02 is available on OMB's Web site at: *http://www.whitehouse.gov/omb/BULLETINS_b00–02/?print=1.*

While we believe that this guidance may also be appropriate for purposes of establishing individuals' most appropriate payment adjustment factor related to racial designation, we intend to consider this issue further and present our analyses in subsequent rulemaking and solicitation of public comments.

In response to the commenters concern that data on the Form 2728 may be incorrect or missing, we believe that for the majority of patients the information is correct. We note that block 49 includes a physician attestation that the information on the form is correct. For this reason, we expect that information collected on the form to be correct and reliable.

In summary, we believe that the use of data collected from the Form 2728 may be appropriate both for purposes of establishing race or ethnicity adjustments and making payment adjustments under the ESRD PPS in the future. However, to ensure consistency with OMB's standards for the collection of race and ethnicity data, we intend to modify the administration instructions for completing the Form 2728 to specify that the information on race and ethnicity must be self reported. We believe that this modification will further improve the accuracy of the race and ethnicity data collected on the Form 2728. In addition, we believe that the physician attestation would verify that the patient had self-reported the racial and ethnic status. At that time we could also consider the extent to which it would be appropriate to expand the race categories.

For the various reasons we discussed above, and after considering the public comments, we are not finalizing race or ethnicity case-mix adjustments in this final rule. We intend to continue efforts in improving Medicare program data on race and ethnicity. As described above, we intend to modify the Form 2728 to ensure consistency with OMB's standards for data collection. We also intend to complete the studies required under MIPPA and ACA that will assist us in identifying and monitoring health disparities on the basis of race or ethnicity. Upon completion of these studies, further analysis of studies referenced by commenters, and using updated data, we intend to re-evaluate the extent to which it would be appropriate to include patient-level case-mix adjustments for race or ethnicity under the ESRD PPS. We will set forth a description of our further analysis and the basis of any proposed race or ethnicity adjustments in rulemaking to the extent that it is warranted.

h. Modality

Section 1881(b)(14)(D)(iv) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the authority to establish an ESRD PPS, which may include payment adjustments as the Secretary determines appropriate. Therefore, the Act gives the Secretary the authority to develop an ESRD PPS under which payment rates are based on dialysis modality.

In the proposed rule, we presented data showing that per treatment composite rate PD costs were approximately 11 percent less than HD costs ($151.15 vs. $168.99) (74 FR 49967). Separately billable PD per treatment payments were about 60 percent less than those for HD payments. (See tables at 74 FR 49967.) We also cited data from the United States Renal Data System (USRDS) (74 FR 49967) showing that the average annual cost for PD patients ($53,327) was substantially less than that for HD patients ($71,889) (74 FR 49967).

Despite these differences in cost between HD and PD, we did not propose to develop an ESRD PPS which uses type of dialysis modality as a payment variable. Using modality as a payment variable would result in increased predictive power in the resulting regression equations. Because composite rate costs and separately billable payments are lower for PD, the use of a modality payment variable would result in substantially lower payments for PD patients. The payment rates for HD patients would be slightly higher, because of the greater volume of HD patients, and the exclusion of the smaller proportion of PD patients from the average payment amount that would apply to HD patients. We stated that we believed the substantially lower payments for PD patients that would result if modality were used as a payment adjuster in the ESRD PPS would discourage the increased use of PD for patients able to use that modality (74 FR 49967). Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we proposed an ESRD PPS which did not rely on separate payment rates based on modality (74 FR 49967). We stated that by establishing prospective payment rates that are higher for PD patients than they otherwise would be if separate payments were established based on modality, we believed home dialysis would be encouraged for patients able to use PD. We invited comments on this approach.

The comments we received and our responses are as follows:

Comment: Several commenters expressed gratitude that CMS had not proposed an ESRD PPS in which differential payments were made based on modality. By using the same base rate for HD and PD, the commenters maintained that this would encourage PD. A few commenters cited their own personal experiences on both HD and PD, pointing out the benefits of home PD, and how their quality of life, certain clinical outcome measures, and sense of well being improved after switching to PD. These commenters stated that more should be done to encourage PD.

Response: We agree with the commenters, and we are finalizing the application of the same base rate payment amount for both HD and PD patients. We are hopeful that this will encourage the use of home PD for those patients able to benefit from that modality.

Comment: One commenter stated that in countries such as Canada and Australia, payers incentivize PD when patients can benefit from dialysis at home. The commenter noted that currently there is no incentive to make PD more available in the U.S., but supported one bundled payment system for both HD and PD.

Response: We believe that by providing one basic payment rate under the ESRD PPS for both PD and HD, facilities will have a powerful financial incentive to encourage the use of home PD among dialysis patients where feasible. Accordingly, we are finalizing the application of the same base rate payment amount under the ESRD PP for both HD and PD patients in this final rule. We will be monitoring the degree to which home dialysis increases in the future under the ESRD PPS.

In the proposed rule, we pointed out that the case-mix adjustments proposed for pediatric patients (74 FR 49981), distinguished between HD and PD as a payment variable. The small number of pediatric dialysis patients, the limited ability of the two-equation regression model to accurately predict the separately billable MAP for pediatric patients, and the far greater prevalence of PD among pediatric patients, led us to examine alternative approaches in devising case-mix adjustments for those patients. The pediatric payment

adjustments described in the proposed rule, used modality, in part, to determine the case-mix adjusters for pediatric dialysis patients.

For responses to the comments on the use of modality as a payment variable in connection with the proposed pediatric payment model, see section II.G. of this final rule.

4. Proposed Facility-Level Adjustments

a. Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic index, such as the index referred to under the existing basic case-mix adjusted composite payment system.

In the current basic case-mix adjusted composite payment system, we use an index based on hospital wage and employment data from Medicare cost reports. In the CY 2006 PFS final rule with comment period (70 FR 70167), we announced our adoption of the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to develop revised urban/rural definitions and corresponding wage index values for purposes of calculating ESRD composite rates under the basic case-mix adjusted composite payment system. OMB's CBSA-based geographic area designations are described in OMB Bulletin 03–04, originally issued June 6, 2003, and is available online at: *http://www.whitehouse.gov/omb/bulletins/b03-04.html.* In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We stated that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index (73 FR 69758). The OMB bulletins may be accessed online at: *http://www.whitehouse.gov/omb/bulletins/index.html.*

We also stated in the proposed rule that we intended to update the current ESRD wage index values annually (70 FR 70167). The ESRD wage index values used in the basic case-mix adjusted composite payment system are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685 and 73 FR 69758). Also as stated in proposed rule, we applied the current ESRD wage index to a 53.711 labor-related share of the composite rate. As we indicated, this labor-related share was developed from the labor-related components of the ESRD composite rate market basket (70 FR 70168). The ESRD wage index in the current basic case-mix adjusted composite payment system applies a wage index budget neutrality factor to ensure that the ESRD wage index is made in a budget neutral manner (70 FR 70170). As we previously noted, in our current basic case-mix adjusted composite payment system, we incorporate the wage index budget neutrality factor into the wage index. We compute a wage index factor and adjust it so that wage index budget neutrality can be achieved by the labor share component only.

In the ESRD PPS proposed rule (74 FR 49968), we proposed to use the same method and source of wage index values as we have been using for the basic case-mix adjusted composite payment system. Specifically, we proposed that the ESRD wage index values to be used in the proposed ESRD PPS, would be calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act, and would utilize pre-floor hospital data that are unadjusted for occupational mix (74 FR 49968). We also proposed to use the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values. Consistent with those definitions, we proposed to define urban and rural areas at § 413.231(b) (74 FR 50024).

Under the current basic case-mix adjusted composite payment system, we apply a floor as a substitute wage index for areas with very low wage index values. However, we have gradually reduced the ESRD wage index floor from 0.90 in CY 2005, to 0.85 in CY 2006, 0.80 in CY 2007, 0.75 in CY 2008, 0.70 in CY 2009, and 0.65 in CY 2010 (74 FR 33637 and 33638). We also stated that a gradual reduction was needed to ensure patient access in areas that have low wage index values, and that we would continue to reassess the need for a wage index floor in future years.

In the ESRD PPS proposed rule, we proposed not to adopt a wage index floor (74 FR 49968). We noted that ESRD facilities affected by the floor may opt to go through the transition to the ESRD PPS, where the portion of their payment that is based on the ESRD PPS would be gradually increased from 25 percent of their payments in 2011 to 100 percent of their payments in 2014. We intended to continue to gradually reduce the ESRD wage index floor for the portion of the payment that is based on the current basic case-mix adjusted composite payment system during the transition. Applying a gradual reduction only to the floor that applies to the existing basic case-mix adjusted composite payment system ESRD wage index was intended to accelerate the decline in the floor so that ESRD facilities would be less dependent on the floor. At the end of the transition, we indicated that we would apply their actual wage index values (74 FR 49968).

In CY 2006, while adopting the CBSA designations for the basic case-mix adjusted payment system, we identified a small number of ESRD facilities in both urban and rural areas where there are no hospital data from which to calculate ESRD wage index values. Since there are ESRD facilities in these areas, we developed policies for each of these areas. The areas with ESRD facilities that have no hospital data are rural Massachusetts, rural Puerto Rico, and Hinesville, GA (CBSA 25980). In the ESRD PPS proposed rule (74 FR 49969), we proposed to continue with our current policies for rural Massachusetts and Hinesville, Georgia (74 FR 49969). For rural Massachusetts, we proposed to adopt the methodology originally adopted, for CY 2008 PFS final rule, in which we compute the entire rural area consists of Dukes and Nantucket Counties. We determined that the borders of Dukes and Nantucket Counties are contiguous with CBSA 12700, Barnstable Town, MA, and CBSA 39300, Providence-New Bedford-Fall River, RI for establishing a wage index value. For Hinesville, GA (CBSA 25980), we proposed to continue to use the methodology, that is, we computed the average wage index value of all urban areas within the State of Georgia, that was adopted in the CY 2007 PFS final rule.

Since the publication of the ESRD PPS proposed rule, we have determined that there is an additional urban area, Anderson, South Carolina (SC) (CBSA 11340), with no hospital data. For this urban area, Anderson, SC, we are using the same methodology we have used for the other urban area with no hospital data, that is, Hinesville-Fort Stewart, GA (CBSA 25980). Under the methodology used for that area, we computed the average of all urban areas within the State of South Carolina. We continue to believe that this method of establishing a wage index value for areas with no hospital data is the most appropriate method.

We did not receive comments on the proposed continuation of our current policies for rural Massachusetts and Hinesville, Georgia. Therefore, in this

final rule we are finalizing the same methodology we have used for areas with no hospital data in the past, that is, compute the average wage index value of all urban areas within the state and use that value as the wage index.

In the ESRD PPS proposed rule (74 FR 49969), we proposed to eliminate the wage index floor under the ESRD PPS and to use the value for rural Puerto Rico (0.4047) that has been used by other payment systems for rural areas that do not use a wage index floor. In particular, we have previously applied the ESRD wage index floor for rural Puerto Rico, because all areas in Puerto Rico that have a wage index were eligible for the ESRD wage index for the proposed ESRD PPS (74 FR 49969).

We also proposed to use the labor-related share as measured by the proposed ESRD bundled market basket, which was 38.160 percent in the proposed rule (74 FR 49969, 50003). Our proposed adjustment for wages was set forth in § 413.231 (74 FR 50024).

For the proposed rule (74 FR 49969), we used the most current final wage index available at that time to complete the analysis. As we indicated, we anticipated that the proposed CY 2011 ESRD PPS wage index data for purposes of the ESRD PPS (that would not include any wage index budget-neutrality adjustment) along with the CY 2011 proposed update to the existing basic case-mix adjusted composite payment system, would be published in the CY 2011 PFS proposed rule (75 FR 40167 through 40168). We also proposed to publish the final CY 2011 ESRD PPS wage index along with the CY 2011 final rule update to the existing basic case-mix adjusted composite payment system in the CY 2011 Physician Fee Schedule final rule, which we expect would be published in November of 2010 (74 FR 49969).

The comments we received on the wage index proposal and our responses are set forth below.

Comment: One commenter indicated that the CMS' use of the composite rate separately billable wage index listed on the facility level impact file is inaccurate and questioned the accuracy of the spreadsheet used in the proposed rule. Also, the commenter believed that the labor-related share of the proposed bundle would be significantly lower than the share under the current rate.

Response: The labor-related share based on the ESRD PPS bundled market basket ESRDB is lower than the labor-related share under the basic case-mix adjusted composite payment system. This is due to the fact that the labor-related share for the current system does not include the labor-related share component associated with separately billable items and services. The labor-related share in the proposed ESRDB market basket was 38.160 percent (74 FR 50003). This share represents the proportion of an ESRD facility's payment that is adjusted for geographic wage differences. For this final rule, in response to public comment, we made several methodological changes to the ESRDB market basket described in section II.J. of this final rule. The revised labor-related share is 41.37 percent.

Comment: Many of the commenters agreed that for some rural facilities, additional staff must be recruited from nearby large cities, and travel costs and wage premiums are paid to encourage employees to endure the long commutes.

Response: The wage data used to construct the wage index are updated annually, based on the most current data available and are based on OMB's definitions when applying the rural definitions and corresponding wage index values. As a result, the wage index reflects increased efforts by rural ESRD facilities.

Comment: Commenters believed that the wage index floor should be maintained for all rural geographic locations to prevent access barriers and resulting rural disparities. The commenters also expressed concern that the proposed removal of this floor would aggravate disparities in care and would impair access to care at rural facilities.

One commenter believed that the elimination of the wage index floor will result in a decline in a per treatment cost and questioned the adequacy of the methodology used to develop the wage index. Commenters from Puerto Rico strongly urged CMS to retract its proposal to eliminate the wage index floor applicable to dialysis services rendered in Puerto Rico in order to avoid endangering timely and accurate renal dialysis services to their patients. The commenters also believed that the wage index values are flawed because of the use of 4-year-old data to calculate current values in all areas of Puerto Rico.

Response: As stated above, the wage data used to construct the wage index are updated annually, based on the most current data available and are based on OMB's definitions when applying the rural definitions and corresponding wage index values. Since publication of the ESRD PPS proposed rule, we have proposed a CY 2011 wage index floor of 0.60 for the case-mix portion of the blended payment for purposes of the transition in the CY 2011 PFS proposed rule (75 FR 40167).

The only CBSAs that would be affected by the proposal to eliminate the wage index floor value for the ESRD PPS wage index are located in Puerto Rico. In Puerto Rico, the majority of ESRD facilities' wage indices are significantly below the current floor. As a result of public comments, we believe maintaining the wage index floor under the ESRD PPS will benefit ESRD facilities that have low wage index values.

Therefore, for this final rule, we will finalize our proposal regarding the use of the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values as proposed. Also, although we proposed to eliminate the wage index floor under the ESRD PPS, we will continue to apply the wage index floor during the transition to the PPS portion of the ESRD PPS payment in 2011. We note that eliminating the wage index floor over the course of the transition, provides an additional cushion to those facilities going through the transition, because they will continue to receive the benefit of the floor as they adjust to payments under the ESRD PPS. Although a commenter suggested that we apply the floor to all rural area values, it is important to note that no rural ESRD facilities outside Puerto Rico would benefit from the current floor because their wage indexes exceed 0.60.

As we indicated in the proposed rule (74 FR 49969), we issued the proposed CY 2011 wage index for the composite rate portion of the blended payment in the CY 2011 PFS proposed rule (75 FR 40167) and will respond to public comments and finalize the CY 2011 ESRD PPS wage index in the CY 2011 PFS final rule later this year. Lastly, we are finalizing 413.231 (Adjustment for wages), however, we are revising the provision to indicate the wage index is applied to the labor-related share of the base rate.

b. Low-Volume Adjustment

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that "reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent."

i. Defining a Low-Volume Facility

As indicated above, section 1881(b)(14)(D)(iii) of the Act authorizes the Secretary to define "low-volume facilities" for purposes of a payment adjustment in the proposed ESRD PPS. As discussed in the proposed rule (74 FR 49969), we believed the low-volume adjustment should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic. For the proposed rule, UM–KECC performed analyses using data from CMS Medicare cost reports, SIMS, and OSCAR for years 2004–2006 to assist us in determining what the ESRD facility-level characteristics are that best demonstrate a low-volume facility (74 FR 49969). In the proposed rule, we described the methodology used to define a low-volume facility by setting the parameters for ESRD facility size. We explained that the term 'year' would be established by the ESRD facility's final-settled cost report, where the final-settled cost report reports costs for 12 consecutive months (74 FR 49970).

For purposes of exploring possible definitions for low-volume facilities, we began by developing a measure for facility size. Under the initial categorization, an ESRD facility that furnished less than 5,000 treatments per year was considered small, an ESRD facility that furnished 5,000 to 10,000 treatments per year was considered medium, and an ESRD facility that furnished 10,000 treatments per year or more was considered large. We then categorized all ESRD facilities into four ESRD facility ownership types: (1) Independent, (2) regional chains, (3) Large Dialysis Organizations (LDOs), and (4) unknown ownership type. Of the hospital-based ESRD facilities, we found that 75.5 percent were independent, 10.7 percent were members of a regional chain/other category, 0.7 percent were members of an LDO, and 13.2 percent had unknown ownership status.

The comparison between ESRD facility size and ownership type indicated that ownership varied with ESRD facility size and smaller ESRD facilities, especially those with less than 3,000 treatments, were relatively more likely to be independent than larger ESRD facilities. The comparison also indicated that while smaller ESRD facilities were less likely to be members of an LDO than larger ESRD facilities, a relatively large fraction of smaller ESRD facilities were members of an LDO. As a result of the comparison between ESRD facility size and ESRD facility ownership type, we chose to use ESRD facility ownership type as a variable in a two-equation regression analysis to test whether cost varied by ESRD facility ownership type within an ESRD facility size category (74 FR 49970).

We also looked at the distribution of ESRD facility size across ESRD facilities that have an urban or rural status. We found that nearly half of the small ESRD facilities were rural and larger ESRD facilities were less likely to be rural. The comparison also indicated that because most ESRD facilities were urban, even with the lower percentage of small ESRD facilities in urban areas, more urban ESRD facilities than rural ESRD facilities would benefit from a low-volume payment adjustment. As a result of the comparison between ESRD facility size and urban/rural status, we used urban/rural status as a variable in a two-equation regression analysis to test whether cost varies by urban/rural status within an ESRD facility size category (74 FR 49971).

In the proposed rule, we discussed the methodology used to identify the factors that could be targeted to ensure that we had the right population of ESRD facilities that were low-volume as well as the methodology used to identify the treatment threshold (74 FR 49971 through 49975). We found that the cost multipliers for small ESRD facilities were greater than 1.1 for any of the definitions for small ESRD facility size with respect to number of treatments per year and that the cost multipliers tended to decline for successively higher cutoffs for defining small ESRD facilities. We also noted that if a payment multiplier fully reflected the cost multiplier, there would be a strong disincentive for ESRD facilities to increase volume above the cutoff. However, to the extent that a payment multiplier was smaller than the cost multiplier, this disincentive was somewhat diminished (74 FR 49974).

We explained that since the analyses included data that spanned a 3-year period (2004–2006), we further evaluated the three ESRD facility size categories that we applied in the previous regression analysis, that is, less than 2,000 treatments, less than 3,000 treatments, and less than 4,000 treatments per year. We were interested to see the number of small ESRD facilities that were able to maintain their ESRD facility size status each year of the 3-year period. We proposed to use a threshold of ESRD facilities that provide less than 3,000 treatments per year across the 3-year period because it struck a balance between establishing an increment in payment that reflected the substantially higher treatment costs incurred by low-volume facilities (an increment that tended to decrease as the low-volume threshold was raised) but still applied to a sufficiently large number of ESRD facilities to have an impact (74 FR 49975).

In the proposed rule, we explained that in accordance with the statute, we defined low-volume facilities in § 413.232, as an ESRD facility that meets the following criteria: (1) Furnished less than 3,000 treatments in each of the 3 years preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year (74 FR 49975).

In the proposed rule, we expressed our awareness that there are Medicare-certified ESRD facilities that solely furnished support services and training for home hemodialysis and home peritoneal dialysis to ESRD beneficiaries. We expressed our concern that it may not be appropriate to extend low-volume eligibility to these types of facilities (74 FR 49975).

In addition, in the proposed rule, we expressed our concerns about potential misuse of the proposed low-volume adjustment. Specifically, our concern was that the low-volume adjustment could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities, thereby leading to unnecessary inefficiencies, in order to obtain the low-volume adjustment. To address our concern, we proposed criteria for ESRD facilities to be eligible for the low-volume adjustment. We proposed that for the purposes of determining the number of treatments under the proposed definition of a low-volume facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments actually furnished by the ESRD facility *and* the number of treatments furnished by other ESRD facilities that are both: (i) Under common ownership with; and (ii) 25 road miles or less from the ESRD facility in question. However, we proposed to grandfather those commonly owned ESRD facilities that had been in existence and certified for Medicare participation on or before December 31, 2010, thereby exempting them from the geographic proximity restriction (74 FR 49975).

In the proposed rule, we discussed that there would need to be a method in place so that existing ESRD facilities that met the definition of a low-volume facility could be identified. We proposed that ESRD facilities could

attest to the FI/MAC that they qualify as a low-volume facility (74 FR 49975 through 49976).

We solicited comment on the change of ownership element of the proposed definition of a low-volume facility. We did not receive any comments and, therefore, we are finalizing the change of ownership element of the low-volume definition at § 413.232.

We did not receive comments on the proposed grandfathering provision nor the ESRD facilities attestation of low-volume status requirement. Therefore, in this final rule, we are finalizing those provisions as proposed. We received a few comments on the appropriateness of applying the low-volume adjustment to training ESRD facilities as set forth below.

Comment: One commenter was opposed to applying the low-volume adjustment to ESRD facilities that solely furnish support services and training to home patients. The commenter believed that because these facilities do not treat patients, they should not be eligible for the low-volume adjustment. Two commenters believed that it is appropriate to apply the low-volume adjustment to eligible ESRD facilities that solely furnish support services and training to home patients. One commenter explained that allowing these types of facilities to be eligible for the low-volume adjustment is consistent with encouraging home dialysis options. Another commenter provided a detailed explanation as to why small facilities that only furnish PD should qualify for the adjustment. This commenter also asked for clarification as to how CMS would identify facilities that solely furnish support services and training and if these facilities would be excluded from the analysis. One commenter expressed concern about CMS' treatment of home dialysis services in the low-volume policy indicating that CMS does not have the ability to properly identify training programs.

Response: We maintain a database of all ESRD facilities and their respective Medicare certifications. We are able to use this database to develop reports and to analyze and monitor the different facility characteristics and trends. The cost reports used in determining low-volume ESRD facilities for the analyses of costs for composite rate and separately billable services identifies both home and in-facility dialysis treatments, including training treatments.

With regard to the comments concerning the facilities that solely furnish support services and training, in our analysis we controlled for the percentage of training treatments in the facility so that the adjustment for low-volume facilities would be independent of costs associated with home dialysis training. Therefore, we are including ESRD facilities that solely furnish support services and training as being eligible for the low-volume adjustment. We believe that including this type of ESRD facility as being eligible for the low-volume adjustment could encourage ESRD facilities in rural areas, to provide home dialysis training. We will monitor the extent to which facilities that solely furnish home dialysis training support receive the low-volume payment adjustment and whether the number of these facilities increases after implementation of the ESRD PPS.

We received many comments on the possible unintended effects of establishing a treatment threshold and other comments on the definition of a low-volume ESRD facility as set forth below.

Comment: Many commenters expressed concern regarding potential disincentives low-volume facilities could have regarding patient care. The commenters suggested that CMS consider strategies for monitoring the low-volume adjustment in addition to those stated in the proposed rule. The commenters claimed that facilities will not offer additional treatments if it means that those additional treatments will render the facilities ineligible for the low-volume adjustment. The commenters also asserted that dialysis chains will establish facilities in a market where another facility is sufficiently servicing a location just to be able to take advantage of the adjustment. The commenter stated that a dialysis chain could create an artificial low-volume facility that purposely operates below its efficiency level in order to receive the adjustment. The commenters recommended that CMS enact controls and measures to prevent gaming of the low-volume adjustment and to ensure that those facilities which serve disadvantaged areas are correctly identified. One commenter suggested that CMS only apply the adjustment to facilities that are not within 30 road miles of another facility.

Response: We share the commenter's concerns and agree that there is potential for gaming as a result of the low-volume adjustment. At this time, we are not finalizing any additional criteria or requirements. We believe that the geographic proximity restriction, as described in the ESRD PPS proposed rule (74 FR 49975), produces the same effect as the commenter's suggestion of not allowing ESRD facilities that are within 30 road miles of another ESRD facility to be eligible for the low-volume adjustment. We believe that the commenter's suggestion is too restrictive in that there could be independent small ESRD facilities that are servicing areas efficiently even if there are within 30 road miles of another independent ESRD facility. We will monitor payments under the ESRD PPS and the location of new facilities to determine if changes in the criteria that qualify ESRD facilities as being low-volume are warranted.

Comment: Many commenters supported the low-volume adjustment indicating that the adjustment would encourage small ESRD facilities to continue to provide access in areas where the patient base is low.

Response: We thank the commenters for their support.

Comment: A couple of commenters questioned the rationale we used in determining the treatment threshold. Specifically, the commenters stated that CMS used an arbitrary selection of 3,000 treatments, which ignores the real and measurable higher costs per treatment incurred by low-volume facilities performing 4,000 or 5,000 treatments per year. A few commenters requested that CMS provide a detailed explanation of its methodology for selecting facilities as being eligible for the low-volume adjustment and verify that facilities identified as low-volume meet the criteria of providing less than 3,000 treatments.

A few commenters expressed concern that the proposed treatment threshold of less than 3,000 treatments would capture too low of a population of small facilities leaving out many facilities that they believe should receive the adjustment. Several commenters expressed concern that most pediatric facilities may not qualify based on the less than 3,000 treatment threshold. The commenters suggested that CMS raise the treatment threshold portion of the low-volume definition to less than 4,000 treatments.

Response: We disagree with the comment that our proposal to establish a threshold of less than 3,000 treatments was arbitrary. As discussed in the proposed rule, we began the development of the low-volume adjustment by analyzing facility size. We determined facility size by looking at the total number of treatments that a facility furnished annually because that was the basis for which they receive payment. We used the total treatment counts from cost reports for 2004, 2005, and 2006. We carefully assessed treatment counts beginning at less than 1,000 and moved upward to more than 10,000. We performed comparisons of

different facility characteristics against the different treatment thresholds and studied the trends. We found that in each comparison, when the number of treatments increased, the cost that facilities incurred for composite rate services decreased (74 FR 49970).

For this final rule, we repeated the analyses using cost reports for 2006, 2007, and 2008. We also used SIMS data for total treatments for calendar year 2008 to see the change in the percentage of certain ESRD facility types that would be eligible with a less than 4,000 treatment threshold that may not have been eligible with a less than 3,000 treatment threshold. As displayed in Tables 23 and 24, we compared characteristics of facilities eligible for a low-volume adjustment that are based on a 3,000 treatment threshold for determining low-volume status to characteristics of facilities eligible for the low-volume adjustment that are based on a 4,000 treatment threshold. We found the percent of Medicare HD-equivalent dialysis treatments that would qualify for the low-volume adjustment increased from 0.7 percent using a 3,000 treatment threshold to 1.9 percent using a 4,000 treatment threshold. The tables also show that when compared to larger facilities, facilities that would be eligible for the low-volume adjustment are more likely to be located in a rural area, less likely to be part of an LDO, more likely to be hospital based, likely to have a somewhat higher percentage of Medicare patients, more likely to be a pediatric facility, more likely to have previously received an isolated essential facilities (IEF) composite rate payment exception, and more likely to concentrate on home dialysis.

Based on the commenter's arguments and our subsequent analysis regarding the treatment threshold, in this final rule, we are finalizing a threshold of less than 4,000 treatments and we are revising the regulation at § 413.232 to reflect this threshold.

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Table 23: Characteristics of facilities eligible for a low volume adjustment that is based on a 3,000 treatment threshold for determining low volume status, 2008*

Facility type	% of Medicare HD-equivalent treatments**	Rural	Facility ownership: Large dialysis organization	Hospital based	% Medicare (based on Cost Reports)	Facilities with at least 50% of Medicare treatments for pediatric patients	Isolated Essential Facility (IEF) before 2005	Facilities with only home dialysis treatments on Cost Reports
Low volume facility: Did not open or close and reported < 3,000 treatments each year from 2006-08^	0.7%	42.0%	38.1%	42.0%	74.3%	12.2%	2.2%	16.2%
Other facilities that reported < 3,000 treatments during 2008	2.2%	26.1%	31.6%	15.7%	69.1%	2.3%	0.5%	9.7%
Facilities with ≥ 3,000 treatments	97.1%	21.8%	64.4%	9.5%	72.1%	0.3%	0.9%	1.0%

*Data on the total number of treatments for each facility were obtained from SIMS. The reported in-center treatments from SIMS were added to the estimated treatments for home dialysis patients, using the number of home dialysis patients reported in SIMS and the average number of treatments per patient year from Medicare outpatient dialysis claims. Excludes facilities with data on total treatments not available in SIMS for 2008 (n=75).
**Based on 37.4M HD-equivalent treatments on Medicare claims for 5,108 facilities in 2008.
^For hospital-based facilities, eligibility for the low volume adjustment was established based on the combined treatment counts for both the parent facility and any affiliated satellite facilities that were identified

Table 24: Characteristics of facilities eligible for a low volume adjustment that is based on a 4,000 treatment threshold for determining low volume status, 2008*

Facility type	% of Medicare HD-equivalent treatments**	Rural	Facility ownership: Large dialysis organization	Hospital based	% Medicare (based on Cost Reports)	Facilities with at least 50% of Medicare treatments for pediatric patients	Isolated Essential Facility (IEF) before 2005	Facilities with only home dialysis treatments on Cost Reports
Low volume facility: Did not open or close and reported < 4,000 treatments each year from 2006-08^	1.9%	44.5%	48.1%	29.1%	76.7%	7.7%	1.4%	11.1%
Other facilities that reported < 4,000 treatments during 2008	3.5%	28.4%	37.1%	15.6%	69.3%	1.8%	1.4%	7.6%
Facilities with ≥ 4,000 treatments	94.6%	20.3%	65.1%	9.0%	71.9%	0.2%	0.8%	0.8%

*Data on the total number of treatments for each facility were obtained from SIMS. The reported in-center treatments from SIMS were added to the estimated treatments for home dialysis patients, using the number of home dialysis patients reported in SIMS and the average number of treatments per patient year from Medicare outpatient dialysis claims. Excludes facilities with data on total treatments not available in SIMS for 2008 (n=75).
**Based on 37.4M HD-equivalent treatments on Medicare claims for 5,108 facilities in 2008.
^For hospital-based facilities, eligibility for the low volume adjustment was established based on the combined treatment counts for both the parent facility and any affiliated satellite facilities that were identified

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Comment: One commenter recommended that CMS consider a stratified differential payment to all ESRD facilities based on treatment thresholds. The commenter further explained that under a differential payment method, facilities would receive the largest adjusted payment for the first 1,000 treatments and then as the number of treatments increases, the payment amount would decrease.

Response: We thank the commenter for their suggestion. We will monitor the number of facilities that are low-volume throughout the initial years of the ESRD PPS and analyze their behaviors to decide if we should develop a different methodology in determining low-volume eligibility in future refinements.

Comment: We received a few comments objecting to our proposal to use total annual treatments as a criterion in the low-volume definition. The commenters explained that there are too many variables associated with using treatments, such as, patients hospitalized, patients who travel, patient-visitors, and missed treatments. The commenters stated that a stable method of determining the volume of a facility is by patient census or by counting the number of chairs available for furnishing treatments (stations) in the facility.

Response: We disagree that a stable method of determining the volume of an ESRD facility would be by patient census or stations in the facility. In the proposed rule, we explained that in the initial analysis, an ESRD facility size was defined by the number of treatments (74 FR 49970). Payments to ESRD facilities are paid on a per treatment basis and we noted that patient census accounted for by the number of treatments that are furnished. We believe that furnishing care to patients that get hospitalized, patients who travel, patient-visitors, and those patients that miss treatments is a universal occurrence among all ESRD facilities and, therefore, these circumstances neither serve as an advantage nor a detriment in an ESRD facility's eligibility for the low-volume adjustment. We do not consider patient census or number of stations as indicators of low-volume status, because these would not reflect the actual number of treatments provided. In addition, we continue to believe the use of total treatments, including those covered by other payers, is necessary to determine eligibility for low-volume status.

Comment: A few commenters from hospital associations requested clarification on which treatments would count toward the proposed treatment threshold, because they furnish both inpatient and outpatient dialysis services.

Response: Payment for renal dialysis services under the current payment system and under the ESRD PPS is made to Medicare-certified ESRD providers of services or renal dialysis facilities for furnishing outpatient maintenance renal dialysis items and services. Given that the ESRD PPS pertains to outpatient maintenance dialysis, the low-volume adjustment treatment threshold only pertains to outpatient dialysis and therefore, the treatments counted do not include inpatient dialysis treatments.

Comment: One commenter suggested that CMS include payer mix as a criterion in determining the eligibility of a low-volume facility. The commenter expressed concern that facilities that have a higher percentage of Medicare-only patients, or patients that are Medicare and Medicaid eligible, have a high risk of having low profit margins.

Response: We disagree with the commenter that payer mix should be used as a criterion in determining low-volume eligibility. As we stated in the proposed rule (74 FR 49969), we believe the low-volume adjustment is intended to encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic. Therefore, we will provide an adjustment based on the volume of treatments provided and not on the basis of a payer mix. We note that many ESRD facilities determined eligible for the low-volume adjustment have a high percentage of Medicare patients (see Table 24).

Comment: Some commenters suggested that the implementation of the low-volume criteria should be more specific and clear in stating eligibility for the adjustment. Two commenters questioned how CMS will determine when a facility reaches its 3000th treatment. The commenters suggested that one way we could determine when a facility reached the 3,000 treatment threshold is to use Medicare claims. The commenter explained that if CMS uses Medicare claims to make this determination, then this would suggest that CMS is not including non-Medicare treatments. The commenters suggested that the alternative to using Medicare claims would be to use cost reports. However, the commenters expressed concern that using cost reports would create too long of lag time from when the facility is no longer eligible for the low-volume adjustment and when the FI/MAC would be able to identify total treatments. The commenters expressed concern that using the cost reports to verify that a facility does or does not continue to be eligible for the low-volume adjustment means that CMS would retroactively collect monies paid out on all treatments that exceeded the threshold in that payment year. Other commenters suggested that CMS use cost reports to terminate the application of the low-volume adjuster at the time the cost report is submitted and to not claw back the dollars already paid out.

Response: We believe that we were explicit in our discussion of criteria in the proposed rule (74 FR 49975), but we agree that we did not discuss the implementation in the proposed rule. We will provide additional information on the implementation of the low-volume adjustment in the future. Therefore, we are finalizing the low-volume definition and the applicable criteria as set forth in § 413.232.

We used all treatments including non-Medicare treatments from the cost reports to establish the low-volume threshold, as we believe that inclusion of all treatments regardless of payer type represents the true volume of treatments that are provided to ESRD patients. If we had not included treatments from other payer types, we would have not determined the actual volume of services provided to individuals with ESRD. Therefore, we will use cost reports to confirm facility status as low-volume.

We agree with the commenter that there is a lag time from when the facility may no longer be eligible for the low-volume adjustment and when the FI/MAC finalizes its cost report for that payment year. It is our understanding that ESRD facilities have accounting systems in place that allow them the ability to record the number of patients that they currently care for, and are therefore aware of the number of treatments it furnishes on a monthly basis.

We recommend that once a facility determines it has furnished over 4,000 treatments in the payment year that it would notify its respective FI/MAC that it no longer qualifies as a low-volume facility and request to no longer have the adjustment applied to its treatments. Where a facility no longer meets the eligibility requirements and does not notify its FI/MAC, CMS will develop procedures to ensure that ESRD facilities receive the appropriate payments. We will address these procedures in detail in the future.

Comment: A few commenters stated that they do not believe that the data CMS used to develop the low-volume adjustment was appropriate. The commenters explained that cost reports

have not been used for purposes of setting payment and that their experience with cost reports is that they typically have extreme values/errors that can distort results. The commenters suggested that CMS perform a more detailed review of the individual facilities that it identified as being qualified to receive the low-volume adjustment to ensure that the correct facilities are being identified. The commenters recommended that we consider adhering to the statutory recommendation of a 10 percent adjustment in absence of clear, concrete data.

Response: We use the cost report information to obtain facility level information that includes facility costs for composite rate services and the number of dialysis treatments provided by a facility. Because the low-volume payment adjustment is a facility level adjustment, whereby an ESRD facility would receive a payment adjustment based on the number of maintenance dialysis treatments it furnished, we believe the cost report would be the appropriate source to obtain that information. We agree with the commenter that in our data analysis for the ESRD PPS, we found that there were individual cost reports with extreme values or errors and a methodology has been used to exclude these records from the analyses (discussed further in section II.C. of this final rule). We will be monitoring the use of the low-volume adjustment to ensure that appropriate ESRD facilities, which have not exceeded the 4,000 treatment threshold, will receive the low-volume payment adjustment. In the meantime, we believe using the adjustment derived from the regressions analysis is a better measure of the costs of low-volume facilities.

Comment: We received two comments requesting clarification of why we used 89 low-volume facilities in the low-volume adjustment analysis but listed 166 low-volume facilities in the impact file. The commenters provided examples of facilities that were identified by CMS as low-volume in the impact analysis, but according to their research, did not meet the low-volume criteria, such as (1) 6 facilities closed in 2007 or 2008; (2) 11 facilities had greater than 3,000 total treatments for cost report year 2006; (3) 2 facilities were start-ups or may have changed ownership in 2007; and (4) 30 facilities have zero workstations which would indicate that they appear to be home dialysis programs. The commenters stated that these examples indicate that CMS is incorrectly identifying facilities as low-volume.

Response: As discussed in the proposed rule (74 FR 49969), the data used for the regression analysis which was used to determine the magnitude of the adjustment for low-volume facilities (not to identify the actual ESRD facility), was made from Medicare cost reports, SIMS, and OSCAR for the years 2004, 2005, and 2006. Using the data available at the time the analysis was completed, we estimated that 89 facilities with cost report data available for the regression analysis would qualify as low-volume facilities (74 FR 49975).

However, to assess the impact of the ESRD PPS in 2011, we used the most recent data available to determine total facility treatments. Because cost reports for 2007 were generally not complete at the time of the analysis, we used SIMS data to identify low-volume facilities that would be eligible for the adjustment. The information in SIMS is populated from the Annual Facility Survey which is submitted by all ESRD facilities on a yearly basis. Based on the data available at the time the impact analysis was completed, 166 facilities met the low-volume definition proposed at § 413.232 (74 FR 50018). Therefore, it is possible that there is conflict between CMS's data and the data that was being analyzed by the commenter due to the timing of when the analysis was completed and the difference in data sources.

Comment: One commenter disagreed with the proposed requirement that an ESRD facility must provide less than the treatment threshold for three consecutive years before becoming eligible for the low-volume payment adjustment if the ESRD facility serves a population of patients located in remote areas. The commenter suggested reducing the qualification time period to one year. One commenter expressed concern that limiting the low-volume adjustment to facilities that have been in operation for three years would freeze the number of ESRD facilities in rural areas, thereby causing patient access issues.

Response: We appreciate the commenter's suggestion however we do not have a mechanism in place to determine if a facility is in a remote area. We discuss rural facilities later in this section of this final rule.

We believe that a 3-year waiting period serves as a safeguard against facilities that have the opportunity to take a financial loss in establishing new facilities that are purposefully small. We structured our analysis of the ESRD PPS by looking across data for three years as we believe that the 3-year timeframe provided us with a sufficient span of time to view consistency in business operations.

Comment: Several commenters recommended that the IEF be considered eligible for the low-volume adjustment regardless of the number of treatments they provide each year. Two commenters expressed concern that twelve of the 37 facilities with current IEF Medicare exceptions exceeded the 3,000 low-volume threshold. The commenters believe that the facilities that currently have IEF status have been deemed as an IEF through the exception process by providing evidence of their excess costs due to furnishing dialysis treatments in areas that are isolated. One commenter suggested that CMS review the cost reports for these IEFs and base the adjustment on current and accurate costs. Another commenter suggested the same idea but added that the adjustment be at least 10 percent.

Response: To be eligible for an IEF exception rate under the current basic case-mix adjusted composite payment system, an ESRD facility was required to demonstrate that it met the criteria established by us. As discussed in section II.L. of this final rule, all exceptions currently in place will no longer apply under the ESRD PPS. The IEFs that retained their exception rate after the implementation of the basic case-mix adjusted composite payment system will no longer be able to retain that rate after the implementation of the ESRD PPS. As a result, there is no mechanism to reassess or grant exceptions. However, in the event that an ESRD facility elects to receive payment under the ESRD PPS transition period, any existing exceptions would be recognized for the purpose of the basic case-mix adjusted composite payment system portion of the blended payment through the transition.

In the proposed rule, we indicated that there are currently 37 facilities that retained their exception rates (74 FR 50018). However, the 37 facilities are not exclusively IEFs. The total represents both facilities that met the criteria for an IEF exception and facilities that demonstrated they have atypical service intensity.

We do not believe that IEF facilities should automatically be considered low-volume because the criteria required for the IEF exceptions differ from the criteria established to be eligible for the low-volume adjustment.

Comment: One commenter recommended that CMS develop a methodology similar to the one used to identify critical access hospitals (CAH). The commenter further explained that this would include mileage proximity to

another dialysis facility as well as number of treatments per year.

Response: We appreciate this suggestion; however, we believe that ESRD facilities and CAHs are not comparable provider types. CAHs, defined at section 1820(c)(2)(B) of the Act, furnish a multitude of services and have provider-specific conditions of participation, and therefore, have criteria established to identify them. We believe that we have developed criteria that are appropriate to establish if an ESRD facility is eligible for a low-volume payment adjustment. Therefore, as we indicated in the previous response, we are finalizing the criteria to be used to determine low-volume eligibility in § 413.232. We will monitor the growth of low-volume facilities to see if additional criteria are warranted in the future.

Comment: Several commenters expressed concern that the low-volume adjustment would not "level the marketplace between competitors and therefore would not help the average small dialysis organization (SDO)". Some commenters stated that CMS should support small businesses because most SDOs are dependent on Medicare patients for the majority of their treatments. The commenters further stated that only facilities that are not part of an LDO should receive the low-volume adjustment because in comparison with the LDOs, SDOs furnish a small percentage of the dialysis patient population. As a result, commenters claimed that they are unable to benefit from the economies of scale of LDOs.

Response: We appreciate the commenters' concerns, however, we continue to believe that the definition of a low-volume facility discussed in the proposed rule (74 FR 49975), and subsequently modified by this final rule which increased the treatment threshold from 3,000 treatments to 4,000 treatments, identifies the ESRD facilities that incur high costs for furnishing renal dialysis items and services in areas that would otherwise be problematic. We believe that with our data analysis which provided empirical evidence of higher costs and our selection of criteria, we have identified those facilities that are low-volume. We note that in response to comments from SDOs, we have done an analysis to compare how the smaller dialysis facilities that are neither low-volume nor affiliated with a large dialysis organization will fair after implementation of the ESRD PPS. This analysis is discussed in section IV.B.1. of this final rule.

We received a few comments on the proposed geographic requirements used to determine the number of treatments furnished by an ESRD facility to be eligible for the low-volume payment adjustment as set forth below.

Comment: One commenter expressed concern that the low-volume adjustment should be developed based on the proximity of a facility to all other facilities and the total volume of services a facility furnishes. The commenter suggested that CMS implement a low-volume adjuster that is based on the total volume and proximity of the facility in question to other facilities. Another commenter suggested that CMS consider the regularity and frequency of dialysis care that patients need when determining the distance threshold as most dialysis patients are treated three times weekly. The commenter indicated the 25 road mile standard may not be appropriate and that CMS may want to consider a shorter distance.

Response: In the proposed rule, we explained that we were concerned about the potential misuse of the proposed low-volume adjustment because the low-volume adjustment could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities leading to unnecessary inefficiencies. Therefore, for the purposes of determining the number of treatments, we proposed that the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 25 road miles or less from the ESRD facility in question. We developed the proximity criteria as a parameter to be used by the FI/MACs when they evaluate eligibility for the low-volume adjustment of new facilities that open in the future (74 FR 49975). We do not believe that the frequency that a patient receives dialysis treatments is relevant to determine the location of a new facility as the distance traveled would be different for each patient.

Therefore, for the reasons above and those set forth in the proposed rule (74 FR 49975), in this final rule we are finalizing the geographic requirements used to determine the number of treatments furnished by an ESRD facility, which is to consider the total number of treatments furnished by an ESRD facility to be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 25 road miles or less from the ESRD facility in question, to be eligible for the low-volume payment adjustment at § 413.232.

Comment: One commenter expressed concern that although they agree with the extra monies being allocated to high cost facilities for meeting the low-volume criteria, the effect on the patients that receive care in these facilities will be an increase in their co-insurance amounts.

Response: We agree with the commenter that the ESRD PPS will affect patient co-insurance amounts. However, we note that this adjustment was required under the statute.

ii. Defining the Percent of Increase

Section 1881(14)(D)(iii) of the Act also requires the ESRD PPS include a "payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment not be less than 10 percent." In the proposed rule, we discussed the definition and our analysis for a low-volume facility (74 FR 49969). Based on the definition and the analysis, the resulting low-volume payment adjustment was determined to be 20.2 percent (74 FR 49974). Using our proposed low-volume criteria, we measured the payments received by these ESRD facilities and determined that 76.4 percent of ESRD facilities meeting the proposed low-volume criteria would get an adjustment of 10 percent or more increase in payment relative to what they received under the current system.

In our proposed rule (74 FR 49977), we proposed a 20.2 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014. The proposed low-volume adjustment policy was set forth at proposed § 413.232 (74 FR 49969). We invited comments on the low-volume facility proposed adjustment, which was discussed above.

In addition, for purposes of determining the appropriate adjustment for the low-volume facilities defined above, we considered other options in addition to the 20.2 percent adjustment (74 FR 49978). As mentioned previously, section 1881(14)(D)(iii) of the Act requires the payment adjustment for low-volume facilities be not less than 10 percent during the transition. One alternative we considered in determining the adjustment for low-volume facilities was the minimum statutory adjustment

of 10 percent. We stated that this adjustment would provide relief to low-volume facilities of the costs they incur to provide services. In addition, providing a lower payment adjustment results in less of a decrease in the ESRD PPS base rate that would apply to treatments furnished by all ESRD facilities and less beneficiary co-insurance obligation.

The other alternative we mentioned for the low-volume adjustment was use of the midpoint between the statutory adjustment of 10 percent and the results of our data analysis which was 20.2 percent (74 FR 49978). We stated that we believed that a 15 percent increase could establish an appropriate adjustment amount that would provide low-volume facilities the incentive to utilize resources more efficiently and control their costs.

We invited comments on these alternative options for determining the percent low-volume adjustment.

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

Comment: Two commenters recommended that we reduce the 20.2 percent increase to the minimum 10 percent permitted by law because at 10 percent, facilities would be less likely to deny treatments to ensure that they remain under the threshold.

Response: For this final rule, we updated our ESRD PPS model with data for 2006, 2007, and 2008 and found that with a treatment threshold of 4,000 treatments, the updated increase to the base rate is 18.9 percent. We believe that since we will be monitoring payments under the ESRD PPS and the location of new facilities as they are established, the 18.9 percent increase to the base rate is an appropriate adjustment that will encourage small facilities to continue to provide access to care. In addition, we believe it is more appropriate to use the regression driven adjustment rather than the 10 percent minimum adjustment mentioned in the statute. We believe that using the regression driven adjustment which is based on empirical evidence allows us to implement a payment adjustment that is a more accurate depiction of higher costs.

Therefore, in this final rule we are finalizing a 18.9 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011.

c. Alaska/Hawaii Facilities

Section 1881(b)(14)(D)(iv) of the Act permits the Secretary to include other payment adjustments as the Secretary determines appropriate. The basic case-mix adjusted composite payment system currently does not provide a separate adjustment for ESRD facilities located in Alaska and Hawaii. However, some prospective payment systems, such as the hospital inpatient PPS and the inpatient psychiatric facility PPS, provide a cost of living adjustment (COLA) for facilities located in Alaska and Hawaii. These COLA adjustments are applied to the non-labor portion of the payment and are based on the rationale that the wage index adjustment to the labor portion of the payment is not sufficient to provide for the higher costs incurred by facilities in Alaska and Hawaii. For example, the same supplies used by an ESRD facility located in Hawaii may cost more because there are additional (higher) transportation costs incurred to receive the same supplies compared to an ESRD facility located in the United States mainland. An analysis completed for the 2008 Report to Congress indicated there was no need for a COLA for these areas. After all adjustments (including wage and other adjustments), our analysis of ESRD facilities located in Alaska and Hawaii did not demonstrate any adverse impact from the ESRD PPS.

In the proposed rule, we stated that our analysis continues to support that the ESRD PPS would adequately reimburse ESRD facilities located in Alaska and Hawaii (74 FR 49978). Therefore, we did not propose to adopt COLA adjustments for ESRD facilities in Alaska and Hawaii under the ESRD PPS. We invited public comments on the proposal.

We received a few comments regarding the COLA for Alaska and Hawaii as set forth below.

Comment: Two commenters believed that the adjustments contained in the proposed ESRD PPS did not adequately address the incremental costs incurred by providing dialysis services and supplies to ESRD patients in Alaska and Hawaii. The commenters urged CMS to reconsider the proposal to not apply a COLA adjustment for these States and indicated that the costs associated with furnishing ESRD treatments in these States remains higher than the cost of providing dialysis services in the contiguous United States.

Response: We recognize the costs incurred by Alaska and the many islands of Hawaii might be attributable to the geographical barriers that may not be a burden to ESRD facilities located in the contiguous United States. However, as we indicated in the ESRD PPS proposed rule (74 FR 49978), the various analyses of ESRD facilities located in Alaska and Hawaii did not demonstrate any adverse impact from the ESRD PPS.

Therefore, we do not believe that application of the COLA would be appropriate. As a result, in this final rule, we are not adopting COLA adjustments for ESRD facilities in Alaska and Hawaii under the ESRD PPS.

d. Rural

Section 1881(b)(14)(D)(iv)(III) of the Act provides that the ESRD PPS may include payment adjustments as the Secretary determines appropriate such as a payment adjustment for facilities located in rural areas. We proposed to define rural facilities at § 413.231(b)(2) as facilities that are outside a Metropolitan Statistical Area or a Metropolitan Division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB (74 FR 49978).

In the proposed rule, we indicated that based on our impact analysis, rural facilities would be adequately reimbursed under the proposed ESRD PPS. Therefore, we did not propose a facility-level adjustment based on rural location and we invited public comments on our proposal (74 FR 49978).

Many of the commenters were concerned about beneficiary access to care that may result from insufficient payment to cover the costs of delivering renal dialysis services to patients in rural areas. This was particularly concerning to commenters who pointed out that ESRD beneficiaries who reside in rural locations already have fewer choices with regard to their care.

We received comments opposing our proposal not to include a facility-level adjustment that is based on rural location, which included the following two assertions: (1) Currently the costs of providing renal dialysis services in rural areas are higher than in urban areas and that costs would further increase by expanding the bundle to include additional medications and laboratory tests; and (2) currently patient access to renal dialysis services in rural areas is limited and insufficient reimbursement would result in closure of these facilities further hindering patient access.

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

Comment: Several ESRD facilities and health care professionals indicated that rural and small facilities have higher operating cost and lower revenue than the larger, urban or suburban facilities. These facilities are forced to operate at a low margin or at a financial loss. Commenters identified several factors

that contribute to higher costs including: higher recruitment costs to secure qualified staff, a limited ability to offset costs through economies of scale, and decreased negotiating power in contractual arrangements for medications, laboratory services or equipment maintenance. One commenter indicated that compared to the large chains, rural dialysis providers will be unable to compete in negotiating prices for drugs and that this would be especially problematic for the manufacturers' monopoly on EPO and Cinacalcet.

Commenters further noted that the lower revenues among rural ESRD facilities are attributed to serving a smaller volume of patients of which a larger proportion are indigent and lack insurance, and a smaller proportion have higher paying private insurance. Several commenters requested that CMS consider cost differentials in determining whether rural ESRD facilities warrant a payment adjuster. Other commenters requested that small rural facilities be paid based on the cost of providing services to allow them to break even.

Response: As indicated in section II.L. of this final rule, rural facilities are expected to experience a −1.5 percent decline in payments in 2011 due to implementation of the ESRD PPS. We note, however, in accordance with section 1881(b)(14)(A)(ii) of the Act and discussed in section II.E.4. of this final rule, the ESRD PPS base rate was reduced by 2.0 percent so that the estimated total amount of payments in 2011 equals 98 percent of what would otherwise be paid if the ESRD PPS were not implemented. Therefore, rural facilities as a group are projected to receive less of a reduction than urban facilities and many other subgroups of ESRD facilities.

We also note that as described in section II.A.3. of this final rule, implementation of oral-only Part D drugs will be delayed until 2014. This delay will provide small, rural facilities additional time to consider negotiating options for obtaining the most favorable prices on drugs possible. For example, small rural facilities may benefit from joining cooperative arrangements to improve negotiating capacity. We intend to monitor how rural ESRD facilities fare under the ESRD PPS and will consider other options if access to renal dialysis services in rural areas is compromised under the ESRD PPS.

Comment: Some commenters claimed that under the proposed rule, some rural facilities may not receive adequate reimbursement to continue to provide dialysis services in remote areas, resulting in compromised patient access to care. Commenters requested that CMS reassess its data for rural facilities following its reassessment of the data for low-volume facilities.

Response: As the commenter suggested, we reassessed the impact on ESRD facilities based on the final payment adjustments described in this final rule. As mentioned previously, the impact analysis conducted for this final rule indicates a 1.5 percent decrease in total payments to rural ESRD facilities. This small decline reflects the fact that 44.5 percent of low-volume ESRD facilities are located in rural areas (as discussed earlier in this section of this final rule).

Comment: One commenter was concerned that the 3 percent transition budget neutrality adjustment may particularly disadvantage the quality of care for rural dialysis patients, given their higher costs for patient transport, staff salary, and facility maintenance costs.

Response: As described in section II.E.5. of this final rule, we are required by section 1881(b)(14)(E)(ii) of the Act to apply a transition budget neutrality adjustment to account for the effect of the transition on aggregate payments in order to stay within the overall requirement for a 2 percent reduction in expenditures in 2011.

Comment: One commenter questioned whether defining every facility not located within a Metro statistical area (MSA) as rural reflects the variation in the degree of geographical isolation and therefore, cost among providers that are not located within an MSA. The commenter noted that cost differences may exist among facilities classified as rural that are further from an MSA compared to facilities closer to an MSA.

Response: We recognize that there may be differences among rural facilities based on distance from an MSA. However, we do not have a separate mechanism to identify additional variation among facilities in the area outside of a particular MSA.

Comment: A few commenters indicated that in rural settings the nephrologist facilitates care for other specialties by drawing laboratory tests or administering medications for conditions other than ESRD. One commenter stated that because the rural patients often do not have transportation to access these services separately from the dialysis visits, the ESRD facility cooperates by drawing these laboratory tests or administering medications ordered by the nephrologist in the interest of providing the patient with efficient healthcare delivery. The commenter stated that non-ESRD-related laboratory tests and medications ordered by the nephrologist should remain separately payable.

Response: In the interest of patient convenience and in minimizing their transportation burden, we will not preclude ESRD facilities from drawing non-ESRD related laboratory tests on behalf of ESRD patients. As described in section II.K.2. of this final rule, the laboratory tests used for non-ESRD-related purposes would be identified with a modifier and paid separately. Similarly, as described in section II.K.2. of this final rule, there may be instances in which non-ESRD-related medications may be administered in the ESRD facility. These medications would also be identified with a modifier and paid separately.

Comment: Several commenters indicated that ensuring access to home dialysis and home dialysis training is essential to successfully serving a rural area.

Response: We share the commenters' view with respect to the importance of ensuring access to home dialysis and home training. As discussed in section II.A.7. of this final rule, all home dialysis services will be included in ESRD PPS payments to ESRD facilities as of January 1, 2011. In addition, as discussed in section II.A.7. of this final rule, we are finalizing a training add-on adjustment to compensate ESRD facilities for the additional resources associated with home dialysis or self-dialysis training.

For the reasons we explained above in response to the public comments and based on the data analysis conducted for this final rule, we are finalizing the proposed definition of rural facilities at § 413.231(b)(2) of this final rule and we are not implementing a facility-level payment adjustment that is based on rural location.

e. Site Neutral ESRD PPS Rate

For dialysis services furnished before January 1, 2009, the basic case-mix adjusted composite rate differentiated between hospital-based and independent ESRD facilities. That is to say, the composite rate for hospital-based facilities was on average $4.00 more per treatment more than the composite rate for independent dialysis facilities.

Section 1881(b)(12)(A) of the Act, requires a site neutral composite rate so that the payment rate for services furnished on or after January 1, 2009, by hospital-based ESRD facilities is the same as the payment rate paid to independent facilities under the current system. In addition, section 1881(b)(12)(A) of the Act requires that

in applying the geographic index to hospital-based facilities, the labor-related share shall be based on the labor-related share otherwise applied to the renal dialysis facilities. In the CY 2009 final rule (72 FR 69881 and 72 FR 69935), we revised § 413.174, which described the methodology for prospective rates for ESRD facilities, to conform to the statutory requirement.

Section 1881(b)(14)(A)(i) of the Act provides that for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to ESRD facilities for renal dialysis services, in lieu of any other payment. Therefore, the site neutral payment provisions discussed above will be incorporated under the ESRD PPS and used to establish a single base rate that will apply to ESRD facilities.

5. Determination of ESRD PPS Payment Adjusters

In the proposed rule, we described the selection of patient characteristics as potential case-mix adjusters using a modeling approach that relied on separate regression equations for CR and SB services (see Table 29 in the proposed rule 74 FR 49979). We stated that the predictive power of the separate estimating equation for CR services in terms of the proportion of variance explained (R^2) was 46.0 percent. The comparable figure for the SB regression equation was 8.7 percent. The overall estimated R^2 for the ESRD PPS payment model is 39.0 percent (74 FR 49978). While the case-mix adjustments were based on separate estimating equations, the equations were combined into a single payment formula for the ESRD PPS. The methodology for combining the separate composite rate and separately billable estimating equations was described in the proposed rule (74 FR 49980 through 49981).

We did not receive any public comments in connection with our methodology for combining the separate composite rate and separately billable estimating equations into a single payment formula for calculating the ESRD PPS payment adjusters. Accordingly, we are using that same methodology to combine the separate composite rate and separately billable payment adjusters using the payment variables adopted for this final rule.

Table A in the Appendix shows how the payment adjusters from the separate CR and SB regressions were combined. The first two columns in Table A in the Appendix represent the CR and SB model results for each of the regression equations, carried to three significant figures. The third column of Table A of the Appendix presents a single payment multiplier for each patient characteristic based on its relationship to resource use for both CR and SB services. The payment adjusters in the third column ($PmtMult_{EB}$) were calculated as the weighted average of the CR and SB multipliers. The weights correspond to each component's proportion of the sum of the average CR costs and SB payments per treatment for CYs 2006–2008, as shown in Table 25.

Table 25—Estimated costs for composite rate and separately billable services, CY 2006-08[1]

	2006		2007		2008		Pooled, 2006-2008	
Measure of resource use	n (facilities or patient months)	Average $ per treatment	n (facilities or patient months)	Average $ per treatment	n (facilities or patient months)	Average $ per treatment	n (facilities or patient months)	Average $ per treatment
Facility composite rate costs[2]	4,158	$173.27	4,331	$177.41	4,485	$182.26	12,974	$177.72
Patient month separately billable Medicare Allowable Payments[3]								
Ages <18	5,907	$51.36	5,491	$52.26	5,744	$46.02	17,142	$49.84
Ages 18 and older	2,833,464	$86.46	2,890,396	$83.99	2,879,465	$81.53	8,603,325	$83.97

[1]Weighted by the number of hemodialysis-equivalent dialysis treatments.
[2]Source: Medicare cost reports for freestanding and hospital-based dialysis facilities.
[3]Source: Medicare dialysis patient claims.

The weights were calculated using the three years of pooled data. Based on this analysis, the average cost for CR services per treatment as computed from the Medicare cost reports was $177.72. The average MAP per treatment for SB services based on Medicare claims for the same period was $83.97. Based on total estimated costs of $261.69 per treatment ($177.72 + $83.97), the relative weights are $weight_{CR} = 0.6791$ for composite rate services ($177.72/$261.69) and $weight_{SB} = 0.3209$ for separately billable services ($83.97/$261.69). The payment multipliers presented in the third column of Table A in the Appendix were calculated as $PmtMult_{EB} = 0.6791 \times PmtMult_{CR} + 0.3209 \times PmtMult_{SB}$. In this manner, the separate case-mix adjusters for composite rate and separately billable services were combined to obtain a single set of multipliers (shown in the third column of Table A in the Appendix) to compute the payment rates under the proposed ESRD PPS.

Six co-morbidities were identified as payment adjusters for separately billable services only, as they did not have a statistically significant association with composite rate costs based on the regression results. These patient characteristic variables have a composite rate multiplier in Table A in the Appendix of 1.000. For these co-morbidities, there is no payment adjuster for composite rate services. Therefore, the payment multiplier is equal to $0.6791 \times 1.000 + 0.3209 \times PmtMult_{SB}$. The payment multipliers in the third column of Table A in the Appendix reflect the combined results from the two-equation model described in this final rule, and represent the case-mix adjustment factors that will be

applied to the base rate to compute the payment amount per treatment under the finalized ESRD PPS.

G. Pediatric Patients

In section IX. of the proposed rule (74 FR 49981 through 49987), we pointed out that section 1881(b)(14)(D)(iv)(I) of the Act gave the Secretary the discretionary authority to develop a pediatric payment adjustment under the ESRD PPS. Consistent with that authority, we proposed our methodology for developing a pediatric payment adjustment and proposed pediatric patient-specific case-mix adjustment factors (74 FR 49987).

Using the same two-equation regression methodology developed for adult patients, the pediatric payment model incorporated the proposed adjustment factor of 1.199 from the adult payment model for patients less than age 18 for the purpose of computing the composite rate portion of the bundled payment for pediatric patients (74 FR 49982). In order to adjust the separately billable portion of the payment rate, we proposed the use of specific adjusters for each of eight pediatric classification categories (*see* Table 32 at 74 FR 49986). These classification groups reflected two age groups (<13 and 13–17), two co-morbidity classification groups (none and one or more) based on the presence of either HIV/AIDS, diabetes, septicemia within 3 months, or cardiac arrest, and two modality groups (PD or HD). The result was a set of eight pediatric classification groups, each of which had its own bundled ESRD PPS payment multiplier. Those multipliers reflected the combined composite rate and separately billable adjustment factors developed in accordance with the two-equation regression methodology used in connection with the adult payment model. These adjustment factors were weighted according to the relative utilization of resources among pediatric patients obtained from the Medicare cost reports for 2004 through 2006 for composite rate services, and 2004 through 2006 claims for separately billable services. The proposed adjustment factors, which would be applied to the base rate under the ESRD PPS, ranged from 0.963 to 1.215 (*see* Table 33 at 74 FR 49987).

We received numerous comments from industry representatives including children's hospitals and other dialysis facilities treating pediatric patients, LDOs, hospital organizations, physician representatives, dialysis industry groups, and laboratories on our proposed pediatric payment model. Commenters were opposed to the methodology used to develop the proposed pediatric payment adjusters. The comments we received and our responses are set forth below.

Comment: Several commenters stated that the proposed methodology underestimated the cost of caring for pediatric patients with ESRD, and that application of the proposed payment adjusters would cause severe financial hardship for facilities treating ESRD pediatric patients. The commenters pointed out that the proposed payment multiplier of 1.199 used to adjust the composite rate portion of the pediatric MAP, as well as the composite rate portion of the MAP, is based on the costs of adult dialysis units, not pediatric specific services. The commenters suggested that the composite rate cost portion of the pediatric MAP, and the composite rate adjustment factor, should be based on actual cost data from pediatric dialysis units.

The commenters believed that the present multiplier of 1.62 applied to the composite rate per treatment for pediatric patients was likely more reflective of actual pediatric costs, not the proposed factor of 1.199. Other commenters recommended that CMS should perform further statistical analysis which uses the actual costs from pediatric ESRD facilities, or the pediatric units of ESRD facilities to determine the composite rate cost portion of the pediatric MAP, and the composite rate pediatric adjustment factor.

Response: In the proposed rule, we pointed out the current pediatric adjustment factor of 1.62 was developed from only those ESRD facilities that sought and obtained an exception to their otherwise applicable composite payment rates (74 FR 49984). This factor only reflected the costs of ESRD facilities which exceeded their composite payment rates. Therefore, the 1.62 adjustment factor was likely biased upward because it was not developed from the costs of ESRD facilities with costs below their composite rates.

However, the commenters raise a valid point. The generally lower payments for treating adult ESRD patients were commingled with pediatric payments in developing the composite rate portion of the proposed base rate. The multipliers from the composite rate and separately billable portions of the proposed pediatric payment adjustments were weighted based on average ESRD composite rate facility costs for 2004 through 2006. The multipliers were developed from data that were not restricted to pediatric ESRD facilities. Similarly, the adjustment factor of 1.199 applied to the composite rate portion of the proposed pediatric payment adjustment factors reflect the composite rate costs of pediatric patients treated in all facilities, not just pediatric ESRD facilities or the pediatric units of dialysis facilities. Because these costs reflect predominantly adult patients, they may be understated if, as is likely, the cost of care for pediatric patients in primarily adult facilities is less than the cost of care for pediatric patients in primarily pediatric facilities. We agree that further additional statistical analysis is warranted to determine whether a robust case-mix adjusted pediatric payment model can be developed based on co-morbid characteristics of pediatric dialysis patients, one which does not dilute the higher composite rate costs of pediatric patients with the generally lower composite rate costs of adult patients.

We agree with the commenters that the proposed pediatric case-mix adjusters reflect composite rate costs that may understate the cost of treating pediatric dialysis patients, because of the predominance of adult patients in ESRD facilities. To respond to the commenters' concern that adoption of the proposed pediatric payment adjusters would not compensate ESRD facilities for the actual costs of furnishing dialysis to pediatric patients, we have modified the proposed payment adjusters applied to pediatric patients (see Table 33 in the proposed rule at 74 FR 49987). The pediatric payment adjusters we have adopted for this final rule reflect the higher average composite rate payment per treatment that we made in CY 2007 for pediatric dialysis treatments compared to those for adult patients and the lower average per treatment payments made for separately billable services furnished pediatric patients in that year. As discussed in section II.E.1. of this final rule, CY 2007 is the year used to develop the ESRD PPS base rate amount. Combined composite rate and separately billable average payments per treatment in CY 2007 for pediatric dialysis patients exceeded the comparable figure for adult patients by 10.5 percent ($264.55 versus $239.39). This differential has been reflected in the pediatric payment adjusters set forth in this final rule.

Comment: Several commenters maintained that the four co-morbidities included in the proposed rule for classifying pediatric ESRD patients into one of eight classification groups (HIV/AIDS, septicemia, diabetes, and cardiac arrest) (74 FR 49987) were not appropriate for the pediatric patient

population and were not frequently encountered. The commenters stated that these co-morbidities, while perhaps relevant in the adult population, do not accurately reflect the complexity and cost of providing dialysis treatments to children. The commenters recommended alternative co-morbidities which they believed would be more reflective of the clinical conditions encountered among pediatric ESRD patients and require more costly resource intensive care. Suggested co-morbidities included developmental delay/mental retardation, growth retardation and renal osteodystrophy, deafness, seizure disorders, anxiety, secondary hyperparathyroidism, and rare genetic disorders such as cystinosis, primary hyperoxaluria, congenital hepatic fibrosis and other congenital diseases, chronic lung disease from hypoplastic lungs, and bone marrow and other solid organ transplants.

Response: We appreciate the commenters' concerns that any co-morbidity used as an ESRD pediatric payment adjustment reflects the cost and intensity of care necessary to provide outpatient dialysis to children. Unfortunately, because ESRD facilities rarely report co-morbidities on the Medicare type 72X claims submitted for payment, we obtained the co-morbidities used to establish the proposed pediatric classification groups from the same Medicare claims data used to identify the co-morbidities in the adult payment model. The small size of the outpatient ESRD pediatric dialysis patient population (about 860 patients in 2008) precluded the development of specific adjusters for individual co-morbidities due to a lack of statistical robustness. Therefore, we used a count of the number of defined co-morbidities in developing the pediatric classification groups.

The commenters' suggestion to use co-morbidities typical of the clinical conditions encountered among ESRD pediatric patients merits consideration, although we believe that it might require a specific data collection effort to obtain the co-morbidities for analysis. Although the co-morbidities in the proposed rule were derived from measures originally developed using claims from the adult population, their inclusion in the pediatric payment model was based on analyses that showed their relationship to cost specifically in the pediatric population. As explained below, we have developed pediatric adjustment factors for this final rule which do not rely on specific co-morbidities. We will consider the commenters' suggested alternative co-morbidities in future refinements to the pediatric payment adjusters adopted in this final rule.

Comment: Several commenters disagreed with the two age classification groups we used in the proposed pediatric payment model (age <13; 13–17). The commenters stated that the use of these two age groups undervalued the complexity and additional facility costs incurred in dialyzing children. Some commenters recommended only one age group (age <18) to simplify the bundle for pediatric dialysis.

Other commenters recommended alternative age groups. One commenter with clinical experience treating pediatric ESRD patients pointed out that dialysis patients under age 5 use one nurse per dialysis station and patients ages 5–12 use one nurse for every two stations. The commenter suggested that adopting age categories using this information would result in three categories for pediatric ESRD patients (<age 5, ages 5–12, and ages 13–18). Another commenter's clinical observations that younger children typically require more staff time than older teenagers or adults, led to a recommendation that we use age groups that match the age groups contained in the codes used for MCPs in Medicare's physician fee schedule (<2, ages 2–11, and ages 12–19).

Response: The two age groups that we used in connection with the proposed pediatric payment adjustments (<13, ages 13–17) reflected the measurable difference in the utilization of separately billable services among ESRD patients due to the onset of adolescence. We found that subdividing these age categories further did not yield statistically significantly more homogeneous groups with respect to separately billable services. As the two age groups presented in the proposed rule were empirically determined, we see no reason to revise them based on the wide range of opinions shown in the comments received. Further, the comments about the nursing intensity of different age groups pertain to composite rate services. For composite rate services, only one age range applies (under 18). Accordingly, in creating pediatric payment adjusters for both composite rate and separately billable services for this final rule, we have adopted the two proposed age groups (<13, ages 13–17) to classify pediatric patients.

Comment: Several commenters acknowledged the difficulty of developing pediatric payment adjustments because of the relatively small number of Medicare ESRD pediatric patients. The commenters stated that because both Congress and CMS have recognized the higher costs of treating children by exempting children's hospitals from the Medicare inpatient PPS, it would be appropriate to exclude pediatric facilities (and by extension, treatments for pediatric patients not treated in pediatric facilities) from the ESRD PPS.

Response: Although we may develop in the future pediatric payment adjusters based on co-morbidities that are prevalent among pediatric dialysis patients after additional research and analysis, we believe the changes we have made with regard to the final pediatric payment adjustments will provide sufficient payment to ESRD facilities that treat pediatric ESRD patients and that excluding pediatric patients from the bundled ESRD PPS would not be appropriate. We have adopted two payment variables from the proposed methodology used to develop the pediatric payment adjusters, that is, age and modality (74 FR 49987). Although, in response to comments, we are no longer adopting co-morbidities with regard to the pediatric payment adjustments, we are using actual payments to ESRD facilities for composite rate services in CY 2007 for treating pediatric dialysis patients to determine payment for pediatric ESRD patients under the ESRD PPS. We believe that modifying the methodology used to develop the proposed pediatric payment adjusters is responsive to commenters' concerns that the proposed composite rate portion of the pediatric payment adjusters predominantly reflected the cost of treating adult patients and understated the composite rate costs of treating pediatric dialysis patients.

Comment: Several commenters opposed the use of modality as a payment variable in the pediatric payment adjustments. The commenters stated that according to the American Society of Pediatric Nephrologists, between 40 and 50 percent of pediatric dialysis patients receive CCPD. They indicated that PD for pediatric ESRD patients is often preferred because it avoids the difficulty of obtaining vascular access in small children, allows fewer dietary restrictions, and permits the ability to attend school regularly because dialysis is provided at home. The commenters maintained that adjusting payment by modality for pediatric patients may undervalue payment for PD and provide a disincentive to provide PD for pediatric patients.

Response: In our proposed rule, we stated that the main problem with a separately billable payment model that does not recognize modality for

pediatric patients is that it results in an underpayment for HD and an overpayment for PD (74 FR 49985). In developing pediatric payment adjustments, analyses that did not differentiate by modality revealed that the average prediction errors (that is, the degree to which the predicted values differed from the actual values) were positive for PD and negative for HD. Moreover, the prediction errors in both directions were large relative to the average predicted values.

By contrast, the prediction errors in alternative analyses that distinguished payment by modality were much smaller and did not consistently favor PD over HD. Payment by modality reduced the difference between the actual and predicted payments. Therefore, use of modality as a payment variable reduced the incentive to steer patients to a particular modality based purely on the payment implications. It also substantially improved the predictive power of the payment models.

We noted that payment by modality in the proposed pediatric payment adjustments was inconsistent with the way modality is treated in the adult payment adjustments, which do not include a modality adjustment (74 FR 49985). We also said that payment by modality was not consistent with the goal of encouraging home dialysis. However, given the already relatively high utilization of PD in the pediatric ESRD population, a point substantiated by the commenters, we pointed out that it may not be necessary to further encourage home therapies for this population.

PD has many advantages for pediatric patients able to utilize that dialysis modality. We do not believe that its prevalence will be diminished by the inclusion of modality as a pediatric payment classification variable. Because the use of modality as a classification variable results in enhanced predictive power, reducing the likelihood of underpaying for pediatric HD patients and overpaying for PD patients, we have retained modality as a payment variable for the pediatric payment adjustments described in this final rule.

Comment: One commenter suggested that CMS undertake a separate rulemaking process to develop a payment model for pediatric patients. The commenter noted the substantially different circumstances in connection with furnishing dialysis to children, and recommended that hospital cost report data and co-morbidity data from claims be used to develop case-mix adjustments that are better reflective of the costs and complexity of treating pediatric dialysis patients.

Response: The Medicare hospital cost reports do not contain patient-specific cost information. Because there are so few pediatric dialysis patients, hospital cost reports, similar to those from independent facilities, largely reflect the total costs of treating adult patients. The co-morbidities in the proposed rule were derived from measures originally developed using claims from the adult population. However, their inclusion in the proposed pediatric payment adjustments was based on analyses that showed their relationship to cost in the pediatric population. Less than 2 percent of dialysis facility claims reflect a co-morbid condition. Therefore, the use of claims data as the commenter suggests based on this current degree of reporting would not be very helpful in developing alternative case-mix adjusters.

Unless ESRD facilities begin to include co-morbid medical conditions on their claims, a separate data collection effort may be necessary to obtain co-morbidities specific to the pediatric dialysis population. Once we have completed the research necessary to determine if co-morbidities prevalent among pediatric dialysis patients can be used to refine the pediatric payment adjusters adopted in this final rule, any proposed revisions would be implemented through rulemaking.

Comment: One commenter noted that training for home dialysis should not be included in a bundled payment system for pediatric patients. The commenter explained that the level and duration of training required varies according to the ability and age of the child and his or her caretaker. Because children rely on adult caretakers, a change in a child's familial or living situation would necessitate one or more periods of retraining. Therefore, training should be reimbursed separately from a bundled ESRD PPS for pediatric patients.

Response: We have developed a separate add-on amount for training that will apply for both adult and pediatric dialysis patients. Although the CY 2007 base rate applicable to both adult and pediatric patients includes payments for training treatments, we point out that training treatments for both adult and pediatric dialysis patients under the ESRD PPS will be increased $33.44, subsequently adjusted for area wage levels using the dialysis facility's applicable wage index, to reflect the additional costs of training. For an explanation of how this adjustment was developed, see section II.A.7. of this final rule.

Comment: One commenter stated that the pediatric case-mix adjusters failed to recognize the unique nature of pediatric facilities by failing to account for higher staffing ratios imposed by state regulatory mandates, additional ancillary and nursing personnel required to treat pediatric ESRD patients, and higher supply costs of these patients.

Response: We agree with the commenter's concerns. As noted previously, the routine operating costs associated with treating pediatric ESRD patients included in the composite rate cost component of the pediatric payment adjustments may be understated because they largely reflect the overhead and operating costs of facilities treating predominantly adult patients. Therefore, in this final rule, we are modifying our methodology for determining the pediatric payment adjustments.

As described later in this section, we have incorporated in the pediatric payment adjusters a 10.5 percent increase (an adjustment of 1.105) to reflect the degree to which total actual CY 2007 payments for composite rate and separately billable services for pediatric ESRD patients exceed the comparable figure for adult patients. In CY 2007, Part B composite rate payments per treatment for pediatric dialysis patients were approximately 38.6 percent higher than those for adult patients ($216.46 versus $156.12), while separately billable payments per treatment were approximately 42.2 percent lower ($48.09 versus $83.27) (see Table 26). The total difference was 10.5 percent ($216.46 + $48.09 = $264.55; $156.12 + $83.27 + $239.39; $264.55/$239.39 = 1.105).

By incorporating this difference in the formula used to develop the pediatric payment adjusters set forth in this final rule, as described in paragraph E below, we believe that we are appropriately reflecting the higher costs for composite rate services furnished to pediatric ESRD patients in the payment adjusters, in response to commenters' concerns that the proposed pediatric payment adjusters would underpay for pediatric patients.

Table 26
Comparison of Pediatric to Adult Payments for Services in an Expanded ESRD PPS, 2007

Service	All ages		Age < 18		Age 18 and older	
	Average per treatment	Total	Average per treatment	Total	Average per treatment	Total
Dialysis patients	--	328,787	--	872	--	328,004
Hemodialysis-equivalent dialysis treatments	--	36,747,662	--	75,478	--	36,672,184
Medicare Allowable Payments for services in the expanded ESRD PPS						
Total for Part B and Part D services	$239.88	$8,809,732,068.05	$267.66	$20,140,444.32	$239.82	$8,789,591,623.73
Total for Part B services	$239.44	$8,799,031,984.47	$264.55	$19,967,531.39	$239.39	$8,779,064,453.08
Composite rate and other dialysis Services	$156.25	$5,741,729,454.44	$216.46	$16,338,032.59	$156.12	$5,725,391,421.85
Composite rate services	$155.65	$5,719,657,831.39	$199.30	$15,043,119.60	$155.56	$5,704,614,711.79
Durable medical equipment and supplies	$0.49	$18,060,482.59	$16.00	$1,207,494.83	$0.46	$16,852,987.76
Dialysis support services	$0.04	$1,447,484.43	$1.08	$81,360.99	$0.04	$1,366,123.44
Ultrafiltration	$0.07	$2,563,656.04	$0.08	$6,057.18	$0.07	$2,557,598.86
Separately billable services (Part B)	$83.20	$3,057,302,530.04	$48.09	$3,629,498.81	$83.27	$3,053,673,031.23
Epogen	$51.08	$1,876,926,573.16	$26.84	$2,026,111.30	$51.13	$1,874,900,461.86
Darbepoetin	$4.57	$167,935,969.83	$1.97	$148,917.20	$4.58	$167,787,052.63
Calcitriol	$0.09	$3,125,612.59	$0.32	$24,190.94	$0.08	$3,101,421.65
Doxercalciferol	$2.09	$76,901,723.05	$0.46	$34,763.13	$2.10	$76,866,959.93
Paricalcitol	$8.79	$322,849,347.85	$5.24	$395,284.33	$8.79	$322,454,063.53
Iron sucrose	$4.52	$166,219,338.55	$1.29	$97,013.96	$4.53	$166,122,324.59
Sodium ferric gluconate	$1.85	$68,086,706.74	$1.00	$75,540.41	$1.85	$68,011,166.33
Levocarnitine	$0.14	$5,026,445.93	$0.18	$13,644.56	$0.14	$5,012,801.36
Alteplase	$0.73	$26,697,321.33	$1.76	$132,629.09	$0.72	$26,564,692.24
Vancomycin	$0.10	$3,583,503.88	$0.16	$11,964.88	$0.10	$3,571,539.00
Daptomycin	$0.03	$1,234,404.70	$0.00	$0.00	$0.03	$1,234,404.70
Other injectables	$0.13	$4,943,934.31	$0.47	$35,594.00	$0.13	$4,908,340.31
Laboratory tests	$8.04	$295,508,409.06	$7.84	$591,436.98	$8.04	$294,916,972.08
Dialysis facility supplies and IV fluids	$1.04	$38,263,239.08	$0.56	$42,408.04	$1.04	$38,220,831.04
Hemodialysis-equivalent dialysis treatments for patients with Part D spending	--	24,737,326	--	55,548	--	24,681,778
Total for Part D services	$0.43	$10,700,083.58	$3.11	$172,912.93	$0.43	$10,527,170.65
Calcitriol (oral)	$0.11	$2,678,711.44	$1.73	$95,936.79	$0.10	$2,582,774.65
Doxercalciferol (oral)	$0.20	$4,965,189.06	$0.56	$31,139.51	$0.20	$4,934,049.55
Paricalcitol (oral)	$0.12	$3,008,544.32	$0.76	$42,381.46	$0.12	$2,966,162.86
Levocarnitine (oral)	$0.00	$47,638.76	$0.06	$3,455.17	$0.00	$44,183.59

1. The Revised Methodology for the Pediatric Payment Adjustments

Section 1881(b)(14)(A)(i) of the Act requires that a single payment apply to "renal dialysis services", including home dialysis, beginning January 1, 2011. These services include composite rate and certain separately billable services. In response to commenters' concerns that the proposed pediatric co-morbidities used to develop the proposed pediatric payment adjusters were not prevalent among pediatric dialysis patients, and that the composite rate costs used to derive the proposed adjusters largely represented the costs of treating adult patients, thereby understating the costs of treating pediatric dialysis patients, we have revised the methodology for calculating the pediatric payment adjusters to reflect the actual average Part B Medicare payment per treatment for pediatric patients in CY 2007. In the following section, we describe the changes.

2. Composite Rate Payments for Pediatric Patients

As part of the basic case-mix adjustment for composite rate services, dialysis treatments furnished to pediatric patients are currently reimbursed at a rate equal to 1.62 percent of the facility's composite payment rate (that is, we use an adjustment factor of 1.62 to the composite rate as the payment for pediatric patients). This composite rate payment adjustment for pediatric patients was established relative to the lowest cost adult age category (age 60–69). The other basic case-mix adjustments for body surface area and body mass index are not applied to claims for pediatric ESRD patients.

In the proposed rule, we described the proposed pediatric payment model which used the two-equation methodology to develop the case-mix adjusters applicable to pediatric patients (74 FR 49982 through 49987). The payment adjustment applicable to composite rate services for pediatric patients was obtained from the facility-level model of composite rate costs for patients less than 18, yielding a regression-based multiplier of 1.199. In response to commenters' concerns that the magnitude of the composite rate portion of the proposed payment multipliers or adjusters for pediatric dialysis patients may be understated, we have revised the methodology for calculating the pediatric composite rate payment amount.

Instead of using the regression-based composite rate multiplier of 1.199, we have incorporated in the pediatric payment adjusters the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate services in CY 2007 based on the 872 pediatric dialysis patients reflected in the data. We selected CY 2007 consistent with our determination that 2007 represented the year with the lowest per patient utilization of dialysis services in accordance with section 1881(b)(14)(A)(ii) of the Act, using the methodology previously described in this final rule. Table 26 reveals that the

average CY 2007 MAP for composite rate services for pediatric dialysis patients was $216.46, compared to $156.12 for adult patients. This difference in composite rate payment is reflected in the overall adjustment for pediatric patients calculated below.

3. Separately Billable Services

Based on comments received that our proposed pediatric co-morbidities were not appropriate because they were not prevalent among pediatric dialysis patients, we modified the payment adjusters for separately billable services for pediatric patients to exclude the co-morbidities we proposed. We developed adjustments using the variables of age (<13, 13–17) and modality (PD or HD). As with the methodology described in the proposed rule (74 FR 49984), all of the analyses were performed using log-linear regression models of the average separately billable MAP per treatment for each of three years (CYs 2006, 2007, and 2008). The data were pooled over the 3-year period, resulting in up to three yearly observations for each pediatric patient.

As with the payment multipliers that were developed in connection with the proposed rule, the payment multipliers developed in connection with this final rule using only two variables, age and modality, often required a statistical "smearing" adjustment to improve the accuracy of the payment adjusters upon transformation of the regression model results from the log dollar scale to the dollar scale (that is, to limit retransformation bias).

Under statistical "smearing", a correction factor is applied to the predictions from a model that is estimated on the logarithmic scale (for example, the log of the average MAP per treatment). In the context of examining healthcare cost or payment data that do not follow the normal distribution curve (that is, are not normally distributed), retransformation bias may occur when converting predicted values that are made on the log scale (that is, log dollars) back to the original scale (that is, dollars), yielding biased estimates of the mean cost in dollars. In order to develop valid payment adjusters that reflect the relationships between patient characteristics and the MAPs (that is, in dollars), it is essential that retransformation bias be limited as much as possible. Because the difference between residuals (that is, the difference between the measured MAP and predicted MAP for each observation) did not vary in the desired random pattern, indicating correlation between the variance of the residuals and some of the patient characteristics based on age and modality (statistically known as "heteroscedasticity"), separate smearing adjustments were applied by patient subgroup. The smearing adjustments were based on the average retransformed residual for each patient category. For further information on the use of statistical smearing, retransformation, and heteroscedasticity, *see* Duan, N., *Smearing estimate: a nonparametric retransformation method,* Journal of the American Statistical Association, 78, 1983, pp. 605–610, and Manning, W.G., *The logged dependent variable, heteroscedasticity, and the retransformation problem,* Journal of Health Economics, 17, 1998, pp. 283–295. To develop the pediatric payment multipliers or adjustments for the four pediatric classification groups adopted for this final rule, we similarly performed statistical smearing adjustments to minimize retransformation bias.

4. No Caps Applied to the Separately Billable MAP per Treatment

In the proposed rule, we explained that we capped the separately billable MAP per treatment for pediatric dialysis patients at $289.00 based on the standard outer fence method for identifying statistically aberrant values (*see* 74 FR 49984). The outer fence was defined as the 75th percentile of the separately billable MAP per treatment, plus three times the interquartile range, which is the 75th percentile minus the 25th percentile.

However, we found that capping the separately billable MAP had little effect on the magnitude of the payment multipliers, suggesting that the predicted payments are not biased through the inclusion of valid or invalid values. Accordingly, we have not applied caps to the computation of the separately billable MAPs for pediatric patients in developing the pediatric payment adjusters presented in this final rule, with the exception of EPO and ARANESP®. Payments for these ESAs were capped at the same medically unbelievable thresholds used in connection with the development of adjustments applied to adult patients.

The final pediatric payment adjustments for separately billable services use two age categories (<13, age 13–17) and dialysis modality (PD or HD), as the bases for classifying pediatric patients, consistent with what we proposed and after consideration of public comments. In addition, as we discussed above, in response to public comments, the final pediatric payment adjustments do not use co-morbidity categories based on the number of specified co-morbidities as one of the variables used to classify pediatric dialysis patients. Accordingly, we are finalizing four pediatric classification groups or cells, not eight as originally proposed (74 FR 49987). Using data for CYs 2006–2008, we present the pediatric payment adjuster or multiplier results in Table 27 below.

Table 27

Calculating Combined Payment Multipliers for Pediatric Patients Based on Adjustments for Age and Modality

Cell	Patient characteristics		Separately billable (SB) payment multiplier[1]	Expanded bundle payment multiplier
	Age	Modality		
1	<13	PD	0.319	1.033
2	<13	Hemo	1.185	1.219
3	13-17	PD	0.476	1.067
4	13-17	Hemo	1.459	1.277

[1]Based on a pediatric patient month level regression model of SB MAP/session for 2006-08 (n=17,142 pediatric patient months) that included age (<13 vs. 13-17) and modality (PD vs. HD). An R-squared value calculated at the patient year level was 34.8%. This calculation was based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed SB MAP per treatment for the patient year. In estimating this R-squared value, a log transformation was applied to both the average predicted and average observed SB values. The R-squared value for the patient month regression model was 32.8%. Subgroup-specific smearing adjustments were applied to the estimated multipliers from the model. The SB payment multipliers presented above were calculated relative to the average SB multiplier among pediatric patients, weighted by treatments, such that the average pediatric SB payment multiplier is 1.000.

For purposes of the payment adjustments, the relevant column is labeled "Separately billable (SB) multiplier". These values reflect the relative costliness of separately billable services for each of the four pediatric patient groups. The SB multipliers were calculated relative to the average SB multiplier among pediatric patients, weighted by treatments, such that the average SB payment multiplier is 1.000.

5. A Combined Composite Rate and Separately Billable Payment Model for Pediatric Patients

Calculation of an overall pediatric adjustment factor reflects the higher payments for composite rate services under the current system, and allows the pediatric payment adjusters for separately billable services to be applied to the total base rate amount. As noted above, the composite rate MAP for pediatric patients is higher than that for adult patients ($216.46 versus $156.12). However, the separately billable MAP is lower for pediatric patients ($48.09 versus $83.27), largely because of the predominance of PD among pediatric patients, in which the utilization of separately billable services is lower, and the smaller body size of younger pediatric patients. The overall difference in the CY 2007 MAP between adult and pediatric dialysis patients is 10.5 percent ($216.46 + $48.09 = $264.55. $156.12 + $83.27 = $239.39. $264.55/$239.39 = 1.105). The use of the 1.105 adjustment to develop the final pediatric adjustment factors set forth in this final rule reflects the higher payment for composite rate services and lower utilization of separately billable services among pediatric dialysis patients.

The pediatric payment adjustments shown in Table B in the Appendix for each of the four classification categories would normally be applied to the separately billable portion of the MAP for pediatric patients. However, for the reasons discussed above, for simplicity of application, we can convert the separately billable pediatric multipliers shown in Table B in the Appendix to values that can be applied to the total base rate amount, reflecting both the composite rate and separately billable components. This can be accomplished as follows:

Let P represent the ratio of the total CR and SB MAP per treatment for pediatric patients relative to adult patients (calculated above to be 1.105), W_{CR} and W_{SB} the proportion of MAP for CR and SB services, respectively, among pediatric patients, C the average case-mix multiplier for adult patients, and $Mult_{SB}$ the SB payment multiplier shown in Table 27. The expanded bundle payment multiplier for CR and SB services for each of the four pediatric classification cells can be calculated as:

$$Mult_{SB} = P * C * (W_{CR} + W_{SB} * Mult_{SB})$$

Based on the average MAP per treatment for CR and SB services of $264.55 for pediatric patients, and $239.39 for adult patients shown in Table 26, P is calculated as:

$$P = \$264.55/\$239.39 = 1.105$$

It should be noted that this method of computing P, which reflects the relative payments for pediatric patients compared to adult patients, is based on CR and SB services covered under Part B only, and does not include payments for oral equivalent drugs under Part D. To be consistent with the two-equation model that is used to determine the payment adjustments for adult patients under the ESRD PPS, the approach that is used to determine the pediatric payment adjustments also reflects comparisons involving Part B services only. This is also consistent with our

proposed pediatric payment methodology (see 74 FR 49986 through 49987).

The CR and SB weights for pediatric patients are calculated as the ratio of the MAP per treatment for CR and SB services relative to the sum of the CR and SB MAP per treatment in 2007, where

W_{CR} = \$216.46/\$264.55 = 0.8182
and W_{SB} = \$48.09/\$264.55 = 0.1818

The average case-mix multiplier for adult patients (C = 1.067) is applied to offset the standardization for case-mix adjustments (that is, BSA, low BMI, onset of renal dialysis, and co-morbidities) which are not used for pediatric patients. If this standardization factor of 1.067 were not used to increase the otherwise applicable pediatric payment adjustments or multipliers, those multipliers would be inappropriately understated by 6.7 percent. (For a discussion of how the difference in the case-mix adjustment variables which apply to adult and pediatric dialysis patients result in different standardization factors for adult and pediatric patients in developing the outlier payment thresholds, see section II.H.1.ii. of this final rule.) For example, the expanded payment multiplier for pediatric classification group 1 (cell 1) is calculated as:

$Mult_{EB}$ = 1.105 * 1.067 * (0.8182 + 0.1818 * 0.319) = 1.033

This formula yields the four pediatric payment multipliers shown in Table B in the Appendix that are applied to the overall adjusted base rate amount of \$229.63 per treatment, depending upon each pediatric patient's classification cell.

6. Adult Payment Adjustments That Do Not Apply to Pediatric Patients

As explained above, the payment adjustments developed for pediatric dialysis patients do not reflect co-morbidities, which are included as payment adjustments for adult patients. Similarly, the payment adjustments based on BSA, low BMI, and onset of dialysis were developed for adults based on characteristics of adult patients and their relationship with measured costs for services in the ESRD PPS, and, therefore, do not apply to pediatric patients. Pediatric dialysis patients under the ESRD PPS which we are finalizing in this rule will not be eligible for case-mix adjustments based on BSA, low BMI, and the onset of dialysis. In addition, the low-volume adjustment described in section II.F.3. of this final rule will not apply to pediatric patients.

We point out that the payment adjusters for pediatric patients reflect a 10.5 percent increase to account for the overall difference in average payments per treatment for pediatric patients compared to adult patients. While the difference overall is 10.5 percent, payments for composite rate and other dialysis services for pediatric patients exceeded those for adult patients by 38.6 percent (\$216.46 versus \$156.12; see Table 26). The average composite rate payments for pediatric patients under the current basic case-mix adjusted composite payment system include the 62 percent increase otherwise applied to pediatric patients, plus any exception payments dialysis facilities may have received under § 413.184–§ 413.186 of the Medicare regulations. (It should be noted that the pediatric payment adjustment under the basic case-mix adjusted payment system increased pediatric payments by 62 percent relative to the lowest cost adult age group, ages 60–69, and not relative to the average adult patient overall. Further, pediatric patients were not eligible for other adjustments under the basic case-mix adjusted composite payment system. As a result, the average pediatric payment under this system will be less than 62 percent higher than the average payment for adults.) Both the pediatric basic case-mix adjustment and these facility exception payments were developed to account for the higher costs of facilities that treat pediatric patients.

To the extent the additional payments currently provided for pediatric patients under the basic case-mix composite payment system are likely to reflect higher costs for smaller dialysis facilities otherwise qualifying for the low-volume adjustment under the ESRD PPS, application of the low-volume adjustment for pediatric patients would be duplicative. Therefore, the low-volume payment adjuster of 1.189 that we are finalizing will only be applicable to adult patients, and will not be used in calculating the payment rate per treatment for pediatric dialysis patients. Facilities qualifying for the low-volume adjustment which treat both adult and pediatric patients, may only receive the low-volume adjustment for adult dialysis patients. We point out that the training add-on amount of \$33.44 per treatment, subsequently adjusted by the area wage index, is applicable to both adult and pediatric patients.

For comprehensive examples showing the application of the pediatric payment adjusters shown in Table B in the Appendix in connection with computing the payment amounts per treatment for pediatric dialysis patients, *see* section II.I. of this final rule.

Based on the comments received and the responses provided above, we are revising § 413.235(b) to reflect the revised pediatric ESRD patient adjustments of age and modality. In addition, as payment under § 413.235(b) is limited to claims for patients under 18 years of age, we are revising § 413.171 to define a pediatric ESRD patient as an individual less than 18 years of age who is receiving renal dialysis services.

H. 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 variations in the amount of ESAs necessary for anemia management. In the proposed rule, we discussed our rationale for outlier payments to facilities under the ESRD PPS (74 FR 49987) and proposed that the ESRD outlier policy parallel the outlier policies adopted under other Medicare PPSs.

We proposed an outlier policy of 1.0 percent of total ESRD expenditures (74 FR 49993). We stated that we believed an outlier percentage of 1.0 percent strikes an appropriate balance between our objective of paying an adequate amount for the most costly resource intensive patients, while providing an appropriate level of payments for those patients who do not qualify for outlier payments. An ESRD facility would be eligible for an outlier payment when its imputed MAP amount per treatment for the outlier services exceeded the outlier threshold, or the facility's predicted MAP amount per treatment for the outlier services plus the fixed dollar loss amount. Finally, we proposed that the outlier payment would be equal to 80 percent of the amount by which the facility's imputed costs exceeds the outlier threshold.

1. Eligibility for Outlier Payment

We proposed that an ESRD facility would be eligible for an additional payment under the ESRD PPS where the facility's imputed, average per treatment costs for ESRD outlier services furnished to a beneficiary exceeded the predicted per treatment MAP amount for outlier services plus the fixed dollar loss amount, as indicated at § 413.237(b) (74 FR 49993 and 50024). We proposed to base eligibility for outlier payments on what we consider ESRD outlier services, that is, only those items and services that are separately billable under Medicare Part B under the current

basic case-mix adjusted composite payment system, and renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D, rather than all items and services comprising the bundled payment under the proposed ESRD PPS (74 FR 49988).

The comments we received in connection with our proposed outlier payment policy and our responses are set forth below.

Comment: Instead of our proposed approach under which outlier payments would be linked to high utilization of specified outlier services, several commenters suggested that we base eligibility for outlier payment on specific conditions or characteristics including patients undergoing home training or self-care training, patients with gastrointestinal bleeding, infections, including vancomycin resistant infections, chronic fluid overload, obesity, or pregnant patients. These commenters suggested that fixed outlier payment amounts could be made on behalf of the patient each month in which the patient condition or characteristic is present.

Response: We disagree with the commenters' suggested alternative approach to establishing outlier eligibility and for making outlier payments. It does not necessarily follow that dialysis patients with specific conditions or characteristics will utilize resources to the extent that they would always qualify for outlier payments. Conversely, it is very likely that patients without the conditions suggested by the commenters could qualify for outlier payments because of the presence of other co-morbidities, the need for particularly expensive ESRD-related drugs and biologicals, more frequent laboratory testing, or other factors. Neither do we believe that paying a fixed outlier payment amount each month in which a specified co-morbid condition or other suggested patient condition is present is an appropriate method for paying for outlier services, as it does not reflect a patient's actual utilization of resources.

The ESRD PPS described in this final rule provides for case-mix payment adjustments which recognize specified co-morbidities which result in higher treatment costs. The ESRD PPS also includes payment variables that reflect differences in patient size and weight through the BSA and low BMI adjustments. All of these payment adjustments result in the application of a targeted or predicted payment rate per treatment for dialysis services reflecting a patient's particular case-mix. In addition, we have also provided an add-on to a patient's otherwise applicable payment rate per treatment for home dialysis training. Notwithstanding a patient's specific case-mix adjustments, where the utilization of resources exceeds the predicted payment amount per treatment beyond a specified threshold, we believe it is appropriate to make outlier payments. Therefore, we are retaining our proposed outlier policy that is based on higher than predicted utilization of outlier services.

Comment: One commenter indicated that certain conditions, such as sepsis, are associated with higher treatment costs. The commenter specified that post-hospitalization antibiotics that are often administered by the ESRD facility and the debility of septic patients contribute to the added cost, and should be considered for outlier payments.

Response: Antibiotics used for the treatment of non-ESRD-related infections are not included in the ESRD PPS bundle. To the extent these injectable drugs are furnished in an ESRD facility, they would continue to be separately payable. The cost of services that are outside of the ESRD PPS payment bundle, and which remain separately billable, are not eligible for outlier payments.

Comment: One commenter stated that the co-morbidities that would trigger outlier payment do not have validity in children.

Response: The presence of a co-morbid condition alone does not trigger outlier payments for either adult or pediatric patients. Rather, it is the provision of additional services that are defined as outlier services that contributes towards outlier eligibility.

Comment: One commenter asserted that the proposed outlier policy would be inadequate to cover the costs associated with home hemodialysis. The commenter believed that the outlier policy would only cover some of the additional expenses incurred as a result of home dialysis patients and providers with a disproportionate number of nursing home hemodialysis patients.

Response: The outlier payment policy is intended to compensate ESRD facilities for treating patients whose consumption of separately billable ESRD-related services results in unusually high costs per treatment beyond a specified threshold which exceeds the predicted cost per treatment. The predicted cost per treatment is determined by multiplying the adjusted base rate by all of the pertinent patient and facility specific payment adjusters that apply.

The payment adjusters do not distinguish between HD furnished in a facility and home HD. Because home HD is provided to only a very small segment of HD patients, the ESRD PPS overwhelmingly reflects the costs of treatment for in-facility patients. Because the availability of compact portable HD machines for home use is a relatively recent phenomenon, we do not yet have sufficient historical data to determine the impact of the predicted payment rates and application of the proposed outlier payment policy on home hemodialysis patients. Therefore, we are unable to determine if the commenter is correct. We point out, however, that our methodology for calculating the amount of outlier payments used the same computation of the separately billable MAP per treatment, regardless of where hemodialysis was performed, and was not biased in favor of any site of service.

a. ESRD Outlier Services

We proposed at § 413.237(a), to base eligibility for outlier payments under the ESRD PPS on a comparison of the predicted MAP amounts and imputed MAP amounts for (1) items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and other ESRD-related services; and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D (74 FR 50024). We referred to those services as the "ESRD outlier services."

In the proposed rule, we also stated that we were considering the extent to which the 50 percent rule pertinent to the Automated Multi-Channel Chemistry (AMCC) separately billable laboratory tests under the basic case-mix adjusted composite payment system should continue to apply under the ESRD PPS (74 FR 49988). Section 1881(b)(14) prohibits the unbundling of services, including laboratory services. In the proposed rule, we indicated that because Medicare would not make a separate payment for ESRD-related laboratory tests under the ESRD PPS, the 50 percent rule would be rendered irrelevant for payment purposes. We indicated that the 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payments.

We requested public comments on whether or not to include the AMCC tests to which the 50 percent rule applies within the definition of outlier services, and retain the 50 percent rule under the proposed ESRD PPS (74 FR 49988). We also invited comment on our proposal to limit the ESRD outlier services to items and services that were separately billable under Part B, and

those renal dialysis service drugs formerly covered under Part D (74 FR 49988).

The comments we received with respect to the proposed definition of ESRD outlier services and our responses are set forth below.

Comment: Several commenters recommended that laboratory tests should be removed from the definition of outlier services, claiming that such testing does not widely vary based on time on dialysis or type of patient. The commenters maintained that the exclusion of laboratory tests from the definition of outlier services would have a minimal impact on the distribution of outlier payments.

Response: Table 26 reveals that in CY 2007, laboratory tests for Medicare ESRD beneficiaries averaged 3.4 percent or $8.04 of the total MAP amount per treatment of $239.88 for patients of all ages. While this amount is relatively small, we point out that the need for laboratory testing can vary widely depending on changes in a patient's condition. For example, the inpatient hospitalization of an ESRD beneficiary, particularly if the patient does not receive his usual dose of dialysis while hospitalized, can result in severe deviations of dialysis clinical indicators from baseline values upon discharge. This often requires additional laboratory testing and above average doses of ESRD-related drugs and biologicals to return them to normal levels. Such a patient could be costly for the dialysis facility in terms of the additional laboratory testing required.

The additional laboratory tests, coupled with higher utilization of ESRD-related drugs and biologicals, could make the patient eligible for outlier payments. Accordingly, we do not believe that it would be appropriate to exclude ESRD-related laboratory testing services from the separately billable services which comprise the definition of ESRD outlier services.

Comment: Several commenters supported a narrow definition of outlier services limited to intravenous drugs. The commenters believed that utilization of these drugs is the primary driver of variation in patient costs.

Response: While high utilization of injectable drugs, such as ESAs, may largely determine the need for outlier payments for many patients, these drugs and biologicals are not the only reason an ESRD facility incurs unusually high costs in treating patients. A greater need for ESRD-related laboratory testing subsequent to a hospitalization or for other reasons can also contribute to high separately billable expenditures. Oral drugs can also be an important factor. Because it is a patient's total utilization of separately billable items and services that is relevant in determining eligibility for outlier payments, we have not limited these payments to a particular category in this final rule.

Comment: One commenter asserted that to the extent we specify the ESRD-related laboratory tests that would be included in the payment bundle, it would not be necessary to identify these tests on the claim for purposes of the outlier payment computation.

Response: The commenter is incorrect. Laboratory tests included in the ESRD PPS payment bundle represent laboratory tests that were included in the composite rate of the basic case-mix adjusted composite payment system, and tests that prior to January 1, 2011, were separately billable under Part B. To establish whether a laboratory test qualifies as an eligible outlier service, it is necessary to determine whether the test had been (or would have been for new ESRD-related laboratory tests) separately billable under Part B prior to January 1, 2011.

Despite the list of laboratory tests considered ESRD-related included in Table F of the Appendix to this final rule, all laboratory tests furnished an ESRD beneficiary must be specified on the facility claim in order that we can determine which meet the definition of a separately billable service and determine any potential outlier payments. We recognize that some laboratory tests that would otherwise be considered ESRD-related may be ordered for ESRD beneficiaries for purposes other than ESRD. These tests will be excluded from the ESRD PPS payment bundle, will remain separately billable, and would not be considered an eligible outlier service.

Comment: One commenter suggested that given the high cost of blood transfusions and their unpredictable rate of utilization, blood transfusion procedures should be classified as outlier services.

Response: As explained elsewhere in this final rule, blood and blood products have been excluded from the ESRD PPS payment bundle and remain separately billable. Items and services excluded from the payment bundle are not considered outlier services.

Comment: Several commenters favored broadening the definition of outlier services, while others suggested narrowing the definition, claiming that a smaller list of services would simplify the administrative burden associated with billing. One commenter in favor of a broader definition of outlier services maintained that all renal dialysis services should be considered within the definition of outlier services, not only items and services that were previously separately billable. The commenter stated that the separately billable designation, a feature of the basic case-mix adjusted composite payment system, is obsolete under the ESRD PPS because all items and services within the payment bundle, including composite rate services, are classified as renal dialysis services.

Response: Cost information regarding ESRD-related services considered to be composite rate services are not available on a patient-specific basis, only at the ESRD facility level, based on average costs collected from the Medicare cost reports. Neither do the Medicare claims identify specific composite rate items and services for ESRD patients. Therefore, if all renal dialysis services included in the ESRD PPS payment bundle were considered under the definition of outlier services, variation in the patient-specific utilization of resources would reflect only differences in non-composite rate services (that is, separately billable drugs and biologicals, laboratory tests, and medical supplies). This would occur because in the cost report, facilities identify the average of all composite rate costs across all patients treated at the ESRD facility.

We stated in the proposed rule that if we were to include all ESRD-related items and services in our definition of outlier services, including composite rate services, we would need to collect patient-level data on composite rate items and services utilized, and modify the ESRD facility claim form (74 FR 49989). Such an undertaking is not possible prior to the January 1, 2011 implementation of the ESRD PPS. Accordingly, we have developed our outlier payment policy based on the utilization of separately billable items and services.

The commenter who pointed out that the distinction between composite rate and separately billable services will become irrelevant under the ESRD PPS, in which bundled services are classified as Part B renal dialysis services, is correct. However, we find that it is necessary to maintain the distinction at this time in order to identify ESRD-related items and services eligible for outlier payments. Based on the commenter's suggestion, however, we have revised the definition of "separately billable items and services" as defined in § 413.171 to clarify that outlier services include items and services that were, or would have been, prior to January 1, 2011, separately payable.

With respect to the commenter's suggestion that a smaller list of outlier services would simplify the administrative burden associated with billing, we point out that ESRD facilities currently are required to report all separately billable items and services furnished each ESRD beneficiary. We did not propose revisions to the ESRD facility claim form. Therefore, for purposes of determining eligibility for outlier payments, separately billable items and services would continue to be reported on ESRD facility claims.

Comment: Several commenters stated that removing laboratory tests from the definition of outlier services would render the 50 percent rule unnecessary and relieve some of the reporting burden. Another commenter maintained that the 50 percent rule is based on a panel of AMCC tests included in the composite rate in 1983 and no longer reflects current medical standards.

Response: The specification of all ESRD-related laboratory tests as either composite rate or separately billable for the purpose of determining outlier eligibility renders the 50 percent rule moot. However, we cannot, as the commenter suggests, eliminate the 50 percent rule at this time, because it is necessary in order to calculate the basic case-mix adjusted composite rate portion of the blended payment during the three year transition period.

As described in section 40.6 of the Medicare Claims Processing Manual, Publication 100–04, chapter 16—*Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests,* for a particular date of service to a beneficiary, if 50 percent or more of the covered laboratory tests are noncomposite rate tests, Medicare allows separate payment beyond that included in the composite rate. If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests are included within the composite payment and no separate payment in addition to the composite rate is made for any of the separately billable tests. If less than 50 percent of the covered tests are composite rate tests, all AMCC tests submitted for the date of service for that beneficiary are separately payable.

Because we need to retain the 50 percent rule to compute the basic case-mix adjusted portion of the blended payment during the ESRD PPS transition and, we believe that it is appropriate to also retain the 50 percent rule to determine whether AMCC panel tests would be considered composite rate or separately billable for the ESRD PPS portion of the blended payment, we are retaining the 50 percent rule and laboratory tests as outlier services. Individual laboratory tests comprising an AMCC panel in which the majority of the laboratory tests are separately billable, would be considered all separately billable for the purpose of determining outlier eligibility.

In order to consistently apply this policy during the transition period, both ESRD facilities that opt out of the transition period and those that go through the transition, will be required to follow the 50 percent rule until the transition period ends January 1, 2014. With respect to a commenter's concern that the 50 percent rule was based on a panel of AMCC tests that no longer reflects current medical standards, once the transition period ends, we will reevaluate the application of the 50 percent rule and determine its future status in relation to laboratory tests which qualify as outlier services.

Comment: One commenter believed that we should replace the 50 percent rule with a reasonable alternative. Specifically, the commenter recommended that we determine the dollar value of the AMCC tests in the current composite rate. The commenter asserted that for purposes of calculating outlier payments, the imputed value of these tests performed above the composite rate value should be calculated based on the same AMCC panel rates that apply to all clinical laboratories.

Response: We believe the commenter is suggesting an approach in which the dollar value of the composite rate laboratory tests included in an AMCC panel would need to be determined. The laboratory fee schedule value in excess of this amount, regardless of the number of composite rate or separately billable individual laboratory tests comprising the panel, would then be considered eligible for outlier payments. Determining the composite rate "payment" value of all individual composite rate laboratory tests which are part of AMCC panel tests for the purpose of the commenter's suggested calculation would be problematic.

In addition, we do not believe we should create an alternative policy for distinguishing composite rate laboratory tests at this time. Once the transition is over and we no longer need to use the 50 percent rule to compute blended payments under the ESRD PPS, we plan to reconsider continuation of the 50 percent rule in connection with our outlier payment policy. Accordingly, we have not adopted the commenter's suggestion.

Comment: Several commenters asserted that outlier payments on behalf of patients with higher drug costs may not be enough to prevent ESRD facilities from withholding non-calcium phosphate binders and cinacalcet.

Response: As indicated in section II.A.3. of this final rule, we are delaying the implementation of oral-only ESRD-related drugs until January 1, 2014, after the transition period ends. We intend to further assess this concern in a future notice of proposed rulemaking.

Comment: One commenter believed that the additional cost of providing extra treatments and supplies should be accounted for within the outlier payment policy.

Response: As discussed elsewhere in this final rule, with medical justification, payments will continue to be made for additional treatments required beyond the usual three per week under the ESRD PPS. Most medical supplies associated with furnishing dialysis treatments are currently included in the composite rate of the basic case-mix adjusted composite payment system. However, medical/surgical supplies used to administer ESRD-related drugs that prior to January 1, 2011, were separately billable, but are included in the ESRD PPS payment bundle, would be included in the definition of outlier services. These supplies would count towards outlier eligibility and potential outlier payments.

Comment: One commenter requested that CMS provide guidance as to how it intends to deal with the allocation of services that occur at infrequent, but routine and predictable intervals (for example, monthly), and that appear on a claim with a high imputed value on one day in a claim.

Response: The commenter is correct that we described much of the outlier methodology in terms of per treatment amounts consistent with the per treatment unit of payment under the ESRD PPS (74 FR 49993 through 49994). In other words, we have not developed individual outlier adjustments applicable to infrequently furnished costly items and services.

We believe that our methodology is consistent with a bundled payment approach that takes into account the aggregate monthly use of resources. We clarify that in instances in which a facility's imputed costs exceed the proposed outlier threshold plus the fixed dollar loss amount, outlier payments would apply to all treatments the ESRD facility furnished the patient that month, and reported on the monthly claim, regardless of the frequency with which these services were provided.

Comment: One commenter requested clarification as to whether we will make

outlier payments to ESRD facilities that do not line item bill outlier services on the monthly claim.

Response: To calculate outlier eligibility and payments, ESRD facilities must identify which outlier services have been furnished. To the extent that an ESRD facility fails to identify outlier services on the monthly claim, we would have no way of making outlier eligibility determinations or any potential corresponding outlier payments. We view this billing approach as similar to the way in which ESRD facilities currently bill under the basic case-mix adjusted composite payment system. That is, currently ESRD facilities identify by line item date of service all separately billable items and services. Because our definition of ESRD outlier services is based on ESRD-related items and services that were or would have been, prior to January 1, 2011, separately billable, we believe that ESRD facilities are well positioned to identify outlier services on their monthly claims and this reporting should not result in substantial burden.

Comment: Several commenters asserted that our approach for determining outlier payment adjustments is too complex, and will increase administrative costs as facilities will need to submit itemized summaries of formerly separately billable expenses and analyze whether each treatment meets the criteria for outlier payments. Specifically, the commenters pointed out that the timely transfer of information on oral drugs dispensed or purchased from pharmacies will need to occur in order for the ESRD facility to itemize these drugs on the monthly claim. Another commenter stated that the outlier policy could harm small ESRD facilities lacking the resources to properly evaluate and bill for high cost patients.

Response: We believe that ESRD facilities are currently well positioned to continue the reporting of all separately billable items and services used by ESRD patients in order to determine their eligibility as outlier services, and potential for triggering outlier payments. CMS will automate the pricing and calculation of outlier payments to the maximum extent feasible. We agree that ESRD facilities will need to report the purchase and payment for the oral drugs and biologicals (excluding oral-only drugs until 2014) for ESRD beneficiaries as soon as practicable for reporting on the monthly claim. Although we appreciate the commenters' concerns with respect to the need to report all outlier eligible services on the monthly claim, this is necessary in order to calculate any potential outlier payments.

Once claims data can be collected which reflect the utilization of outlier services under the ESRD PPS, we intend to analyze those data to identify which outlier services are associated with the greatest proportion of outlier payments. We intend to weigh those results against the administrative burden of continuing to collect and record each outlier eligible service on the claim. We would propose any alterations to the definition of outlier services in a future notice of proposed rulemaking.

Comment: MedPAC recommended that CMS develop clinical criteria, similar to the ESA Claims Monitoring Policy, for the utilization of drugs and laboratory tests under our outlier payment policy to ensure their appropriate use.

Response: At this point, we believe it is premature to determine whether a monitoring policy is necessary to determine the appropriate utilization of separately billable services under our outlier payment policy. If we determine based on data analysis of the consumption of outlier eligible services under the ESRD PPS that inappropriate use of outlier services is leading to excessive outlier payments, we will reconsider MedPAC's suggestion and propose revisions to the outlier policy in the future.

After consideration of all public comments received, we are modifying our proposed definition of ESRD outlier services set forth in proposed § 413.237 (74 FR 50024) in order to clarify our definition of eligible outlier services. That section references proposed § 413.171 (74 FR 50022) with respect to the definition of separately billable items and services that will be considered eligible outlier services. We are revising the definition of separately billable services set forth in proposed § 413.171 to read as follows: "Separately Billable Items and Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act".

We are finalizing the definition of outlier services to include the following items and services that are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, notwithstanding the delayed implementation of ESRD-related oral-only drugs effective January 1, 2014.

We point out that with respect to the former Part D drugs, other than the oral-only drugs that are delayed for inclusion in the ESRD PPS payment bundle until January 1, 2014, the current outlier eligible drugs are limited to drugs and biologicals required to regulate bone and mineral metabolism and cellular metabolism. Currently these drugs are calcitriol, paracalcitol, doxercalciferol, and levocarnitine. The list of separately billable items and services that will be considered ESRD outlier services is dynamic. If new ESRD-related laboratory tests or new oral drugs emerge within the classifications noted, they will be considered eligible for outlier payments, provided they would have been considered separately billable under Part B or covered under Part D prior to January 1, 2011. We intend to publish a list of currently eligible separately billable outlier services in a subsequent administrative issuance.

We are revising § 413.237 of the regulations to define outlier services as separately billable items and services as defined in § 413.171 of this part and renal dialysis service drugs and biologicals proposed for inclusion in the ESRD PPS that currently are covered under Medicare Part D (including those Part D oral-only drugs that are bundled but for which implementation is delayed until after the ESRD PPS transition period ends).

b. Predicted ESRD Outlier Services MAP Amounts

We proposed that predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments (74 FR 49989).

The predicted separately billable MAP amounts in the proposed rule were based on the patient-level regression for separately billable services. Thus, it was possible to predict patient-specific separately billable MAP amounts for

these services by multiplying the average separately billable MAP amounts by the separately billable case-mix adjusters.

We provided tables that listed the case-mix adjustment multipliers for outlier services for adult and pediatric patients (74 FR 49989 through 49990) and described the process for calculating the adjusted average outlier services MAP amount (74 FR 49990). The proposed adjusted average outlier services MAP amount was $64.54 (74 FR 49991). That amount was multiplied by the product of the patient-specific outlier services payment multipliers to yield the predicted outlier services MAP amount. Lastly, the fixed dollar loss amount was added to this amount.

In the proposed rule, we stated that we intended to include former Part D drugs and biologicals into the separately billable services regression model that generates the case-mix payment adjusters (74 FR 49989). However, for reasons set forth in section II.F. of this final rule, we have been unable to include payments for former Part D drugs in the regression model used to develop the separately billable case-mix adjusters. Payments for these drugs, however, have been included in the computation of the CY 2007 base rate to which the case-mix adjustments are applied.

Accordingly, effective January 1, 2011, the outlier services payment adjustments are based solely on the items and services that, prior to January 1, 2011, were separately billable under Medicare Part B. Therefore, in this final rule, the outlier services multipliers are represented by the separately billable services payment multipliers. The updated list of outlier services payment multipliers on behalf of adult patients is presented in Table A of the Appendix under the heading "separately billable services." The updated list of outlier services payment multipliers on behalf of pediatric patients is presented in Table B of the Appendix under the heading "SB payment multiplier."

The average outlier services MAP amount per treatment in this final rule is based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. In the proposed rule, we used a single outlier services MAP amount based on the average utilization of separately billable services for all Medicare ESRD patients (74 FR 49991). For this final rule, we have adopted separate outlier services MAP amounts for adult and pediatric patients. We did this because of the change in methodology for developing the final pediatric payment adjustments, and to ensure that the outlier thresholds for determining outlier payments for pediatric patients were not inappropriately high, resulting in fewer outlier payments. This change in methodology is appropriate because of the lower utilization of separately billable dialysis services among pediatric patients compared to adult patients. The final average outlier services MAP amounts are $54.14 for patients < 18, and $86.58 for patients age 18 and older.

In the proposed rule, we described how the average MAP amount per treatment for outlier services was adjusted by the case-mix and wage index standardization factor in order to avoid duplicate payments, because adjustments for case-mix and the wage index are applied to the adjusted MAP amount per treatment to compute the ESRD PPS payment amount for each patient (74 FR 49990). Although the standardization factor cited in the proposed rule reflected low volume payments, we inadvertently omitted stating that this standardization factor also included any estimated low-volume payments. After application of this standardization factor (0.7827 in the proposed rule), we also applied the 1.0 percent reduction for total estimated outlier payments (0.99 outlier reduction) and the 2.0 percent reduction mandated under MIPPA (MIPPA reduction factor of 0.98) (74 FR 49990 through 49991). After application of reductions described above, the resulting adjusted average outlier services MAP amount would be multiplied by the applicable patient-specific case-mix adjustments to obtain the predicted outlier services MAP amount (74 FR 49991). As described further in section d., "Outlier Percentage and Fixed Dollar Loss Amounts" below, the fixed dollar loss amount would be added to this amount to obtain each patient's outlier threshold. Total separately billable payments per treatment will have to exceed this amount in order for outlier payments to apply.

In the proposed rule, the standardization factor reflected all of the proposed case-mix and facility-level adjustment variables, including estimated low-volume payments (74 FR 49991). Because we have revised the proposed payment methodology for adult patients to reflect a patient month approach to determine the separately billable regression adjustments and excluded certain case-mix adjustments as described below, and eliminated co-morbidities entirely from the proposed pediatric payment methodology as discussed in section II.G. of this final rule, we have recomputed the proposed standardization factor (0.7827) for case-mix and the wage index to reflect the following final patient characteristics for adult patients: Age, BSA, underweight (BMI < 18.5), time since onset of renal dialysis < 4 months, pericarditis (acute), bacterial pneumonia (acute), gastro-intestinal tract bleeding (acute), hereditary hemolytic or sickle cell anemia (chronic), myelodysplastic syndrome (chronic), monoclonal gammopathy (chronic), and the low-volume adjustment as discussed in section II.E.3. of this final rule.

For pediatric patients, no standardization for outlier services is necessary since the final pediatric adjustments for outlier services were calculated such that the average overall pediatric multiplier is 1.000. The final adjustments are based on age (< 13 and 13–17) and modality (PD or HD) as discussed in section II.G. of this final rule. It should be noted that the low-volume adjustment will not apply to pediatric dialysis patients for reasons explained in section II.G. of this final rule.

As shown in Table 28 below, the average outlier service MAP amount per treatment, adjusted for the standardization, MIPPA reduction, and outlier payment factors just described for adult and pediatric patients, results in the adjusted average outlier services MAP amounts, which are multiplied by the patient-specific case-mix adjustments, to yield a patient's predicted outlier services MAP amounts. As described further in section "d. Outlier Percentage and Fixed Dollar Loss Amounts" below, the fixed dollar loss amounts for adult and pediatric patients will be added to these amounts to obtain each patient's outlier threshold for separately billable services. This is the amount which must be exceeded on a per treatment basis in order for outlier payments to apply.

Table 28--Adjusted Average Outlier Services MAP Amount

Adjusted Average Outlier Services MAP Amount		
	Patient age	
	< 18	18 and older
Average outlier services MAP amount per treatment[1]	$54.14	$86.58
Adjustments		
Standardization for outlier services[2]	1.000	0.9756
MIPPA reduction	0.98	0.98
Adjusted average outlier services MAP amount[3]	$53.06	$82.78
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold[4]	$195.02	$155.44

[1]Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts are based on 2007 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that are in place under the current ESA Claims Monitoring Policy were applied. The outlier services MAP amounts were also inflation adjusted to reflect projected 2011 prices for outlier services.
[2] Applied to the average outlier MAP per treatment. For patients 18 and older the standardization for outlier services is based on the following patient characteristics: Age, BSA, underweight (BMI < 18.5), time since onset of renal dialysis < 4 months, pericarditis (acute), bacterial pneumonia (acute), gastro-intestinal tract bleeding (acute), hereditary hemolytic or sickle cell anemia (chronic), myelodysplastic syndrome (chronic), monoclonal gammopathy (chronic) and the low volume adjustment. For patients ages <18, no standardization for outlier services is necessary since the pediatric adjustments for outlier services were calculated such that the average overall pediatric multiplier based on age (<13 and 13-17) and modality (PD or Hemo) is 1.000.
[3]This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.
[4]The fixed dollar loss amounts were calculated using 2007 data to yield total outlier payments that represent 1% of total projected payments for an expanded ESRD PPS.

We received the following comments in connection with our proposed outlier payment methodology. The comments received and our responses are set forth below.

Comment: One commenter expressed concern that the outlier services MAP amount would be decreased by 25 percent as a result of the standardization for case-mix and wage adjustments, the MIPPA reduction, and the outlier policy reductions.

Response: We believe the commenter was concerned about the magnitude of the reduction. Under the proposed rule, the standardization for case mix, low-volume payments, area wage level adjustments, the 2 percent reduction required by MIPPA, and the 1 percent outlier policy, resulted in a 24.1 percent reduction from the base rate. Based on the revisions to the payment models used to develop the payment adjustments finalized in this rule, application of the revised standardization factor (for case-mix, low-volume payments, and area wage levels), the MIPPA reduction, and outlier policy reduction factors, has reduced the reduction to the outlier services MAP amount to 6.9 percent for pediatric patients, and 4.4 percent for adult patients. Based on our updated analyses conducted for purposes of this final rule, we are finalizing the adjusted average outlier services MAP amounts of $53.06 for pediatric patients and $82.78 for adult patients.

c. Estimating the Imputed ESRD Outlier Services MAP Amounts

As discussed above, we proposed to base eligibility for outlier payments on a comparison of an ESRD facility's predicted MAP amount per treatment for ESRD outlier services to the facility's imputed MAP amount per treatment for those same services. In the proposed rule, we discussed our proposed methodology for determining the predicted outlier services MAP amounts for a patient (74 FR 49988) and the imputed outlier services MAP amounts for a patient (74 FR 49991). We proposed to estimate an ESRD facility's imputed costs for the ESRD outlier services based on the actual utilization of separately billable services.

We noted that although ESRD facilities currently identify costs associated with certain outlier services such as EPO and vaccines, our analysis revealed that other ESRD-related drugs and biological appear to be under-reported or not reported. For this reason, we did not believe that a cost-to-charge ratio that would be based on such reported information would accurately reflect an ESRD facility's cost

for drugs. As a result, we proposed to estimate a provider's costs based on available pricing data rather than applying a cost-to-charge ratio to facility charges to impute their cost (74 FR 49991).

i. Data Used To Estimate Imputed ESRD Outlier Services MAP Amounts

With respect to estimating the imputed MAP amounts of ESRD outlier services that are separately billable under Part B, we proposed to use ASP data for the Part B ESRD-related drugs (which is updated quarterly), and the annual laboratory fee schedule for the previously separately billable laboratory tests (74 FR 49991). We proposed to use various pricing mechanisms for the other separately billable ESRD-related services. Specifically, for medical/surgical supplies used to administer separately billable drugs, we proposed to estimate MAP amounts based on the predetermined fees that apply to these items under the current base case-mix adjusted composite payment system. For example, we pay $0.50 for each syringe identified on an ESRD facility's claims form.

For other medical/surgical supplies such as IV sets and gloves, the Medicare Claims Processing Manual (CMS Pub. 100–04) currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug Topics Red Book, Med-Span, or First Data Bank (CMS Pub. 100–04, Chapter 8, Section 60.2.1). We proposed that the FI/MAC would continue to use the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B to estimate costs for these other medical/surgical supplies.

We proposed to estimate hospital-based and independent ESRD facilities' costs for blood, supplies used to administer blood, and blood processing fees using the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B (74 FR 49991). We did not propose a specific mechanism for estimating the imputed MAP amounts for drugs formerly covered under Medicare Part D but that would become renal dialysis service drugs when the ESRD PPS would be implemented in 2011. Rather, we requested public comments on the five potential approaches for estimating the imputed MAP amounts of these drugs and on alternative approaches. In the proposed rule, we discussed our rationale for each approach (74 FR 49992).

To summarize, we considered the following pricing mechanisms: (1) ASP, (2) national average Part D plan prices, (3) wholesale acquisition cost (WAC), (4) national average prescription drug event (PDE) Part D claims data, and (5) ESRD facility costs net of manufacturer rebates, discounts, and other price concessions.

The comments received on the pricing data proposed for use in estimating imputed ESRD outlier services MAP amounts and our responses are set forth below.

Comment: Several commenters requested that we clarify the specific pricing mechanism that will be used in estimating the imputed outlier services MAP amounts for separately billable drugs within the outlier calculation. Several commenters believed that ASP+6 would be a reasonable approximation of average acquisition, preparation and handling costs for the Part B separately billable drugs that are included in the definition of outlier services.

Response: We solicited public comments on the various pricing approaches that we proposed (74 FR 49992), but received very few comments, each of which are addressed below. As discussed below, only one commenter cited a preference for a particular pricing methodology among those presented. Because ASP data for the Part B ESRD-related drugs and biologicals are updated quarterly, and is the current basis for payment for these drugs, in this final rule we are finalizing the use of ASP pricing for these drugs and biologicals for the purpose of determining outlier eligibility and payments. The prices for estimating payments for Part B drugs and biologicals that were separately billable prior to January 1, 2011, will be determined by continuing to apply ASP+6 pricing for these drugs as we do currently under the basic case-mix adjusted composite payment system.

Comment: One commenter expressed concern that the separately billable prediction equation predicts 8.7 percent of the payment model's variance. The commenter believed that it would be better to pay providers based on actual spending on high cost outliers.

Response: We believe that by referring to actual spending, the commenter meant their cost for outlier services. We appreciate the commenter's input on the pricing scheme for outlier services, as noted above, we are not using provider cost for pricing of outlier services. As we explained in the proposed rule (74 FR 49991), although ESRD facilities currently identify costs associated with certain ESRD outlier services such as EPO and vaccines, our analysis revealed that charges for other ESRD-related drugs and biologicals appear to be under-reported or not reported. For this reason, we do not believe that a cost-to-charge ratio that would be based on such reported information would accurately reflect an ESRD facility's cost.

After implementation of the ESRD PPS, we intend to analyze the extent of outlier payments under the ESRD PPS and may reconsider the commenter's suggestion that we use actual provider cost (net of rebate, discounts, or other reductions) for high cost patients. We note that the updated analysis using 2006–2008 data yielded an R-squared value for the patient-level separately billable payment model of 3.3 percent due to revisions in the payment adjustments described in section II.F.3. and 4, and II.G. of this final rule.

Comment: A drug manufacturer stated that it would be willing to voluntarily report its ASP for ESRD-related drugs. One commenter encouraged CMS to rely on current Part D pricing information as a basis for calculating outlier eligibility. The commenter recommended that payment for oral ESRD-related drugs be based on the price at which the SDO would need to buy the drug from a pharmacy under arrangements. The commenter stated that contract pharmacies will expect a profit on contracting arrangements, thus penalizing SDOs. Another commenter suggested that in light of the difficulties in attempting to impute Part D drug costs for purposes of the outlier calculation, it would be best to limit the payment bundle to only those Part D covered drugs that are the oral equivalent form of an intravenous drug now covered under Part B, and separately billed by ESRD facilities.

Response: We appreciate the drug manufacturer's willingness to report ASP pricing for drugs that are covered under Part D. Although CMS does not have the authority to compel drug manufacturers to submit such data, we are encouraged by the willingness of some manufacturers to report such data, and may consider the use of ASP data in the future, including whether a voluntary reporting approach would be appropriate or feasible to determine pricing for ESRD-related drugs formerly covered under Part D. Although one commenter suggested using wholesale acquisition cost (WAC)(*see* comment below), with the exception of the use of ASP pricing, no other commenters expressed a preference for a particular pricing approach among the ones proposed.

We have elected to adopt the national average drug prices based on the Medicare Prescription Drug Plan Finder.

Similar to acquisition costs, the prices retrieved from the Medicare Prescription Drug Plan Finder reflect pharmacy dispensing and administration fees. Those prices also reflect the negotiated prices of both large and small prescription drug plans. We urge ESRD facilities to indicate on the claims their acquisition costs for ESRD-related oral drugs that are used as substitutions for injectable drugs. In this way, we can compare acquisition costs to the prices from Medicare Prescription Drug Plans.

We share the commenter's concern about imputing oral drug costs and note that, as described previously, the implementation of oral-only Part D drugs within the ESRD PPS is delayed until after the transition period ends and will be discussed in a future notice of proposed rulemaking.

Comment: One commenter requested clarification as to whether blood, blood products and blood transfusion procedures are included in calculating eligibility for outlier payments. The commenter requested that we specify the pricing mechanism that would be used to estimate the imputed MAP amounts for blood and blood products.

Response: As indicated in section II.A.3. of this final rule, we are not finalizing the bundling of blood, blood products, and blood transfusion procedures in the ESRD PPS payment. These services will continue to be separately payable. Therefore, these services do not meet the definition of ESRD outlier services and the imputed MAP amounts for use in the outlier calculation will not include payments for these services.

Comment: One commenter stated that payment for outpatient medications should be based on evidence-based guidelines. This commenter asserted that because there is no evidence supporting the superiority of brand name Vitamin D receptor drugs, the reasonable cost of generic equivalents would be an appropriate basis for pricing these and other drugs.

Response: The listing of ESRD outlier service drugs and their corresponding prices is not limited to brand name-only drugs.

Comment: One commenter requested that new technologies be included in the definition of outlier services suggesting that we consider paying for the full cost of any innovative drug or technology when an outlier payment is triggered. The commenter believed that this approach could serve as an interim measure until CMS and ESRD facilities acquire experience with the new drug or technology.

Response: We appreciate the commenter's suggestion for assessing outlier eligibility and calculating potential outlier payments for new technologies. We intend to publish a list of ESRD outlier services for implementation on January 1, 2011, in a subsequent administrative issuance along with the methodologies for updating the list. We plan to continue to assess options for accounting for the cost of new technologies within the ESRD PPS, whether through the outlier payment policy or some other feature of the ESRD PPS. We would include our assessment and any proposed options in future notices of proposed rulemaking.

Comment: One commenter suggested that CMS use wholesale acquisition cost (WAC) for purposes of pricing new drugs.

Response: Although the commenter suggested the use of WAC for pricing new drugs, no reason was given. With respect to new Part D drugs, we would rely on the national average drug price by NDC code based on data from the Medicare Prescription Drug Plan Finder as discussed previously in this section. As such, we will be unable to establish prices for new drugs that would meet the definition of ESRD outlier services until prices for those drugs are included in the Prescription Drug Plan Finder and we have updated the ESRD outlier services list to reflect the new drug and established the price in CMS systems that price ESRD claims. We point out that although new drugs would only be eligible for outlier payment after the outlier services list has been updated, the otherwise applicable ESRD PPS bundled payment rate would still apply to any new drugs within the classification categories. We intend to update the ESRD outlier services list annually to reflect new prices and new drugs within our classification categories described in section II.A.3. of this final rule.

As a result of the public comments received, we are finalizing the bases for estimating imputed outlier services MAP amounts as follows: "(1) Part B drugs that were or would have been separately billable prior to January 1, 2011, will continue to be priced based on the most current ASP pricing plus 6 percent". (2) Laboratory tests that were or would have been separately billable prior to January 1, 2011, will continue to be priced based on the most current laboratory fee schedule amounts. (3) ESRD-related supplies used to administer separately billable Part B drugs (for example, syringes) that prior to January 1, 2011, were or would have been separately billable, will continue to be priced as they are currently. (4) Renal dialysis drugs and biologicals that prior to January 1, 2011, were or would have been separately covered under Part D, including ESRD-related oral-only drugs and biologicals for which we have delayed implementation until January 1, 2014, will be priced by NDC code based on the national average pricing data retrieved from the Medicare Prescription Drug Plan Finder".

ii. Determining the Imputed per Treatment ESRD Outlier Services MAP Amount

In the proposed rule, we indicated 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 (74 FR 49992). We proposed that the ESRD facility would identify by line item on the monthly claim, all ESRD outlier services furnished to the patient. We would then estimate the imputed MAP amount for these services applying one of the proposed pricing methodologies discussed above. The imputed outlier services MAP amounts for each of these services would be summed and divided by the corresponding number of treatments identified on the claim to yield the imputed outlier services MAP amount per treatment. An ESRD facility would be eligible for an outlier payment if the imputed average outlier services MAP amount per treatment exceeded the sum of the predicted outlier services MAP amount per treatment and the fixed dollar loss amount.

We did not receive comments on our proposed methodology for determining the imputed ESRD outlier services MAP amounts per treatment, beyond those already addressed in the previous section. For this reason and because it is a reasonable method to determine the amount that would have been paid for these services absent the ESRD PPS, we are finalizing our methodology for imputing an outlier services MAP amount per treatment.

d. Outlier Percentage and Fixed Dollar Loss Amounts

In the proposed rule, we indicated that payments under section 1881(b)(14)(D)(ii) of the Act for outlier cases would be applied in a budget neutral manner (74 FR 49992). Therefore, we proposed to reduce the base rate by the proposed outlier percentage (that is, 1.0 percent), reflecting the total amount of estimated payments for outlier cases, as discussed in section II.E.4. of this final rule. In the proposed rule, we discussed our rationale for determining outlier

payments and outlier percentages for the ESRD PPS (74 FR 49992).

We proposed that the outlier percentage would be 1.0 percent of total ESRD PPS payments (74 FR 49993). We stated that we believed an outlier percentage of 1.0 percent struck an appropriate balance between our objectives of paying an adequate amount for for the most costly patients, while providing an appropriate level of payment for those patients who did not qualify for outlier patients. We also said that this percentage is consistent with other Medicare PPSs, such as the 1 percent outlier policy under the outpatient PPS (74 FR 49993). We also proposed that the fixed dollar loss amounts that would be added to the predicted, outlier services MAP amounts would differ for adult and pediatric patients due to differences in the use of separately billable services among adult and pediatric patients, particularly drugs (74 FR 49993). We proposed separate fixed dollar loss amounts, defined in proposed § 413.237(a), of $134.96 for adult patients and $174.31 for pediatric patients (74 FR 49993, 50024).

We received the following comments on our proposals pertaining to these features of the outlier policy.

Comment: Many commenters supported the proposed features of the outlier policy including the 1.00 percent outlier percentage, indicating that it will assist all facility types including independent, hospital-based, and pediatric facilities in providing adequate care to complex and costly patients. However, to maximize the base rate amount, commenters urged CMS to keep the outlier percentage as small as possible.

Another commenter urged us to eliminate the outlier policy and pay the same bundled rate for all patients asserting that the 1.0 percent outlier reduction from the base rate for small and midsized dialysis facilities would have a punitive impact, because these facilities are not able to spread their outlier risk over a large patient population.

Response: As indicated in the proposed rule, we believe that a 1.00 percent outlier percentage strikes an appropriate balance between our objectives of paying an adequate amount for the most costly patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We have updated the information in the Table 37 that appeared in the proposed rule (74 FR 49993) based on the ESRD PPS adopted in this final rule to show how outlier payment reductions in the base rate beyond 1 percent would revise the number of estimated patient months that would qualify for outlier payments for both adult and pediatric patients. *See* Table 29 below.

Table 29: Impact of Outlier Percentage on Patient Months Qualifying for Outlier Payment

	Outlier percentage				
	1%	1.5%	2%	2.5%	3%
Age 18 and Older: Patient Months Qualifying for Outlier Payment	4.7%	6.4%	8.2%	10.0%	11.9%
Age < 18: Patient Months Qualifying for Outlier Payment	2.2%	3.5%	5.0%	6.7%	9.0%
Age 18 and Older: Fixed Dollar Loss Amount*	$155.44	$127.41	$106.13	$89.02	$74.84
Age < 18: Fixed Dollar Loss Amount*	$195.02	$140.88	$103.19	$76.16	$56.29

*The fixed dollar loss amounts were calculated using 2007 claims data to yield total outlier payments that represent a certain percentage (e.g., 1%) of total projected payments in an expanded ESRD PPS, and reflect an outlier loss sharing percentage of 80%. In determining the fixed dollar loss and outlier payment amounts, EPO and darbepoetin payments were capped to reflect the medically unbelievable edit thresholds in place under the ESA monitoring policy starting January 1, 2008 (400,000 units for EPO and 1,200 mcg for darbepoetin). The outlier payment would be based on 80% of the outlier services Medicare Allowable Payment (MAP) that exceeds the sum of the predicted outlier services MAP for each patient and the fixed dollar loss amount for the patient's age group (<18 or 18 and older).

As with Table 37 in the proposed rule (74 FR 49993), we believe that Table 29 continues to support our belief that a 1 percent outlier payment percentage balances the need for paying for unusually costly resource intensive cases, while at the same time ensuring an adequate base rate for patients who do not qualify for outlier payments. Based on the updated analysis, a 1.0 percent outlier policy results in 4.7 percent of patient months qualifying for outlier payment compared to 5.3 percent based on the analysis conducted for the proposed rule. An increase in the outlier percentage would result in a lower fixed dollar loss threshold and more patient months qualifying for outlier payment.

However, each percent increase in the outlier percentage decreases the base rate applied to all patient months. Public comments addressed in previous sections of this final rule advocating for fewer adjustments, a lower standardization reduction, and a higher base rate provide additional support for a 1.0 percent outlier policy.

With respect to the commenter who urged us to eliminate the outlier payment policy, we point out that section 1881(b)(14)(D)(ii) of the Act requires us to have an outlier payment

adjustment. Accordingly, we are finalizing the 1.0 percent outlier percentage.

Comment: One commenter stated that an independent analysis revealed that an outlier payment policy similar to that proposed by CMS was "optimal" in that it resulted in minimal reduction to the base rate and provided a reasonable distribution of outlier payments to providers. The commenter found that outlier payments were distributed in higher proportion to African American patients than for other racial groups.

Response: We note that the outlier percentage of 1.0 percent which we have adopted in this final rule comports with our analysis and the commenter's analysis.

Comment: Several commenters recommended that we re-evaluate outlier payments and the outlier percentage on an ongoing basis and adjust it periodically as needed, adding back any excessive reduction in the base rate if projected outlier payments exceed actual outlier payments. Similarly, another commenter believed that because ESRD facilities may not receive adequate payment for outlier expenses, we should return any unanticipated decrease in reimbursement to providers on a pro rata basis at the end of the year. The commenter asserted that this would ensure budget neutrality, not budget negativity.

The commenters concluded that adjustments must reflect the changes in the reported cost of care for the outlier patient population to ensure equity in access for all ESRD patients.

Response: We disagree with the commenters' recommendations. We have put forth our best effort to project the impact of a 1.0 percent outlier payment policy on the magnitude of the fixed dollar lost amounts for adult and pediatric patients in order to calculate the outlier payment thresholds. The ESRD PPS is intended to provide a fixed reliable payment rate per treatment for the cost of furnishing outpatient dialysis services.

While we intend to update the fixed dollar loss amounts on an annual basis in order to maintain a 1.0 percent outlier percentage, and evaluate the degree to which our estimated projections of outlier payments match actual outlier expenditures, we do not intend to adjust the base rate in future years to reflect the difference between actual and projected outlier payments. We have taken the same position in connection with other PPSs, and do not believe a departure from this policy would be appropriate. Therefore, we have not adopted the commenters' suggestion that we make prospective corrections in the base rate amounts to correct for over/underestimates in projected outlier payments for prior years.

Based on our review of all public comments received, the updated data analyses conducted for purposes of this final rule, and for the reasons discussed above, we are finalizing the fixed dollar loss amounts and outlier percentage as set forth in proposed § 413.237(a). Specifically, we are finalizing fixed dollar loss amounts of $155.44 and $195.02 for adult and pediatric patients, respectively, and a 1.0 percent outlier percentage.

2. Outlier Payments

In the proposed rule, we proposed an 80 percent loss sharing percentage as the percentage of costs exceeding the fixed dollar loss amount that would be paid by Medicare (74 FR 49993). We conveyed our interest in preserving the efficiency incentives inherent under a PPS, stating that an 80 percent loss sharing percentage would strike a reasonable balance between the policy objective of paying an adequate amount for high cost cases, while at the same time preserving the efficiency incentives inherent in a PPS. We also stated that an 80 percent loss sharing percentage was consistent with that used in other Medicare payment systems. We also proposed to implement an annual monitoring process that would identify patterns of increased utilization of outlier services, and any associated outlier payments across ESRD facilities (74 FR 49993).

For treatments eligible for outlier payments, we proposed that the per treatment outlier payment equal 80 percent (the loss sharing percentage) of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted, outlier services MAP amount per treatment, and the fixed dollar loss amount, as specified in proposed § 413.237(c). We indicated that for treatments eligible for the outlier payments, the outlier payment would be added to each ESRD PPS per treatment payment amount.

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

Comment: One commenter stated that to facilitate cost containment, outlier payments, by design, do not cover all losses. This commenter asserted that ESRD facilities pay for the treatment of infections in the interest of continuity of care when these infections may have little to do with dialysis care. The commenter estimated an outlier payment for a high cost patient based on AWP pricing for daptomycin and concluded that the facility would lose $1,600 in one month after accounting for the outlier policy's loss sharing feature. The commenter believed that to compensate for this loss, ESRD facilities would either reduce the provision of medications to other patients, defer this treatment to be provided at home or in infusion centers, or turn the patient away.

Response: As discussed in section II.A.3. of this final rule, we will provide a mechanism whereby an ESRD facility can identify and be paid separately for antibiotics (and other drugs and biologicals) that are administered in the ESRD facility, but are not renal dialysis services. Because non-renal dialysis services do not meet the definition of an outlier service, they would not be included in the calculation of outlier eligibility or payments.

Comment: One commenter stated that pay for performance does not clearly define how to prevent penalty for non-compliant patients or patients with underlying disease as related to adequacy or anemia. The commenter considered these cases to be "outliers."

Response: The commenter is apparently using the term "outliers" in a manner different than that addressed in the proposed and final rules with respect to our establishment of an outlier payment policy. The types of cases which the commenter cites may be aberrant or unusual, but they would not necessarily qualify as outlier cases in the context of this final rule. We refer readers to section II.M. of this final rule for more information about the pay-for-performance element of the ESRD PPS, referred to as the QIP.

As a result of the public comments and for the reasons we have explained above and in the proposed rule, we are finalizing § 413.237(c) of the regulations to provide that the per treatment outlier payment equal 80 percent (the loss sharing percentage) of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount.

3. Hypothetical Outlier Payment Examples Hypothetical Example—Adult Patient

Martha, a 66 year old female who is 167.64 cm. tall, weighs 105 kg., and has a recent diagnosis of GI bleeding. A patient of this weight and height is not below the threshold for underweight status and thus would not qualify for a low BMI adjustment.

The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

Martha's BSA is calculated as:

$BSA_{Martha} = 0.007184 * 167.64^{.725} * 105^{.425} = 0.007184 * 40.9896 * 7.2278 = 2.1284$

Table 29 reveals that the separately billable multiplier for BSA is 1.014. Martha's case-mix adjustment based on her BSA of 2.1284 would be:

$= 1.014^{(2.1284 - 1.87/0.1)}$

$= 1.014^{2.584}$

= 1.037

Step 1: Determine the predicted, ESRD outlier services MAP amount using the product of all applicable case-mix adjusters.

The product of the patient-level outlier services case-mix adjusters as identified in Table 29:

= 66 year old: 1.000, BSA: 1.037, and GI bleeding: 1.571:

= 1.000 * 1.037 * 1.571

= 1.6291

The adjusted, average, ESRD outlier services MAP amount = $82.78

The adjusted, average ESRD outlier services MAP amount * product of the outlier services case-mix adjusters:

= $82.78 * 1.6291

= $134.86

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount based on utilization of all separately billable services on the monthly ESRD facility bill.

Assume the imputed monthly ESRD outlier services amount = $4,000 and that the corresponding total number of treatments in the month = 10

The imputed, average, per treatment, outlier services MAP amount

= $4,000/10

= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $155.44

The predicted, ESRD outlier services MAP amount = $134.86

= $134.86 + $155.44

= $290.30

Step 4: Calculate outlier payment per treatment.

Outlier payment = imputed average, per treatment, outlier services MAP amount − (predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:

= ($400.00 − $290.30) * .80

= $109.70 * .80

= $87.76

Hypothetical Example—Pediatric Patient:

John, is a 13 year old HD pediatric patient.

Step 1: Determine the predicted, ESRD outlier services MAP amount.

As specified in Table 29, determine the patient-level ESRD outlier services case-mix adjuster:

= 13 year old HD patient = 1.459

The adjusted, average, ESRD outlier services MAP amount = $53.06

The adjusted, average, ESRD outlier services MAP amount * the product of the outlier services case-mix adjusters:

= $53.06 * 1.459

= $77.41

Step 2: Determine the imputed, average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = $4,000

Assume the corresponding total number of treatments = 10

The imputed, average, per treatment, outlier services MAP amount =

= $4,000/10

= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $195.02

The predicted, ESRD outlier services MAP amount = $77.41

= $77.41 + $195.02

= $272.43

Step 4: Calculate outlier payment per treatment.

Outlier payment = imputed, average, per treatment, outlier services MAP amount − (predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:

= ($400.00 − $272.43) * .80

= $127.57 * .80

= $102.06

The outlier payment amount would be added to the ESRD PPS payment amount, per treatment. For a detailed description of calculating the ESRD PPS payment amount per treatment, please refer to the hypothetical examples in the Comprehensive Payment Examples presented later in this section of this final rule.

4. Application of Outlier Policy During the Transition and in Relation to the ESA Monitoring Policy, Other Claims Processing Tools, and Other CMS Policies

In the proposed rule, we indicated that the outlier payment policy would be limited to the proposed ESRD PPS (74 FR 49994). We proposed that for those ESRD facilities that do not elect to be excluded from the three year transition, outlier payments would be limited to the portion of the blended rate based on the payment rates under the proposed ESRD PPS.

We also indicated that nothing within the proposed outlier payment policy would replace the claims monitoring implications related to the utilization of separately billable ESAs including currently available epoetin alfa (EPOGEN®, or EPO), darbepoetin alfa (ARANESP®) or any ESAs that may be developed in the future and used by beneficiaries receiving renal dialysis services (74 FR 49994).

The comments received on application of our proposed outlier policy during the transition and in relation to the ESA Claims Monitoring Policy and our responses to them are set forth below. Approximately half of the commenters supported and half opposed the continuation of our claims monitoring policy with respect to the utilization of ESAs.

Comment: Some commenters stated that they believed there would be no incentive to overuse ESAs once the ESRD PPS is implemented in 2011 and, therefore, the ESA Claims Monitoring Policy should be discontinued. Other commenters supported continuing to apply the ESA Claims Monitoring Policy under the ESRD PPS, maintaining that it would help ensure that ESAs would not be overutilized in order to obtain outlier payments. One commenter suggested that in instances where the patient's ESA and iron therapies are within the QIP parameters, then CMS should provide outlier payments. The commenter believed that it would be appropriate to include the costs of ESA therapy while the patient's hemoglobin remained at 13 or lower and the patient's iron stores were adequate, but exclude from the outlier calculation the costs of ESA therapy in instances where a patient's hemoglobin exceeded 13, or if the patient's iron level was above an adequate level.

Response: Currently there are two claims processing edits associated with the ESA Claims Monitoring Policy—the reduction in the payable ESA amount based on reported hemoglobin (or hematocrit) level, and medically unbelievable edits (MUEs) based on the ESA total administered dose. During the transition, ESRD facilities will be expected to meet our quality measures under the QIP, notwithstanding that the implementation of the QIP does not occur until January 1, 2012, in addition to complying with other policies for coverage and claims processing.

With respect to the basic case-mix adjusted composite payment system portion of the blended payment during the transition, we will continue to apply

both ESA Claims Monitoring Policy processing edits and implement any corresponding payment reductions. Although several commenters believed that the implementation of the ESRD PPS would provide sufficient incentives not to overutilize ESAs, obviating the need for continuation of the ESA Claims Monitoring Policy, we believe that the continued application of this policy will help ensure the proper dosing of ESAs, and provide an added safeguard against the overutilization of ESAs, particularly where the consumption of other separately billable services may be high, in order to obtain outlier payments.

With respect to the commenter's suggestion that payments for ESAs should only be considered outlier eligible payments when a patient's hemoglobin is at 13 or lower, and excluded when the value exceeds 13, this recommendation does not consider the fact that hemoglobin levels can be volatile even when proper doses are administered. Fluctuations will occur because of the time required to titrate levels in response to the patient's specific condition. Therefore, linking ESA eligibility for outlier payments to a patient's achieved hemoglobin level is not a feasible payment option.

With respect to the ESRD PPS portion of the blended payment, we will apply dosing reductions resulting from the application of the ESA Claims Monitoring Policy prior to any calculations of outlier eligibility. We believe that continuation of this policy is necessary in order to provide a disincentive for overutilization of ESAs in order to receive outlier payments, notwithstanding that the implementation of the ESRD PPS will tend to discourage overuse of ESAs, as ESAs are part of the payment bundle.

The ESA dose edits will be applied prior to pricing so that we do not overvalue these services in determining eligibility for outlier payments. We note that the ESA Claims Monitoring Policy provides an opportunity for appeal to address those situations where there might be medical justification for higher hematocrit or hemoglobin levels. Beneficiaries, physicians, and dialysis facilities may submit additional documentation to justify medical necessity, and any payment reduction amounts may be subsequently reinstated when documentation supports the higher hematocrit or hemoglobin levels. To the extent successful appeals impact the amount of outlier payments on behalf of beneficiaries, those claims will be reprocessed to reflect the correct amount of outlier payments.

Comment: One commenter believed that EPO dosing among ESRD patients has been historically high and recommended that we cap the EPO contribution in the base rate at 14,000 units per week. Similarly, the commenter questioned whether the inclusion of current ESA dosing parameters within the outlier calculation would be in the best interest of the patient and suggested that high doses related to hyporesponsiveness should be further investigated. The commenter recommended that we cap ESA dosing at 160,000 units per month (IV administration) until further valid studies have determined safer dosing levels.

Response: With respect to the commenter's specific concern about the extent to which the cap on ESA dosing is appropriate, we note that this concern is beyond the scope of this rule. We appreciate the commenter's concern about potential excess ESA dosing of ESRD patients but, as discussed in section II.E. of this final rule, the amount of ESA payment included in the base rate comports with limits established under the ESA Claims Monitoring Policy.

We stated in the proposed rule that both the base rate and the features of the outlier policy, including the outlier percentage and fixed dollar loss thresholds, were based on 2007 claims data (74 FR 49990). In developing the base rate for the proposed rule we applied a medically unbelievable EPO limit of 30,000 units per treatment. This edit contributed to lower fixed dollar loss amounts. For purposes of the final rule, we have revised the ESA medically unbelievable edits to comport with CMS's own ESA Claims Monitoring Policy. Specifically, in 2007, the ESA claims monitoring policy included a monthly medically unbelievable edit threshold of 500,000 for EPO and 1,500 mcg. for ARANESP®. The medically unbelievable edit thresholds were reduced to 400,000 units for EPO and 1,200 mcg. for ARANESP® in 2008 (Transmittal 1307, Change Request 5700 (July 20, 2007)).

For purposes of this final rule, the base rate and the features of the outlier policy, including the outlier percentage and the fixed dollar loss thresholds as reflected in Table 28 were based on 2007 data. Although the medically unbelievable edits that were in place for EPO and ARANESP® were 500,000 units and 1,500 mcg., respectively in 2007, we chose to apply the edits that are currently in place. That is, we applied medically unbelievable edits of 400,000 units for EPO and 1,200 mcg. for ARANESP® in establishing the outlier policy's fixed dollar loss amounts. We believe that this edit is necessary for purposes of reflecting current CMS policy and to bring the projected fixed dollar loss amounts into line with ESA dosing that is consistent with the current ESA Claims Monitoring Policy. We point out that we applied a similar edit to the calculation of the base rate, in that the medically unbelievable edits that were in place for EPO and ARANESP® in 2007 were also used to calculate the components of the base rate that reflect payments for ESAs.

Comment: One commenter responded to our request for identifying potential safeguards against the overuse of ESAs under the ESRD PPS. This commenter noted that there are certain diseases in which ESAs should not serve as the primary treatment approach for anemia where transfusion may be the better choice. This commenter suggested that we could implement measures to ensure that ESAs are not administered or reimbursed in the absence of evidence of iron depletion.

Response: We agree with the commenter that there are multiple causes (for example, iron deficiency anemia, vitamin B12 deficiency, or folic acid deficiency) and treatment approaches for anemia. We expect that patients will be evaluated to determine the cause of their anemia and treated appropriately. We would also expect that ESRD facilities that administer ESAs in accordance with their patients' plans of care would do so in accordance with the FDA's approved indications.

Comment: One commenter requested that we do further research into higher hemoglobin levels because the commenter believes that some patients do not do well with lower hemoglobin levels and therefore need more EPO.

Response: Although we are not performing such research, we would agree that any research that attempts to examine the relationships among hemoglobin levels, ESA utilization, and clinical outcomes is welcome and should be encouraged.

Comment: One commenter expressed concern that establishing reimbursement policy based on what the commenter believed are "misguided/unguided and perhaps dangerous treatment patterns," eroded the opportunity to improve quality of care and establish a financially sound policy. The comment included a copy of a report from the Department of Health and Human Services' Office of the Inspector General (US DHHS OIG) which described inconsistencies in ESRD facilities' policies and protocols for administering ESAs. Other commenters submitted comments indicating that there have not been studies that have reported an

appropriate target hematocrit and expressed concern that the proposed rule might encourage underutilization of EPO.

Response: We are closely following the growing body of scientific evidence that describes the usage patterns of ESAs, as well as their potential benefits and harm. In order to further evaluate this body of evidence, CMS held a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on March 24, 2010. The purpose of the MEDCAC was to provide independent guidance and expert advice to us about the evidence on the use of ESAs in the management of anemia in patients with chronic kidney disease and end-stage renal dialysis disease. On June 16, 2010, we formally opened a new National Coverage Determination (NCD) regarding ESAs.

Comment: Several commenters questioned specific features of the ESA Claims Monitoring Policy and ESA dosing of patients with chronic kidney disease (CKD).

Response: We thank the commenters for stating their concerns. However, we solicited public comments on the extent to which we should continue to apply the ESA Monitoring Policy under the proposed ESRD PPS, which is a payment system applicable to Medicare beneficiaries with end-stage renal disease, not CKD. Comments concerning the ESA Claims Monitoring Policy and ESA dosing of patients with CKD are beyond the scope of this final rule.

In developing this final rule, we have considered the extent to which it would be appropriate to extend the ESA Claims Monitoring Policy to include home dialysis patients who self-administer ESAs. Currently, the ESA Claims Monitoring Policy does not apply to ESA claims for patients who receive their dialysis at home and self-administer their ESAs and we will continue this policy in 2011.

We expect ESRD facilities managing home dialysis patients to use prudent judgment in ESA dosing and monitoring hemoglobin levels. Because outlier payments may be made on behalf of home dialysis patients as well as in-facility ESRD patients, we intend to monitor outlier payments for any unusual trends in outlier payments for all patients, including home dialysis patients who self-administer ESAs. We will continue to evaluate outlier payments and, if necessary, will address changes in the future.

As a result of the public comments received and for the reasons we addressed above, we will continue to apply the ESA Claims Monitoring Policy edits on ESRD facility claims for purposes of calculating the basic case-mix adjusted composite payment system portion of the blended payment during the transition period, and in connection with determining the eligibility of ESA payments for outlier payments.

I. Comprehensive Payment Model Examples

In section II.D. of this final rule, we demonstrated how the case-mix adjustments based on separate estimating equations for CR and SB services (that is, the two equation model) were combined to obtain a single payment formula under the ESRD PPS. Table A in the Appendix contains the case-mix adjustments applicable to adult patients. In section II.G. of this final rule, we addressed the pediatric payment adjustments under the ESRD PPS. Table B in the Appendix contains the four pediatric classification categories and corresponding case-mix adjusters that will be applied to pediatric patients. In this section, we explain how the area wage index and case-mix adjustments will be applied to the adjusted base rate amount described in section II.E.4. of this final rule, reflecting combined CR and SB services, resulting in a patient-specific per treatment payment amount under the ESRD PPS, as set forth in § 412.56. We demonstrate how the case-mix adjustments presented in Tables A and B in the Appendix would be applied for eight hypothetical ESRD patients to obtain the per treatment payment amounts under the ESRD PPS. We refer to the product of the applicable case-mix adjustment factors as the patient multiplier or PM. The ESRD PPS case-mix adjusters are shown in Table A in the Appendix for adult patients and Table B in the Appendix for pediatric patients.

Each example uses the adjusted base rate of $229.63, covering Part B renal dialysis services and self-care home dialysis services as set forth under section 1881(b)(4) of the Act. Each example also assumes an ESRD wage index value of 1.1000. The labor-related share derived from the ESRD PPS market basket, described in section II.J. of this final rule, is 41.737 percent. Therefore, the starting point in each example prior to determining the patient-specific PM is a wage index adjusted base rate of $239.21. This amount was computed as follows:

Base rate $229.63
Labor-related share of base rate ($229.63 * .41737 = $95.84) $95.84
Wage index adjusted labor-related share ($95.84 * 1.1000 = $105.42) $105.42
Non labor-related share of base rate ($229.63 * (1 − .41737) = $133.79 $133.79
Wage index adjusted base rate ($105.42 + $133.79 = $239.21) $239.21

We also point out that each case-mix adjusted payment amount is reduced by 3.1 percent through the application of an adjustment factor of .969 to account for budget neutrality during the transition period. This is referred to as the transition budget neutrality adjustment, and is included as the last item in the computation of the payment amount for each patient, after application of all other case-mix adjustment factors (that is, all PMs), including any applicable add-on amounts for training treatments. It also applies to any outlier payments.

Example 1—Relatively Healthy ESRD Patient With No ESRD Payment Co-Morbidities; No Outlier Payments Apply

John, a 45 year old male Medicare beneficiary, is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. John was diagnosed with ESRD in early 2010 and has been on HD since July 2010. He has chronic glomerulonephritis and hypertension, and has an AV fistula. The patient also has secondary hyperparathyroidism. John's payment rate for treatments furnished in January 2011 would be calculated as follows.

Table A in the Appendix reveals that none of John's co-morbidities is among those for which a case-mix adjustment applies. The only pertinent factors to adjust the base rate amount are age, height, and weight. Using the formula for BMI, we see that John is not underweight, having a BMI of 26.89 kg/m², which is greater than the threshold value of 18.5, the cut-off for underweight status:

$BMI_{John} = weight_{kg} / height\ (m^2)$
$= 95/1.8796^2$
$= 95/3.5329$
$= 26.89$

Therefore, there is no case-mix adjustment for low BMI. The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

John's BSA is calculated as:

$BSA_{John} = 0.007184 * 187.96^{.725} * 95^{.425}$
$= 0.007184 * 44.5346 * 6.9268$
$= 2.2161$

Using the Table A in the Appendix multiplier of 1.020, John's case-mix adjustment or payment multiplier (PM) based on his BSA of 2.2161 is computed as follows:

$PM_{BSA} = 1.020^{(2.2161-1.87)/0.1}$
$= 1.020^{3.461}$

= 1.0709

John's PM would reflect the applicable case-mix adjustments from Table A in the Appendix for both age and BSA and may be expressed as:

$PM_{John} = PM_{age} * PM_{BSA}$
= 1.013 * 1.0709
= 1.0848

John's ESRD payment rate for treatments furnished in January 2011 would be:

$239.21 * 1.0848 * .969 = $251.45

Example 2—Same as Example 1, Except Dialysis Began November 15, 2010

John's PM would have to include the adjustment for the onset of dialysis, because the treatments for which we are calculating the payment amount occur within 4 months of November 15, 2010. Because the onset of dialysis adjustment is limited to a maximum of 120 days, this particular adjustment would apply for treatments furnished between January 1, 2011 and March 15, 2011. John's applicable case-mix adjustments would be for a patient new to dialysis, age, and BSA, and may be expressed as:

$PM_{John} = PM_{DialQuest} * PM_{Age} * PM_{BSA}$

Using the adjustment factors from Table 10, John's PM is:

$PM_{John} = 1.510 * 1.013 * 1.0709 = 1.6381$

For treatments furnished between January 1, 2011 and March 15, 2011, John's payment rate per treatment would be:

$239.21 * 1.6381 * .969 = $379.70

After March 15, 2011, when the onset of dialysis adjustment has expired, the payment would be $251.45, as calculated in Example 1.

Example 3—ESRD Patient With Multiple Co-Morbidities

Mary, a 66 year old female, is 167.64 cm. (1.6764 m.) in height and weighs 105 kg. She has diabetes mellitus and cirrhosis of the liver. Mary was diagnosed with ESRD in 2006, and has been on HD since that time. Mary was admitted for a two week hospitalization from January 2–16, 2011 due to gastrointestinal tract bleeding, a diagnosis confirmed upon discharge. Mary's hemorrhaging due to her GI bleeding ceased during her hospitalization. While in the hospital, Mary received inpatient dialysis. Mary was also discharged with a diagnosis of monoclonal gammopathy. After convalescing at home for 3 days, she resumed HD at an ESRD facility on January 20, 2010. The facility records the GI bleeding and monoclonal gammopathy diagnoses using the relevant ICD–9–CM codes for treatments received during the month of January. For claims submitted beginning with the month of February and continuing thereafter, the facility reports only the monoclonal gammopathy diagnosis, a chronic condition.

The BMI calculation is:

$BMI = weight_{kg}/height(m^2)$
$BMI_{Mary} = 105/1.6764^2$
= 105/2.8103
= 37.3626

Table A in the Appendix reveals that the PM in this example must be considered using the case-mix adjustments for gastrointestinal tract bleeding, monoclonal gammopathy, age, and BSA. Although Mary has diabetes and cirrhosis of the liver, these co-morbidities are not used in determining the case-mix adjusters under the ESRD PPS. The formula for calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$
$BSA_{Mary} = 0.007184 * 167.64^{.725} * 105^{.425}$
= 0.007184 * 40.9896 * 7.2278
= 2.1284

Using the Table A in the Appendix multiplier of 1.020, Mary's case-mix adjustment or PM based on her BSA of 2.1284 is computed as follows:

$PM_{BSA} = 1.020^{(2.1284 - 1.87)/0.1}$
$= 1.020^{2.584}$
= 1.0525

Although Mary has both an acute co-morbidity (GI bleeding) and a chronic co-morbidity (monoclonal gammopathy) for the month of January, the facility may only be paid using the condition with the higher adjustment factor for the maximum number of 4 consecutive claim months in which payment for both co-morbidities must be considered. Because the case-mix adjustment for GI bleeding (1.183) exceeds that for monoclonal gammopathy (1.024), Mary's case-mix adjustment for co-morbidities will reflect GI bleeding only for treatments received in January 2011 through April 2011. Therefore, for these treatments, Mary's PM may be expressed as:

$PM_{Mary} = PM_{age} * PM_{BSA} * PM_{GIBleed}$
= 1.000 * 1.0525 * 1.183
= 1.2451

For treatments received from January 20, 2011 through April 2011, Mary's payment rate per treatment is:

$239.21 * 1.2451 * .969 or $288.61

Beginning with claims for May, only one co-morbidity applies for payment purposes, monoclonal gammopathy, for which the PM is 1.024. As this is a chronic condition, beginning with treatments furnished in May and continuing thereafter, Mary's PM may be expressed as:

$PM_{Mary} = PM_{age} * PM_{BSA} * PM_{Mono}$
= 1.000 * 1.0525 * 1.024
= 1.0778

For treatments received in May 2011 and thereafter, provided no other co-morbidities apply, Mary's payment rate per treatment would be:

$239.21 * 1.0778 * .969 or $249.83

Example 4—ESRD Patient With Multiple Co-Morbidities, Onset of Dialysis Adjuster, Training Treatments, and Acute Co-Morbidity Recurrence Apply

Ted, a 30-year-old male, began in-center HD on March 20, 2011. Ted has type II diabetes mellitus, sickle cell anemia, and was diagnosed on March 2 with bacterial pneumonia, which was treated with antibiotics. After completing his course of treatment with antibiotics, Ted was declared free of pneumonia on April 15. Because the patient has family caregivers available to assist him, Ted expressed a desire to become a PD patient. His nephrologist agreed that Ted was a suitable candidate for CAPD. On June 20, 2011, Ted began a series of 12 training treatments at his dialysis facility (one which does not qualify for the low-volume adjustment, but which is certified to provide home dialysis training) to transition to CAPD. These training treatments ended on July 21, 2011. Between July 18 and July 21, Ted had 2 training treatments. Ted successfully began CAPD on July 23, 2011, but was again diagnosed with bacterial pneumonia on August 10. After prolonged treatment with antibiotics, Ted was declared free of pneumonia on November 15, 2011.

Ted is 170 cm. (1.70 m.) in height and weighs 78 kg. Table A in the Appendix reveals that the case-mix adjusters which must be considered in this case are those for age, BSA, onset of dialysis, bacterial pneumonia, and sickle cell anemia. As will be shown Ted does not qualify for the low BMI adjustment. In addition, the training add-on of $33.44 per treatment (prior to adjustment for area wage levels) must also be considered in the payment computations.

$BMI_{Ted} = weight_{kg}/height\ (m^2)$
$= 78/1.70^2$
= 78/2.89
= 26.99

Because Ted's BMI exceeds the required threshold value of 18.5, there is no case-mix adjustment for low BMI. The formula for the calculation of a patient's BSA is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

Ted's BSA is calculated as:

BSA_{Ted} 0.007184 * $170^{.725}$ * $78^{.425}$
= 0.007184 * 41.4072 * 6.3700
= 1.8949

Using the Table A in the Appendix multiplier of 1.020, Ted's case-mix adjustment based on his BSA of 1.8949 is computed as follows:

$PM_{BSA} = 1.020^{1.8949-1.87)/0.1}$
$= 1.020^{.249}$
= 1.0049

The onset of dialysis adjustment is applicable in Ted's case, and extends from March 20, 2011 through July 17, 2011 (120 days). During this period, no case-mix adjustments for co-morbidities may be applied because the onset of dialysis adjustment supersedes the application of case-mix adjusters for co-morbidities. Neither may the training add-on be paid for the 10 training treatments furnished during the period the onset of dialysis adjustment is in effect. The only pertinent case-mix adjustments are those for age, BSA, and the onset of dialysis. For the 120 day period from March 20, 2011, through July 17, 2011, Ted's PM is calculated as follows:

$PM_{TED} = PM_{age} * PM_{BSA} * PM_{Dial/Onset}$
= 1.171 * 1.0049 * 1.510
= 1.7769

Ted's ESRD payment rate per treatment from March 20, 2011 through July 17, 2011 would be:

$239.21 * 1.7769 * .969 = $411.88

For the 2 training treatments furnished between July 18 and July 21, the dialysis facility would receive a training add-on for each treatment, computed as follows:

Training rate—$33.44
Wage index—1.10
Training payment—$33.44 * 1.10 = $36.78

Because Ted has a chronic co-morbidity, sickle cell anemia, the payment rate per treatment for dialysis treatments beginning July 18 must reflect case-mix adjustments for age, BSA, and sickle cell anemia:

$PM_{Ted} = PM_{age} * PM_{BSA} * PM_{Sickle}$
= 1.171 * 1.0049 * 1.072
= 1.2615

Ted's ESRD payment rate per treatment (excluding the training add-on amount for 2 training treatments) would be:

$239.21 * 1.2615 = $301.76

Total payments for each of the 2 training treatments provided between July 18 and July 21 would be:

($301.76 + $36.78) * .969 = $328.05

For claims submitted beginning August 2011, Ted's dialysis facility correctly reported the co-morbidities of sickle cell anemia and bacterial pneumonia. Because payment can only be made for the condition which yields the highest payment where two or more co-morbidities apply, Table A in the Appendix reveals that bacterial pneumonia is the condition with the higher case-mix adjuster (1.135). Therefore, this is the co-morbidity that will be reflected in the computation of Ted's PM as follows for claims submitted for the 4 months of August 2011 through November 2011 (the maximum number of claim months an acute co-morbidity case-mix adjuster can be applied without a subsequent recurrence):

$PM_{Ted} = PM_{age} * PM_{BSA} * PM_{Pneum}$
= 1.171 * 1.0049 * 1.135
= 1.3356

Ted's ESRD payment rate per treatment for the months of August 2011 through November 2011 would be:

$239.21 * 1.3356 * .969 = $309.58

After November 2011, the only co-morbidity that would apply in computing the payment rate is Ted's chronic sickle cell anemia, for which the PM is 1.072. Beginning with claims submitted for the months of December 2011 and thereafter, assuming no other changes in Ted's condition, the payment rate per treatment would be based on the following case-mix adjusters:

$PM_{Ted} = PM_{age} * PM_{BSA} * PM_{Sickle}$
= 1.171 * 1.0049 * 1.072
= 1.2615

Beginning with monthly claims for December 2011 and thereafter, Ted's ESRD payment rate per treatment would be:

$239.21 * 1.2615 * .969 = $292.41

Example 5—Aged ESRD Patient With Low BMI (< 18.5kg/m2), History of Hospitalization, Multiple Co-Morbidities, and Treatment in a Facility Qualifying for the Low-Volume (LV) Adjustment

Agnes, an 82 year old female, is 160.02 cm. (1.6002 m.) in height and weighs 45.36 kg. She has longstanding type II diabetes mellitus and was diagnosed with ESRD in 2008. The patient has coronary artery disease and peripheral vascular disease. In January 2009, Agnes began dialyzing with an upper arm AV fistula which had been created the previous year. In March 2010, after an unsuccessful attempt to declot the AV fistula during hospitalization, Agnes experienced additional bleeding complications and has been dialyzed using a catheter ever since. In December 2010, the patient was admitted to the hospital after fainting during an outpatient dialysis treatment. She was diagnosed with pericarditis and discharged January 11, 2011. She resumed outpatient dialysis on January 13, 2011 at a facility which qualifies for the LV adjustment, because it has never had a treatment volume exceeding 3500 treatments since it opened in 2005. Her treating physician declared her free of pericardial inflammation on February 12, 2011. On April 10, 2011, Agnes was hospitalized with bacterial pneumonia and remained hospitalized until April 25. She resumed outpatient dialysis on April 28. Agnes was declared free of bacterial pneumonia on May 15, 2011, after post-hospitalization treatment with antibiotics. The facility submitted monthly claims for the months of January and February 2011 with the reported diagnosis of pericarditis. For dialysis treatments furnished during the month of March, the facility submitted a monthly claim reporting no co-morbidities. For dialysis treatments furnished Agnes during the months of April and May, the facility reported on the monthly claims the co-morbidity of bacterial pneumonia.

We must first use Agnes' height and weight to determine if a case-mix adjustment for low BMI applies and determine Agnes' BSA. BMI is computed as follows:

$BMI_{Agnes} = weight_{kg}/height(m^2)$
$= 45.36/1.6002^2$
= 45.36/2.5606
= 17.71

Agnes' BMI is less than 18.5. Therefore, her PM must include the 2.5 percent case-mix adjustment for underweight status.

The BSA formula is:

$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$

Agnes' BSA is calculated as:

$BSA_{Agnes} = 0.007184 * 160.02^{.725} * 45.36^{.425}$
= 0.007184 * 39.6302 * 5.0592
= 1.4404

Using the Table A in the Appendix multiplier of 1.020, Agnes' case-mix adjustment based on her BSA of 1.4404 is calculated as follows:

$PM_{BSA} = 1.020^{(1.4404-1.87)/0.1}$
$= 1.020^{-4.296}$
= .9184

The applicable factors that should be used to calculate Agnes' PM are the case-mix adjusters for age, BSA, low BMI, pericarditis, bacterial pneumonia, and the facility adjuster for LV.

For the months of January and February 2011, Agnes' ESRD facility reported on her monthly claims the pericarditis co-morbidity. Using the

Table A in the Appendix adjusters, Agnes' PM for the months of January and February may be expressed as:

$PM_{Agnes} = PM_{age} * PM_{BSA} * PM_{BMI} * PM_{Pericard} * PM_{LV} = 1.016 * .9184 * 1.025 * 1.114 * 1.189 = 1.2668$

Agnes' ESRD payment rate for treatments furnished in January, February, and March 2011 would be:

$239.21 * 1.2668 * .969 = $293.64

Although Agnes no longer had pericarditis as of February 12, 2011, her facility is entitled to payments for treatments furnished in March which reflect a case-mix adjustment for this acute co-morbidity, because case-mix for an acute co-morbidity may be applied for claims submitted for four claim months unless another co-morbidity yields a higher payment amount. Agnes' PM for April 2011 reflecting pericarditis is as follows:

$PM_{Agnes} * PM_{age} * PM_{BSA} * PM_{BMI} * PM_{Pericard} * PM_{LV} = 1.016 * .9184 * 1.025 * 1.114 * 1.189 = 1.2668$

Her PM reflecting the co-morbidity of bacterial pneumonia is:

$PM_{Agnes} = PM_{age} * PM_{BSA} * PM_{BMI} * PM_{Pneum} * PM_{LV} = 1.016 * .9184 * 1.025 * 1.135 * 1.189 = 1.2907$

Agnes' dialysis facility normally would be entitled to a payment adjustment for treatments reflecting the pericarditis co-morbidity for 3 claim months after February 2011, because a payment adjustment reflecting a co-morbidity may be paid for 4 claim months, including the month in which the diagnosis was present and dialysis treatments were furnished. However, in April Agnes was diagnosed with bacterial pneumonia. Because Agnes' PM based on pneumonia is higher than that for pericarditis, her payment rate for April 2011 will be based on the bacterial pneumonia co-morbidity as follows:

$239.21 * 1.2907 * .969 = $299.18

Because Agnes' dialysis facility is entitled to payments reflecting the bacterial pneumonia co-morbidity for claims for 4 claim months, the payment rate of $299.18 per treatment would apply for all treatments furnished in April through the month of July 2011, provided there are no other changes in Agnes' condition.

Example 6—Same as Example 1, With Outlier Payments (For a Description of the Outlier Payment Methodology, *See* Section II.H. of This Final Rule)

John receives HD 3 times weekly. However, in January 2011 he suffered a compound ankle fracture and was hospitalized for 4 days from January 10 through 14. During the hospitalization John did not undergo any dialysis treatments. After discharge John resumed his dialysis treatments, but it was noted that his dialysis clinical indicators were markedly perturbed from baseline values, requiring additional laboratory testing and above average doses of several injectable drugs, particularly EPO, to return them to normal levels. During January 2011 John received 9 outpatient HD treatments at his usual facility. The facility submitted a claim for allowable outlier services including drugs and biologicals, laboratory tests, and supplies totaling $3,000.00

Using Table A in the Appendix, we begin by computing the predicted outlier services MAP per treatment based on the SB case-mix adjustment factors for the PM variables applicable to John, age and BSA:

$SBPM_{John} = PM_{ageSB} * PM_{BSASB}$

John's BSA from Example 1 is 2.2161. Applying the SB adjustment factor from Table 10 for BSA, John's outlier services PM for BSA is computed as follows:

$SBPM_{BSA} = 1.014^{(2.2161 - 1.87)/0.1} = 1.014^{3.461} = 1.0493$

John's outlier services PM is calculated as:

$SBPM_{John} = .992 * 1.0493 = 1.0409$

From Table 28, we determine that the outlier services MAP per treatment for adult patients is $82.78. Therefore, the case-mix adjusted predicted outlier services MAP per treatment for John is:

$82.78 * 1.0409 = $86.17

Next, we determine the imputed outlier services MAP amount per treatment which reflects the cost of outlier services actually incurred by the ESRD facility. John's outlier services imputed amount averaged $3000.00/9 or $333.33 per session.

Next, we must determine if John's dialysis facility is entitled to outlier payments by comparing the predicted outlier services MAP amount to the imputed outlier services MAP amount. But first, we must add the fixed dollar loss amount to the predicted outlier services MAP amount.

The fixed dollar loss (FDL) amount for the predicted outlier services MAP, reflecting the case-mix adjustments for John for age and BSA is:

$John_{FDL} = $86.17 + $155.44 = 241.61

Because John's average outlier services MAP for the outlier services services received was $333.33, which exceeds the outlier services MAP plus the FDL totaling $241.61, John's ESRD facility is eligible for outlier payments beyond the otherwise applicable ESRD PPS payment amount of $251.45.

The outlier payments are calculated as follows:

Amount by which the imputed amount exceeds the predicted amount plus the FDL— $333.33 − $241.61 = $91.72

Loss sharing ratio—80%

Outlier payments per treatment—$91.72 * .80 = $73.38

Outlier payments—$73.38 * 9 treatments * .969 = $639.95

Regular ESRD payments for January 2011—$251.45 * 9 = $2263.05

Total ESRD PPS payments for January 2011—$2263.05 + $639.95 = $2903.00

Example 7—Pediatric ESRD Patient Receiving Treatments in a Low-Volume (LV) Facility; Outlier Payments Apply

Timmy is a 16 year old male with ESRD due to renal hypoplasia. The patient was on PD until 2009, when he received a deceased donor kidney transplant. Timmy's transplant failed in August 2010, and he has been on HD since that time. The patient receives dialysis through an AV graft. Timmy has a history of post-transplant lymphoma, which is in remission. He also has diabetes mellitus, which developed after the kidney transplantation. Timmy weighs 66.2 kg. and is 161.6 cm. in height. He was hospitalized in December 2010 with Staph bacteremia. As part of his HD, Timmy receives ARANESP® 60 mcg. IV q 2 weeks, paracalcitol 4 mcg. IV 3 times a week, and iron dextran 100 mg. IV every 2 weeks. The patient also takes 2 tablets, 667 mg. each of calcium acetate 3 times per day. Timmy had 12 HD treatments in January 2011. The ESRD facility, which qualifies for the LV adjustment for adult patients, submitted a January claim for allowable outlier services including drugs and biologicals, laboratory tests, and supplies totaling $3800.00.

Co-morbidities are not used to determine a pediatric patient's ESRD payment rate because these factors have been taken into account in the pediatric payment adjustments. Neither is the LV adjustment applicable to pediatric dialysis patients. The only variables relevant in determining Timmy's payment amount per treatment, without regard to outlier payments, are age and dialysis modality. Because Timmy is 16 and undergoes HD, Table B in the Appendix reveals that his pediatric classification group is category 4, for which the PM is 1.277. Timmy's payment rate per treatment, without regard to outlier payments, is:

$239.21 * 1.277 * .969 = $296.00

Timmy's dialysis facility would receive $296.00 for each of the 12

treatments it furnished in January 2011. Table B in the Appendix reveals that the SB case-mix adjustment factor for Timmy's pediatric classification group (cell 4) is 1.459.

From Table 28, we determine that the outlier services MAP per treatment for pediatric patients is $53.06. Therefore, the case-mix adjusted predicted outlier services MAP per treatment for Timmy is:

$53.06 * 1.459 = $77.41

Next, we determine the imputed outlier services MAP amount per treatment which reflects the cost of outlier services actually incurred by the ESRD facility. Timmy's outlier services imputed amount averaged $3800.00/12 or $316.67 per treatment.

We then determine if Timmy's dialysis facility is entitled to outlier payments by comparing the predicted outlier services MAP amount to the imputed outlier services MAP amount. But first, we must add the fixed dollar loss amount to the predicted outlier services MAP amount. The fixed dollar loss (FDL) amount for the predicted outlier services MAP, reflecting Timmy's pediatric classification group, is:

$Timmy_{FDL}$ = $77.41 + $195.02 = $272.43

Because Timmy's average outlier services MAP for the outlier services received was $316.67, which exceeds the outlier services MAP plus the FDL totaling $272.43, Timmy's ESRD facility is eligible for outlier payments beyond the otherwise applicable ESRD PPS payment amount of $296.00.

The outlier payments are calculated as follows:

Amount by which the imputed amount exceeds the predicted amount plus the FDL—$316.67 − $272.43 = $44.24
Loss sharing ratio—80%
Outlier payments per treatment—$44.24 * .80 = $35.39
Outlier payments—$35.39 * 12 treatments * .969 = $411.51
Regular ESRD payments for January 2011—$296.00 * 12 = $3552.00
Total ESRD PPS payments for January 2011—$3552.00 + $411.51 = $3963.51

Example 8—Pediatric ESRD Patient Receiving Training Treatments in a Low-Volume Facility

Andrew, a 12 year old male with diabetes mellitus, has been on CCPD since June 2010. Andrew's father has been deceased for 5 years. His mother, who assists him with his dialysis at home, will be unable to assist Andrew with dialysis beginning on February 10, 2011, because of major surgery which will leave her physically unable to participate in her son's care for an extended period of time. Andrew's Aunt Millie, who lives nearby, has agreed to be Andrew's caregiver and assist him with his dialysis. Millie required 17 training sessions at Andrew's dialysis facility, which is certified to provide home dialysis training, in order to become knowledgeable and skilled sufficiently to perform this role. These training sessions began February 16 and ended March 10. Andrew's dialysis facility, which has been open for 5 years, has never furnished more than 3100 treatments in a year, and qualifies for the low-volume (LV) adjustment.

Table B in the Appendix reveals that Andrew's pediatric dialysis classification group is cell 1, with an associated PM of 1.033. Although Andrew's dialysis facility is eligible for the LV adjustment for its adult patients, the LV multiplier does not apply to pediatric patients. During the months of January and February 2011, Andrew's ESRD payment rate per HD-equivalent treatment would be:

$239.21 * 1.033 * .969 = $239.44

However, Andrew's dialysis facility is entitled to receive payment for a maximum of 15 training treatments furnished in connection with Andrew's new caregiver, Aunt Millie. Because the amount of the training add-on is adjusted by the dialysis facility's wage index (1.10), the amount of the training add-on is calculated as follows:

Training rate—$33.44
Wage index—1.10
Training payment—$33.44 * 1.10 = $36.78

For the maximum number of 15 training treatments for which the training adjustment may be provided in connection with a PD patient, Andrew's payment rate, including the training add-on, would be:

($239.21 * 1.033 + $36.78) * .969 = $275.08

J. ESRD Bundled Market Basket

Under section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401 of Public Law 111–148, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute further provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. Under section 1881(b)(14)(F)(ii) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of Public Law 111–148, the ESRD bundled rate market basket increase factor will also be used to update the composite rate portion of ESRD payments during the ESRD PPS phase-in period from 2011 through 2013, though beginning in 2012, such market basket increase factor will be reduced by the productivity adjustment. We intend to address in future rulemaking the productivity adjustment that will be applicable beginning in 2012. With regard to application of the ESRD bundled rate market basket in CY 2011, we note that as a result of amendments by section 3401(h) of Public Law 111–148 to section 1881(b)(14)(F) of the Act, a full market basket will be applied to the composite rate portion of the blended payment during the first year of the transition (*i.e.,* 1.0 percentage point will not be subtracted). Therefore, we have modified § 413.196 by making conforming changes as a result of the Affordable Care Act.

As required under section 1881(b)(14) of the Act, effective for CY 2012 (and for purposes of the first year of the transition, CY 2011), CMS has developed an all-inclusive ESRD bundled rate (ESRDB) input price index. Although "market basket" technically describes the mix of goods and services used to produce ESRD care, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from that market basket. Accordingly, the term "ESRDB market basket" as used in this document refers to the ESRDB input price index.

A market basket has historically been used under the Medicare program to account for the price increases of the requisite inputs associated with the services furnished by providers. The percentage change in the ESRDB market basket reflects the average change in the price of goods and services purchased by ESRD facilities in providing renal dialysis services. Since a single payment rate exists for both operating and capital-related costs, the ESRDB market basket for ESRD facilities includes both operating and capital-related costs.

In the proposed rule (74 FR 49997 through 50003), we discussed the development of the proposed cost categories and their respective weights for the ESRDB market basket using CY 2007 as the base year, the choices of price proxies, and an explanation of the methodology and results of the proposed ESRDB market basket. As described in the proposed rule (74 FR 49997), using a base year of CY 2007 and Medicare cost report data, we first

computed cost shares for the following nine major expenditure categories: (1) Wages and Salaries, (2) Employee Benefits for direct patient care, (3) Pharmaceuticals, (4) Supplies, (5) Laboratory Services, (6) Blood Products, (7) Administrative and General and Other (A&O), (8) Housekeeping and Operations, and (9) Capital-Related costs. We then supplemented the Medicare Cost Report data with additional data sources and expanded these cost categories to ultimately derive the 16 proposed ESRDB market basket cost categories and weights (74 FR 49998 through 50001). Also in the proposed rule, we described our selection of, and the rationale for, the appropriate price proxies to measure the rate of price change for each category (74 FR 50001 through 50002), as well as provided the projected annual rates of growth in the ESRDB market basket for CY 2009 through CY 2019 based on the most recent forecast available at the time. Additionally, we proposed that the ESRDB labor-related share equal 38.160 percent, which represented the sum of the weights for the following cost categories: Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the cost weight for Professional Fees, and 46 percent of the weight for Capital-related Building and Equipment expenses (74 FR 50003).

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

Comment: A commenter expressed concern that the proposed ESRD bundled PPS suggests that 42.8 percent of the facility's ESRD treatment costs are labor-related. The commenter was concerned that staff levels will be reduced to compensate for the revenue loss realized by the regressive formula of the proposed payment system.

Response: The labor-related share in the ESRD bundled proposed rule was 38.160 percent (74 FR 50003). We are uncertain how the commenter calculated 42.8 percent. To provide clarification for the commenter, we note that the labor-related share of the ESRDB market basket is defined as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. This share represents the proportion of an ESRD facility's payment that is adjusted for geographic wage differences. As discussed below, we have made several methodological changes to the ESRDB market basket based on the public comments received. The new labor-related share is 41.737 percent. We will closely monitor the cost structure of the ESRD industry and the labor-related share of the ESRDB market basket, following implementation of the ESRD PPS. If new data show material shifts in the average cost structure for ESRD providers, including changes in the labor-related share, we will propose to rebase the ESRDB market basket, as technically appropriate.

Comment: Several commenters recommended using 2008 or 2009 as the base year for the ESRDB market basket in order to more accurately represent the changes in facility operating costs that resulted from the compliance with the Conditions for Coverage and other trends. Commenters stated that cost reports from 2008 are available for CMS to use, and although they are not settled, MedPAC analysis found little difference between submitted and settled cost reports.

Response: We agree with the commenters with regard to the issue of using more updated data for the base year for the development of the CY ESRDB market basket. As we indicated in the proposed rule, we proposed to use CY 2007 because it was the most recent year that both relatively complete Medicare cost report data and supplemental data from the Census' Business Expenditure Survey (BES) were available (74 FR 49997). That is, the proposed ESRDB market basket was developed over the winter of 2008 and spring of 2009. At that time, 2007 Medicare cost reports (MCR) represented the most complete set of data available. Therefore, the methodology used to finalize the proposed ESRDB market basket estimates was completed well in advance. The 2007 MCR data are comprised of financial data for ESRD facilities reporting on different fiscal years, including but not limited to federal fiscal, calendar, and "state" fiscal year (July 1 to June 30). A facility's MCR data are typically available between nine months and one year from the end of the facility's fiscal period. Since publication of the proposed rule, we have reviewed the 2007 MCR data using a complete sample and found that the cost weights are not materially different relative to those found in the proposed 2007 ESRDB market basket.

The agency monitors market basket cost weights regularly to determine if significant changes have occurred from one year to the next. To that end, and based on public comment, we have constructed and analyzed cost weights from the newly available 2008 MCRs and determined there has been a material shift in the cost structure of ESRDs from 2007 to 2008. Specifically, there was a notable decrease in the Pharmaceuticals cost weight for 2008 compared to 2007 (as discussed in more detail below). Therefore, we believe it is appropriate to use the 2008 MCR data for the base year cost weights of the ESRDB market basket. We will continue to closely monitor the cost report data as the ESRD PPS is implemented; and should we observe any additional material changes in the cost structure of the industry, we will propose to rebase and revise the ESRDB market basket accordingly.

Comment: Several commenters applauded CMS's decision to use the Producer Price Index (PPI) for prescription drugs as the price proxy for measuring price growth in ESRD drugs in the proposed ESRDB market basket.

Response: We appreciate commenters' support for using the PPI for prescription drugs as the price proxy for measuring price growth for the ESRD drugs cost category. In this rule, we are finalizing the selection of this proxy for the following three reasons:

(1) *Relevance:* This index contains an appropriate level of aggregation for use in the Medicare market baskets (including former Part D drugs covered in the ESRD bundle), as well as reflects competitive pricing observed in efficient markets.

(2) *Reliability:* This index represents a consistent time series and allows for projections of future price changes that are based on technically sound econometric modeling techniques that are widely accepted.

(3) *Timeliness/Public Availability:* The Bureau of Labor Statistics independently publishes this data on a monthly basis with no significant methodological changes.

Comment: Several commenters believe that a better price proxy for drugs in ESRD facilities is the National Health Expenditure (NHE) estimate of prescription drug spending.

Response: We believe the NHE estimate of prescription drug spending growth is not an appropriate price proxy for use in the ESRDB market basket. NHE growth rates reflect changes in total spending (that is, prices and quantities). The ESRDB market basket is intended to only reflect price changes, holding quantities fixed in a base year. For the reasons outlined above, we believe the PPI for prescription drugs is the appropriate price proxy to apply to the drugs cost category in the ESRDB market basket.

Comment: Several commenters opposed the use of the Employment Cost Index (ECI) for Health Care and Social Assistance as the price proxy for Wages and Salaries. These commenters recommended that CMS use the ECI for Hospitals as the price proxy because

they claim it more accurately reflects the occupational mix in ESRD facilities than the ECI for Health Care and Social Assistance.

Response: In the proposed rule, we proposed to use the ECI for Health Care and Social Assistance to proxy the Wages and Salaries cost category (74 FR 50001). That selection was largely driven by the ESRD industry's inclusion in the North American Industry Classification System's (NAICS) category 621, Ambulatory Health Care Services, which is one component that makes up the ECI for Health Care and Social Assistance (NAICS 62).

In response to commenters' concerns, we have reviewed the occupational mix of ESRD facilities and compared it in detail to that of hospitals (found in NAICS category 622), nursing and residential care facilities (found in NAICS category 623), and the compilation of industries contained in the Health Care and Social Assistance category (NAICS category 62). To do this, we compared Full Time Equivalent (FTE) data from the ESRD Medicare cost reports with occupational composition data found in the Occupational Employment Statistics produced by the Bureau of Labor Statistics (BLS). We found that ESRD facilities have a somewhat unique occupational mix that differs, to varying degrees, from hospitals, nursing and residential care facilities, and the compilation of industries found in the health care and social assistance classification. These three comparisons were selected as they represent the health industries for which ECIs are available.

Based on our analysis, we agree with the commenters that it would be appropriate to consider the use of the ECI for Hospitals as a price proxy for this category. In our follow-up analysis, we noted that the ESRD industry's occupational and skill mix (including physicians, registered nurses (RN), licensed practical nurses (LPN), and a variety of technicians) is not fully represented in NAICS category 62 (Health Care and Social Assistance). In comparing the ESRD occupational mix to the occupational mix of hospitals, we found that for many of the higher skilled occupations, the ESRD industry did bear certain similarities to that of the hospital industry. As a result, we have determined it would be appropriate to account for the unique occupational mix in ESRD facilities by utilizing a blended price proxy for the Wages and Salaries cost category. The blended proxy will incorporate the Wages and Salaries ECI for Health Care and Social Assistance (representing 50 percent of the blend) and the Wages and Salaries ECI for Hospitals (representing the other 50 percent of the blend). In addition to using a blended ECI as the price proxy for Wages and Salaries, we will also use a blended ECI as the price proxy for the Benefits cost category using the same 50/50 ratio. Those ECIs include the Benefits ECI for Health Care and Social Assistance (50 percent) and the Benefits ECI for Hospitals (50 percent).

Comment: Several commenters requested that CMS provide additional detail on the ESRDB market basket, stating that there were holes in documenting the methodology for its development. Particularly, the commenters stated that CMS omitted a significant amount of detail on the price proxies and did not provide the prospective reference data from which the price proxies are extracted. These commenters requested that CMS put the detailed forecast of the price proxies on the CMS Web site for public view. They noted that the information provided should be available to replicate the results of the ESRDB market basket, as proposed.

Response: We agree that the public should be able to replicate the methodology used to construct the ESRDB market basket. We disagree, however, with the commenters' claim that the proposed rule lacked significant documentation regarding the methodology used to construct the ESRDB market basket. The proposed rule provided a detailed description of the data sources used to develop the ESRDB market basket cost weights (74 FR 50001). Likewise, as indicated in the proposed rule, the price proxies used in the ESRDB market basket were listed for each cost category and are based on data maintained and published by the BLS (74 FR 50001 through 50002). We would refer the commenter to BLS regarding any specific information on the detailed price proxies.

To assist the commenter and other interested stakeholders in locating these price proxies on the BLS Web site, we have provided the individual BLS series codes for the indexes in the price proxy discussion of this final rule (below). The price proxies can be obtained by entering these codes at the BLS Web site (*http://data.bls.gov/cgi-bin/srgate*). Regarding the individual forecasts of the price proxies used to develop the CY 2011 ESRDB market basket update factor, these forecasts are developed by IHS Global Insight, Incorporated (IGI), a nationally recognized economic and financial forecasting firm. We purchase IGI's detailed price proxy projections for use in the Medicare market baskets. As a matter of practice, we publish all of the underlying detail for each price proxy for the historical period. However, because the projections of each individual price proxy are proprietary, we typically aggregate those projections into higher level categories and then publish the results with usually a one-quarter lag. Since the ESRDB market basket is a new market basket that is still progressing through the rule-making process, we have not published additional detail other than what has been published in the proposed rule. Following implementation of this PPS, we will begin publishing the ESRDB market basket, including the detail as described above, on the CMS Web site (*http://www.cms.hhs.gov/MedicareProgramRatesStats/04_MarketBasketData.asp#TopOfPage*).

Comment: Several commenters stated that CMS did not specify a plan for the frequency of rebasing and revisions of the ESRDB market basket. Commenters stated that CMS usually rebases on a 4-year cycle in other provider indexes. They noted that this is an appropriate timeframe for the rebasing of the ESRDB market basket.

Response: We monitor the market basket cost weights regularly to determine if significant changes have occurred from one year to the next. In general, we have typically proposed to rebase and revise the market baskets roughly every five years; although we have proposed alternatives to that rate when technically appropriate or when mandated by law (for example, the Inpatient Hospital Prospective Payment System (IPPS) market basket is required to be rebased more frequently than every five years, in accordance with Section 404 of Pub. L.108–173). We are unable to provide a specific rebasing schedule for the ESRDB market basket, in part, because this is a new payment system that is being implemented making it particularly difficult to say with certainty how frequently rebasings would be technically appropriate. In general, we do not explicitly state how often any market basket will be rebased or revised, unless there is a mandated rebasing schedule. As is the agency's practice, we will continuously monitor the composition of the new ESRDB market basket to determine the next technically appropriate time to rebase and revise the index. At that time, the agency will go through the notice and comment rulemaking process including proposing and finalizing any changes after consideration of public comments.

Comment: One commenter believes that the ESRDB market basket update will not address the low margins for small dialysis organizations (SDOs), especially in the context of a two

percent reduction in payments under the ESRD PPS. The commenter stated that ESRDB market basket updates to payments in the following years should reflect increases in costs, and that it will likely not be enough to increase the SDO margins even to current levels.

Response: The impact on SDOs is addressed in section IV.B of this final rule. The ESRDB market basket calculations produced by the Office of the Actuary in CMS are constructed entirely independent from any margins analysis. The ESRDB market basket updates represent the net result of combining price projections for each individual cost category with that category's respective cost weight.

Notably, the CMS market baskets are not intended to update payments based on projected costs, which are equal to prices multiplied by quantities. The purpose of the ESRDB market basket, rather, is to update the base payment rate to account for the projected input price inflation associated with the goods and services required to provide ESRD bundled services while holding that market basket of goods and services constant.

As a result of public comments, we have made several methodological changes to the proposed ESRDB market basket. First, as discussed above, we are using a 2008 base year rather than a 2007 base year for the ESRDB market basket. This year represents the latest year for which appropriately complete data are available. Second, we have changed the price proxies for the Wages and Salaries and the Benefits cost categories from ECIs for Health Care and Social Assistance (NAICS category 62) to blended indexes of the ECIs for Hospitals and the ECIs for Health Care and Social Assistance (as detailed above). Third, we are no longer including blood and blood products in the ESRDB market basket.

In the proposed rule, blood and blood products were included in the proposed ESRDB market basket (74 FR 49999) since these products were included in the proposed ESRD bundled payment. However, as explained in section II.A.4. of this final rule, we have decided to remove blood and blood products from the bundled payment in response to public comment. Therefore, since blood and blood products are no longer included in the ESRD bundled payment, it is no longer appropriate to include that category in the ESRDB market basket.

Lastly, we are delaying the inclusion of costs associated with oral-only drugs and biologicals formerly covered under Part D that have no injectable equivalents (or other form of administration) in the ESRDB market basket. Similar to blood and blood products, these costs were included in the ESRDB market basket in the proposed rule (74 FR 49999) due to these products being included in the proposed ESRD bundled payment. However, in response to public comment, CMS has decided to delay implementation of including ESRD-related oral-only Part D drugs (without injectable equivalents or other forms of administration) in the bundled payment, as stated in section II.A.3. of this final rule. Therefore, it is no longer appropriate to include the costs associated with these products in the ESRDB market basket for this final rule.

Below we discuss the ESRDB market basket we are finalizing, including the changes noted above. Additionally, in response to public comments, where relevant, we include the applicable BLS series code for the various price proxies. We believe this provides added transparency for the new ESRDB market basket.

Cost Category Weights

The ESRDB market basket cost weights in this final rule are based on the CY 2008 cost report data for independent ESRD facilities. We refer to the ESRDB market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2008 = 100. Source data included CY 2008 Medicare cost reports (Form CMS–265–94), supplemented with 2002 data from the U.S. Department of Commerce, Bureau of the Census' Business Expenditure Survey (BES). The BES data were aged to 2008 using appropriate price proxies to estimate price growth. The price proxies used for the aging of the BES data come from publicly available price indexes such as various producer price indexes (PPI), consumer price indexes (CPI), or employment cost indexes (ECI). All of these price proxies are based on data published by the U.S. Department of Labor, Bureau of Labor Statistics (BLS).

Using Worksheets A, A2, and B from the CY 2008 Medicare cost reports, we first computed cost shares for eight major expenditure categories: Wages and Salaries, Employee Benefits for direct patient care, Pharmaceuticals, Supplies, Laboratory Services, Administrative and General and Other (A&O), Housekeeping and Operations, and Capital-Related costs. In the proposed rule, we had initially computed cost shares for nine major expenditure categories (74 FR 49997); however, as stated earlier, we are now removing blood and blood products from the ESRDB market basket for this final rule, and therefore, we now yield one less major expenditure category than stated in the proposed rule. Edits were applied to include only cost reports that had total costs greater than zero. In order to reduce potential distortions from outliers in the calculation of the cost weights for the major expenditure categories, cost values for each category less than the 5th percentile or greater than the 95th percentile were excluded from the computations. The resulting data set included information from approximately 3,869 independent ESRD facilities' cost reports from an available pool of 4,299 cost reports. Expenditures for the eight cost categories as a proportion of total expenditures are shown in Table 30 below. We note that the values calculated for the cost weights in this table differ from those that were published in the proposed rule (74 FR 49998). This is a result of several factors including: The use of 2008 Medicare cost report data rather than 2007 Medicare cost report data, the removal of blood and blood products costs from the ESRDB market basket, and the removal of costs associated with ESRD-related oral Part D drugs without injectable equivalents from the ESRDB market basket. While some of these changes in the cost weights are minor, we discuss the more notable differences in the CY 2007 and CY 2008 cost weights in the text below.

Table 30—Initial 2008-Based End-Stage Renal Disease Bundled Rate Major Cost Categories and Weights Determined from the Medicare Cost Reports

Expense Category	CY 2008-Based Weights
Wages and Salaries	26.338%
Benefits for Direct Patient Care	5.163%
Pharmaceuticals	26.358%
Supplies	9.726%
Laboratory Services	0.356%
Housekeeping and Operations	3.604%
Administrative and General, and Other	17.594%
Capital-Related Costs	10.861%
Total	100.000%

Note: Totals may not sum to 100 percent due to rounding

Some costs that are required to be included in the ESRD bundled payment are not reported on the Medicare cost report. As a result, we supplemented Medicare cost report data with expenditure estimates for various ESRD-related oral drugs with injectable equivalents that are currently covered by Medicare Part D, as well as with additional lab expenses. The estimates for both of the aforementioned expenditures were provided by Kidney Epidemiology and Cost Center of the University of Michigan (UM–KECC). There are also costs that are reported on the Medicare cost report that are not included in the ESRD bundled payment. For instance, expenses related to vaccine costs were removed from total expenditures since these are excluded from the ESRD bundled payment.

We expanded the expenditure categories developed from the Medicare cost reports to allow for a more detailed expenditure decomposition. To expand these cost categories, BES data were used as the Medicare cost reports do not collect detailed information on the items in question. Those categories include: Benefits for all employees, professional fees, telephone, utilities, and all other services. We chose to separate these categories to more accurately reflect changes in ESRD facility costs. We describe below how the initially computed categories and weights were modified to yield the final ESRDB market basket expenditure categories and weights presented in this final rule.

Wages and Salaries

The weight for Wages and Salaries that was initially computed was derived from Worksheet B of the Medicare cost report. However, because Worksheet B only includes direct patient care salaries, it was necessary to derive a methodology to include all salaries, not just direct patient care salaries, in order to calculate the appropriate ESRDB market basket cost weight. This was accomplished in four steps, as follows:

(1) From the trial balance of the cost report (Worksheet A), we computed the ratio of salaries to total costs in each cost center. The cost centers for which we calculated this ratio were drugs, housekeeping and operations, A&O, supplies, laboratories, capital-related machinery, and EPO.

(2) We then multiplied the ratios computed in step 1 by the total costs for each corresponding cost center from Worksheet B. This provided us with an estimate of non-direct patient care salaries for each cost center.

(3) The estimated non-direct patient care salaries for each of the cost centers on Worksheet B estimated in step 2 were subsequently summed and added to the direct patient care salary figure (resulting in a new total salaries figure).

(4) The estimated non-direct patient care salaries (*see* step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

As a result of this process, we moved from an estimated Wages and Salaries cost weight of 22.297 percent (as estimated using only direct patient care salaries as a percent of total costs found on the Medicare cost report) to a weight of 26.338 percent (capturing both direct and non-direct patient care salaries and, again, dividing that by total costs found on the Medicare cost report), as seen in Table 30. For comparison purposes, we note that the Wages and Salaries cost weight in the proposed rule was 25.106 percent (74 FR 49998).

When we add the expenditures related to laboratory expenses that were previously paid for under the Medicare fee schedule, and are not included in the Medicare cost report, the expenditures for ESRD-related oral drugs with injectable equivalents that are currently covered under Part D that are not included in the Medicare cost report, and remove the estimated vaccine costs that are to be paid outside of the bundle, then the cost weight for the Wages and Salaries category falls to 24.965 percent.

The final adjustment made to this category is to include contract labor costs. These costs appear on the Medicare cost report; however, they are embedded in the Administrative and General and Other category and cannot be disentangled using the Medicare cost reports alone. To move the appropriate expenses from the A&O category to Wages and Salaries, we used data from the BES. We first summed total contract labor costs in the survey. We then took 80 percent of that figure and added it to Wages and Salaries. At the same time, we subtracted that same amount from A&O. The 80-percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor). The resulting cost weight for Wages and Salaries increases to 26.755 percent.

Benefits

The Benefits weight was derived from the 2002 BES data aged forward to 2008 as a benefit share for all employees is not available from the ESRD Medicare cost report. Due to the change in the base year from CY 2007 (used in the proposed rule (74 FR 49998)) to CY 2008 (used in this final rule), the 2002 BES data for each of the appropriate cost categories were aged to 2008 as opposed to 2007. The cost report only reflects benefits associated with direct patient care. In order to include the benefits related to non-direct patient care, we estimated this marginal increase from

the BES Benefits weight. This resulted in a Benefits weight that was 1.143 percentage point larger (6.306 vs. 5.163) than the Benefits weight for direct patient care calculated directly from the cost reports. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.143 percentage point for Benefits from Pharmaceuticals, Administrative and General and Other, Supplies, Laboratory Services, Housekeeping and Operations, and the Capital-related Machinery components. This calculation reapportions the benefits expense for each of these categories using a method similar to the method used for distributing non-direct patient care salaries as described above.

The final adjustment made to this category is to include contract labor costs. Once again, these costs appear on the Medicare cost report; however, they are embedded in the Administrative and General and Other category and cannot be disentangled using the Medicare cost report alone. To move the appropriate expenses from the A&O category to Benefits, we followed the same methodology used to apportion contract labor wages and salaries noted immediately above. For Benefits, we applied the remaining 20 percent of total contract labor costs, as estimated using the BES, and included that in the Benefits cost weight. At the same time, we subtracted that same amount from A&O. The 20-percent figure that was used was determined by summing direct patient care benefits (as estimated using the Medicare cost report) and non-direct patient care benefits (as estimated using the BES) and taking that sum as a percentage of total compensation (excluding contract labor). The resulting cost weight for Benefits increases to 6.754 percent.

Utilities

We developed a weight for Utility expenses using the 2002 BES data, as utilities are not separately identified on the Medicare cost report. We aged these 2002 BES-based utility expenditures to 2008. We then disaggregated the Utilities category to reflect three subcategories: Electricity, Fuel (Natural Gas), and Water and Sewerage. We computed the ratio of each BES category to the total BES operating expenses. We then applied each ratio to the total operating expense percentage share as calculated from the cost reports, including the additions of ESRD-related oral drugs with injectable equivalents that are currently covered under Part D and additional lab expenses, to estimate the ESRD facility weight for each utility expenditure category. These amounts were then deducted from the share of the combined Operation & Maintenance of Plant and Housekeeping cost category, where the expenses are included on the Medicare cost report (but cannot be separately identified). The resulting Electricity, Fuel (Natural Gas), and Water and Sewerage ESRDB market basket weights are 0.621, 0.127, and 0.516 percent, respectively, yielding a combined Utilities cost weight of 1.264 percent.

Pharmaceuticals

The ESRDB market basket includes expenditures for all drugs included in the ESRD bundled payment, including separately billable drugs and ESRD-related oral drugs with injectable equivalents that are currently covered under Medicare Part D. We were able to calculate an expenditure weight for pharmaceuticals directly from the Drugs cost center on Worksheet B plus the expenditures of EPO which are reported on worksheet A2 of the Medicare cost reports. Vaccine expenditures, which are mandated as separately reimbursable, were excluded when calculating this cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these drugs are excluded from other prospective payment systems, we exclude them from the ESRDB market basket, as well. We estimate that expenditures for these three vaccines are approximately 1 percent of the total Medicare-allowable payments for separately billable drugs. The resulting cost weight determined from the Medicare cost report for Pharmaceuticals is 26.358 percent, as seen in Table 30. For comparison purposes, we note that this cost weight in the proposed rule was 28.775 percent (74 FR 49998).

Expenditures in 2008 for ESRD-related oral drugs with injectable equivalents that are currently covered under Part D were added to cost report totals. The estimate we used for these ESRD-related Part D drugs with injectable equivalents, provided by UM–KECC, is approximately $15 million for 2008. Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with the Drugs and Epoetin cost centers. This resulted in an ESRDB market basket weight for Pharmaceuticals of 25.52 percent. EPO expenditures accounted for 17.359 percentage points of the Pharmaceuticals weight, ESRD-related oral drugs with injectable equivalents that are currently covered under Part D accounted for 0.153 percentage point of the Pharmaceuticals weight, and all other drugs accounted for the remaining 7.541 percentage points of the Pharmaceuticals weight.

Supplies

We calculated the weight for Supplies included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Supplies cost center on Worksheet B of the Medicare cost report. Supplies that are separately billable are reported as a separate line item on the cost reports and were also included. This total was divided by total expenses to derive a weight for the Supplies component in the ESRDB market basket. The computed weight for this category was reduced by the non-direct patient care salaries and benefits associated with the Supplies cost center. The resulting ESRDB market basket weight for Supplies is 9.216 percent.

Laboratory Services

We calculated the weight for Laboratory Services included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Laboratory cost center on Worksheet B of the Medicare cost report. The cost report expenditures do not include laboratory services paid for under the Medicare fee schedule, only facility-furnished laboratory tests. Since a large majority of laboratory tests are paid via the fee schedule, we adjusted the laboratory fees upward. The inflation factor was computed from the ratio of ESRD facility Medicare laboratory payment data to the other facility Medicare laboratory payment data. This provides a measure of the extent to which laboratory services fall under the Medicare fee schedule. The weight for this category was similarly reduced by the non-direct patient care salaries and benefits associated with the Laboratory cost center. The resulting ESRDB market basket weight for Laboratory Services is 5.497 percent.

Housekeeping and Operations

We developed a market basket cost weight for this category using data from Worksheet A of the Medicare cost reports. Worksheet B combines the capital-related costs for buildings and fixtures with the Operation and Maintenance of Plant (Operations) and Housekeeping cost centers, so we were unable to calculate a weight directly from Worksheet B. We separated these

expenses from capital-related costs because we believe housekeeping and operations expenditures, such as janitorial and building services costs, are largely service-related and would be more appropriately proxied by a service-related price index. To avoid double-counting, we subtracted from the Housekeeping and Operations weight the utilities proportion described above, as well as the non-direct patient care salaries and benefits share associated with the Operations and Housekeeping cost center. The resulting ESRDB market basket cost weight for Housekeeping and Operations is 2.029 percent.

Administrative and General and Other (A&O)

We computed the proportion of total A&O expenditures using the A&O cost center data from Worksheet B of the Medicare cost reports minus the A&O expenditures related to the Blood Products and Vaccine categories. As described above, we exclude contract labor from this cost category and apportion these costs to the salary and benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude salaries and benefits associated with the A&O cost center. The resulting A&O cost weight is 13.899 percent. This A&O cost weight is then fully apportioned to derive detailed cost weights for Professional Fees, Telephone, All Other Labor-Related Services, and All Other Nonlabor-related Services.

Professional Fees

A separate weight for Professional Fees was developed using the 2002 BES data aged to 2008. Professional fees include fees associated with the following: advertising, accounting, bookkeeping, legal, management, consulting, administrative, and other professional services fees. To estimate professional fees, we first calculated the ratio of BES professional fees to a total of administrative and other expenses from BES. We applied this ratio to the A&O total cost weight to estimate the proportion of ESRD facility professional fees. The resulting weight is 1.773 percent. This cost weight is then separated into Labor-related Professional Fees (1.549 percent) and Nonlabor-related Professional Fees (0.224 percent), which is described in more detail below.

Telephone

Because telephone service expenses are not separately identified on the Medicare cost report, we developed a Telephone Services weight using the 2002 BES expenses aged to 2008. We estimated a ratio of telephone services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the proportion of ESRD facility telephone expenses. The resulting ESRDB market basket cost weight for Telephone Services is 0.597 percent.

All Other Labor-Related Services

A separate weight for All Other Labor-related Services was developed using the 2002 BES data aged to 2008. All other labor-related services include repair and maintenance fees. We estimated a ratio of all other labor-related services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the cost weight for ESRD facility All Other Labor-related Services. The resulting ESRDB market basket cost weight is 1.219 percent.

All Other Nonlabor-Related Services

A separate weight for All Other Nonlabor-related Services was developed using the 2002 BES data aged to 2008. Non labor-related services include insurance, transportation, shipping, warehousing, printing, data processing services, and all other operating expenses not otherwise classified. We estimated a ratio of all other nonlabor-related services expenses to total administrative and other expenses from BES. We applied this ratio to the total A&O cost weight to estimate the cost weight for ESRD facility All Other Nonlabor-related Services. The resulting ESRDB market basket cost weight is 10.311 percent.

Capital

We developed an ESRDB market basket cost weight for the Capital category using data from Worksheet B of the Medicare cost reports. Capital-related costs include depreciation and lease expense for buildings, fixtures, movable equipment, property taxes, insurance, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because housekeeping and operations costs are included in the Worksheet B cost center for Buildings and Fixtures capital-related expense, we excluded these costs and developed a separate expenditure category as noted above. Similar to the methodology used for other ESRDB market basket cost categories with a salaries component, we computed a share for non-direct patient care salaries and benefits associated with the Capital-related Machinery cost center. We used Worksheet B to develop two capital-related cost categories, one for Buildings and Fixtures, and one for Machinery. We reasoned this was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Fixtures could move differently than those associated with Machinery, we believe that separate price proxies would be more appropriate to track price changes for the different capital-related categories over time. The resulting ESRDB market basket cost weights for Capital-related Buildings and Equipment and Capital-related Machinery are 7.459 and 2.074 percent, respectively.

Table 31 lists all of the expenditure categories in the ESRDB market basket and their corresponding CY 2008 cost weights and proxies, as developed in accordance with the methodology described above. For comparison purposes, we have added the corresponding CY 2007 cost weights as published in the proposed rule (74 FR 50010).

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Table 31—ESRDB Market Basket Cost Categories, Price Proxies, and Cost Weights

Cost Category	Price/Wage Variable	ESRDB Market Basket CY 2008 Weights (Percent)	ESRDB Market Basket CY 2007 Weights (as proposed) (Percent)
Total Compensation		33.509	30.693
Wages and Salaries	Blend of Wages and Salaries ECI for Hospitals and Wages and Salaries ECI for Health Care and Social Assistance	26.755	24.516
Employee Benefits	Blend of Benefits ECI for Hospitals and Benefits ECI for Health Care and Social Assistance	6.754	6.177
Utilities		1.264	1.180
Electricity	PPI - Commercial Electric Power	0.621	0.586
Natural Gas	PPI - Commercial Natural Gas	0.127	0.111
Water and Sewerage	CPI - Water & Sewerage Maintenance	0.516	0.483
All Other Materials		39.765	44.161
Pharmaceuticals	PPI – Pharmaceuticals for Human Use (Prescription)	25.052	30.743
Supplies	PPI- Medical, Surgical, and Personal Aid Devices	9.216	8.543
Laboratories	PPI- Medical and Diagnostic Laboratories	5.497	4.875
All Other Services		15.929	15.383
Telephone	CPI - Telephone Services	0.597	0.590
Housekeeping and Operations	PPI – Janitorial Services	2.029	1.766
Labor-related		2.768	2.641
Professional fees Labor-related	ECI - Compensation for Professional and Related Occupations (Priv.)	1.549	1.478
All Other Labor-related Services	ECI - Compensation for Service Occupations (Priv.)	1.219	1.163
Nonlabor-related		10.535	10.386
Professional fees Nonlabor-related	ECI- Compensation for Professional and Related Occupations (Priv.)	0.224	0.214

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Price Proxies

Once we determined the CY 2008 ESRDB market basket expenditure categories and weights, appropriate wage and price series or proxies were selected to measure the rate of price change for each category. All of the proxies are based on BLS data, and are grouped into one of the following three BLS categories:

(1) *PPIs:* PPIs measure changes in the prices producers receive for their outputs. PPIs are the preferable price proxies for goods and services that ESRD facilities purchase as inputs in producing dialysis services, since these facilities generally make purchases in the wholesale market. The PPIs that we use measure price change at the final stage of production.

Cost Category	Price/Wage Variable	ESRDB Market Basket CY 2008 Weights (Percent)	ESRDB Market Basket CY 2007 Weights (as proposed) (Percent)
All Other Nonlabor-related Services	CPI - All Items Less Food and Energy	10.311	10.172
Capital Costs		9.533	8.547
Capital Related-Building and Equipment	CPI – Owner's Equivalent Rent	7.459	6.653
Capital Related-Machinery	PPI - Electrical Machinery and Equipment	2.074	1.894

Note: Detail may not add to total due to rounding. The detailed cost weights for the proposed ESRDB CY 2007 Market Basket in this table do not sum to 100 percent since the Blood and Blood Products cost category is not listed. As described above, we are no longer including these costs in the ESRDB market basket.

(2) *CPIs:* CPIs measure changes in the prices of final goods and services purchased by the typical consumer. Because these indexes may not reflect the prices faced by a producer, we used CPIs only if an appropriate PPI was not available, or if the expenditure more closely resembled a retail rather than wholesale purchase. For example, we used the CPI for telephone services as a proxy for the Telephone cost category because there is no corresponding PPI, and we reasoned that commercial and residential rates change similarly.

(3) *ECIs:* ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. They are fixed-weight indexes that strictly measure changes in wages and benefits per hour, and are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs we use meet these criteria.

Wages and Salaries

As discussed above, we use a blend of the Wages and Salaries ECI for Hospitals (Civilian) (50 percent)(series code CIU1026220000000I) and the Wages and Salaries ECI for Health Care and Social Assistance (Civilian) (50 percent) (series code CIU1026200000000I) as the measure of price growth for Wages and Salaries in ESRD facilities. This particular blend was chosen to—(1) account for the presence of ESRDs in NAICS 62 (Health Care and Social Assistance), and (2) reflect the similarities observed in the occupational mixes between the ESRD industry and the hospital industry. We believe this approach results in an appropriate price index that reflects changes in the price of wages and salaries in the ESRD industry.

Benefits

As discussed above, we use a blend of the Benefits ECI for Hospitals (Civilian) (50 percent) and the Benefits ECI for Health Care and Social Assistance (Civilian) (50 percent) as the measure of price growth for Benefits in ESRD facilities. We believe this approach results in an appropriate price index that reflects changes in the price of benefits in the ESRD industry.

Professional Fees

We use the Compensation ECI for Professional and Related Occupations (Private) (series code CIU2010000120000I) as the proxy for professional fees. We selected this price proxy because it includes occupations such as lawyers, accountants, and bookkeepers that are represented in this cost category.

Utilities

We use the PPI for Commercial Electric Power (series code WPU0542) and the PPI for Commercial Natural Gas (series code WPU0552) as the proxies for the Electricity and Natural Gas cost categories, respectively. We use the CPI for Water and Sewerage Maintenance (series code CUUR0000SEHG01) as the price proxy for the Water and Sewerage cost category.

Capital-Related—Building and Equipment

We use the CPI for Owner's Equivalent Rent of Residences (series code CUUR0000SEHC) as the price proxy for the Capital-related Building and Equipment cost category. We refer to this price proxy generally as the CPI for Residential Rent. As described earlier, this cost category includes building and fixtures, leased buildings, fixed equipment, and moveable equipment. Because machine equipment, particularly dialysis machines, is reflected in a separate cost category, the bulk of the expenditures captured here are for building and fixed equipment. Therefore, we would prefer to have a proxy that captures the price change associated with this type of capital expense. While there can sometimes be differences in the price levels for residential and commercial rent, we believe the CPI for Residential Rent approximates the change in the underlying costs associated with ESRD facilities' capital costs such as depreciation, interest, taxes, and other capital costs. Given the lack of an ESRD-specific proxy for capital costs, we believe that the CPI for Residential Rent represents the best available proxy for the changes in capital costs facing ESRD facilities.

Capital-Related—Machinery

We use the PPI for Electrical Machinery and Equipment (series code

WPU117) as the price proxy for the capital-related machinery cost category. This PPI includes dialysis machines, which are a significant component of machine equipment costs reported by ESRD facilities. Therefore, we believe that this price proxy is the best measure of the price growth of this cost category.

Pharmaceuticals

ESRD facilities use a variety of drugs during dialysis treatment including EPO which is currently a separately billable drug and accounts for the majority of ESRD facility drug expenses. We pay for erythropoietic agents to treat chronic anemia in ESRD patients. At present, Epogen© and ARANSP© (both manufactured by a single supplier) are two of the prevailing erythropoietic drugs available to treat anemia in ESRD patients. Medicare is the dominant purchaser of EPO since it is mainly used to treat kidney dialysis patients. For the ESRDB market basket, we use the PPI for Pharmaceuticals for Human Use (Prescription) (series code WPUSI07003) as the price proxy for the Pharmaceuticals category. We refer to this price proxy generally as the PPI for Prescription Drugs. We use this proxy for a variety of reasons. First, all of the market baskets that we produce include price proxies that are intended to reflect the efficient average price increase associated with the purchase of the particular input category. Accordingly, we have chosen to proxy the Pharmaceuticals cost category in the ESRDB market basket, which includes the mix of all prescription drugs purchased by dialysis facilities, by the PPI for Prescription Drugs because it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. Second, we anticipate the price changes associated with the assortment of drugs administered in ESRD facilities should, over time, be similar to the average prescription drug price changes observed across the entire economy. Finally, this price series was chosen as it is both publicly available and regularly published.

Supplies

We use the commodity-based PPI for Medical, Surgical, and Personal Aid Devices (series code WPU156) as a proxy for changes in ESRD supply prices. Many of the supplies used in dialysis are included in this PPI, such as dialyzers, catheters, I.V. equipment, syringes, and other general medical supplies used in dialysis treatment.

Laboratory Services

We use the PPI for Medical and Diagnostic Laboratories (series code PCU6215—6215—) as the price proxy for the ESRD Laboratory Services cost category. Most of the laboratory tests used in dialysis are blood chemistry tests (a covered component of the PPI for Medical and Diagnostic Laboratories). Additionally, some ESRD facilities are using diagnostic imaging services to monitor patient site access, and the points where waste exchange takes place (also a covered component of this price proxy).

Telephone

We use the CPI for Telephone Services (series code CUUR0000SEED) as the price proxy for the Telephone cost category. This index is used as the price proxy for Telephone Services in other market baskets produced by CMS.

Housekeeping and Operations

We use the PPI for Janitorial Services (series code PCU561720561720) as the price proxy for the Housekeeping and Operations cost category. This is the same price proxy that was used in the proposed rule; however, we referred to this proxy as the PPI for Building, Cleaning and Maintenance in the proposed rule (74 FR 50002). This PPI includes housekeeping, janitorial, and maintenance (excluding repairs) services, and is representative of the types of costs included in this cost category.

All Other Labor-Related Services

We use the Compensation ECI for Service Occupations (Private) (series code CIU2010000300000I) as the price proxy for the All Other Labor-Related Services cost category. This category includes expenses related to repair services. We feel that the service occupations most accurately reflect the costs for these types of repair and maintenance services purchased by ESRD facilities.

All Other Nonlabor-Related Services

We use the CPI for All Items Less Food and Energy (series code CUUR0000SA0L1E) as the price proxy for the All Other Nonlabor-Related Services cost category. This category includes costs such as data processing, purchasing, taxes, home office costs, and malpractice costs. The costs represented in this category are diverse and are primarily associated with the purchase of services. These costs are best represented by a general measure of inflation such as the CPI for All Items Less Food and Energy. Food and energy are excluded from the index to remove the volatility associated with those items. Additionally, energy prices are already captured in the utility price proxies.

ESRDB Market Basket Increases

The final ESRDB market basket reflects the combination of cost weights and price proxies discussed above. As explained above, under section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of Public Law 111–148, for 2012 and each subsequent year, the Secretary shall reduce the market basket increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is equal to "the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period)". For purposes of providing a forecast, Table 32 contains the projected rate of growth for CY 2011 through CY 2020 for the ESRDB market basket (adjusted, where applicable, based on the estimated productivity adjustment for a given year). Although we provide a forecast here, we will address in future rulemaking the implementation and application of the productivity adjustment to the ESRDB market basket increase factor that will be required beginning in 2012. Also, as we indicated above, in CY 2011, we note that as a result of amendments by section 3401(h) of Public Law 111–148 to section 1881(b)(14)(F) of the Act, a full market basket will be applied to the composite rate portion of the blended payment during the first year of the transition.

Table 32--Forecast of the 2008-Based ESRDB Market Basket Percent Change, Adjusted for Productivity, where applicable, for CY 2011 and Beyond

CY beginning January 1st	ESRDB Market Basket Percent Change - Unadjusted	ESRDB Market Basket Percent Change – Adjusted for Productivity
CY2011	2.5	N/A
CY2012	2.7	1.3
CY2013	2.7	1.5
CY2014	2.6	1.6
CY2015	2.6	1.9
CY2016	2.6	2.0
CY2017	2.6	1.9
CY2018	2.6	1.8
CY2019	2.6	1.9
CY2020	2.6	1.9

Note: The market basket changes adjusted for productivity will be used for update purposes for CY 2012 through CY 2020, as mandated by the Affordable Care Act.
Source: 2010 1st Quarter Forecast from IHS Global Insight

ESRD Labor-Related Share

The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of the Capital share from a given market basket. We used the 2008-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities under a bundled system. Under the ESRDB market basket, the labor-related share for ESRD facilities is 41.737 percent; as shown in Table 33 below. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below).

Table 33—ESRDB Market Basket Labor-Related Share

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

The labor-related share for Professional Fees (87 percent) reflects the proportion of ESRD facilities' professional fees expenses that we believe varies with local labor market. As stated in the proposed rule (74 FR 50003), we recently conducted a survey of ESRD facilities to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Therefore, we are including 87 percent of the cost weight for

Professional Fees in the labor-related share.

The labor-related share for capital-related expenses (46 percent of ESRD facilities' adjusted Capital-related Building and Equipment expenses) reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages. Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

K. Implementation

1. Transition Period

Section 1881(b)(14) of the Act replaces the current basic case-mix adjusted composite payment system with a case-mix adjusted bundled ESRD PPS, for Medicare outpatient ESRD facilities beginning January 1, 2011. Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide "a four-year phase-in" of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. Although the statute uses the term "phase-in", other Medicare payment systems use the term "transition" to describe the timeframe during which payments are based on a blend of the payment rates under the prior payment system and the new payment system. For purposes of this ESRD PPS final rule, we use the term "transition" to describe this timeframe.

Section 1881(b)(14)(E)(i) of the Act further requires that the transition occur "in equal increments," with payments under the ESRD PPS "fully implemented for renal dialysis services furnished on or after January 1, 2014." In addition, section 1881(b)(14)(E)(ii) of the Act permits an ESRD facility to make a one-time election to be excluded from the transition from the current basic case-mix adjusted composite payment system, with its payment amount for renal dialysis services based entirely on the payment amount under the ESRD PPS. This election must be made prior to January 1, 2011. Lastly, section 1881(b)(14)(E)(iii) of the Act requires that we make an adjustment during the transition so that payments during the transition equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget-neutrality adjustment policy is set forth at § 413.239 and is discussed further in section II.E.5. of this final rule.

In accordance with section 1881(b)(14)(E) of the Act, we proposed to implement the transition from the current basic case-mix adjusted composite payment system in equal increments, so that renal dialysis services furnished on or after January 1, 2014, would be paid entirely based on the payment amount under the ESRD PPS. Specifically, we proposed that for renal dialysis services provided during the transition period beginning January 1, 2011 and ending December 31, 2013, ESRD facilities would receive a blended payment for each dialysis treatment consisting of the payment amount under the basic-case mix adjusted composite system and the payment amount under the ESRD PPS (74 FR 50003). We noted that, because ESRD facilities would receive an all-inclusive payment during the transition period for all renal dialysis services, other entities, such as Method II DME suppliers and laboratories would no longer bill Medicare beginning January 1, 2011 for renal dialysis services furnished to ESRD patients. These entities would need to seek payment from the patient's ESRD facility (74 FR 50003).

The comments we received and our responses are set forth as follows:

Comment: Many commenters suggested that we consider implementing Part D drugs in the bundled payment during the last year of the transition and, indicated that the inclusion of these drugs would impact an ESRD facility's decision of whether to elect to go into the transition period or to receive full payment under the ESRD PPS. The commenters believed that we should collect accurate data on the costs of Part D drugs before they are implemented as part of the ESRD PPS bundle.

Response: In this final rule and in response to public comment, we are delaying implementation of payment under the ESRD PPS of ESRD-related oral-only drugs that are currently separately paid under Part D until January 1, 2014. The decision to delay implementation of oral-only drugs is discussed in section II.A.3.a. of this final rule. The implementation of ESRD-related drugs and biologicals under the ESRD PPS is discussed in section II.A.3. of this final rule. Because we are implementing all other ESRD-related former part D drugs and biologicals effective January 1, 2011, we included a $0.49 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system to account for those drugs. To derive the $0.49 adjustment, we used the 2011 price inflated payment amounts divided by the Part D HD-equivalent treatments for Part D enrollees as discussed in section II.F.5. of this final rule. We will continue to analyze the prices paid under Part D for oral-only ESRD-related drugs so that we are able to appropriately price these drugs in the ESRD PPS base rate.

Comment: Many commenters suggested that we consider implementing laboratory tests in the bundled payment during the last year of the transition. The commenters explained that there will be administrative burden in contracting for laboratory services during the transition period. The commenters indicated that even if laboratories are willing to enter into a contract, they are concerned about their ability to negotiate reasonable prices given the low volume of services that they would request from the laboratories.

Response: Section 1881(b)(14)(A)(i) of the Act requires CMS to include all renal dialysis services, which include ESRD-related diagnostic laboratory tests, into one single payment effective January 1, 2011. Section 1862(a)(24) of the Act prohibits unbundling of expenses for renal dialysis services (as defined in section 1881(b)(14)(B) of the Act). Therefore, we do not have the authority to pay laboratories directly for ESRD-related diagnostic laboratory tests. We note, under the current basic case-mix adjusted composite payment system, certain ESRD-related laboratory tests are included in the composite rate. ESRD facilities would have been required under the current basic case-mix adjusted composite payment system to establish arrangements with laboratories to perform these laboratory tests and receive payment from the ESRD facility. Therefore, we do not agree that bundling all ESRD-related laboratory tests under the ESRD PPS will pose a significant burden.

For CY 2011, we proposed to make payments based on 75 percent of the payment rate under the basic case-mix adjusted composite payment system and 25 percent of the payment rate under the ESRD PPS. For CY 2012, we proposed to make payment based on 50 percent of the payment rate under the basic case-mix adjusted composite payment system and 50 percent of the payment rate under the ESRD PPS. For

CY 2013, we proposed to make payment based on 25 percent of the payment rate under the basic case-mix adjusted composite payment system and 75 percent of the payment rate under the ESRD PPS. For renal dialysis services furnished on or after January 1, 2014, we proposed that payment to ESRD facilities would be based on 100 percent of the payment amount under the ESRD PPS (74 FR 50003).

We did not receive public comments on the proposed blending methodology for the transition from the basic case-mix composite payment system to the ESRD PPS bundled payment system and, therefore, we are finalizing the blending methodology as proposed in § 413.239(a).

We proposed that the portion of the blended rate based on the payment amount with regard to the basic case-mix adjusted composite payment system would be comprised of the composite payment rate (which is adjusted by the basic case-mix adjustments and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B by Medicare to entities other than the ESRD facility. We also proposed to include a $14 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system during the transition to account for the ESRD-related drugs and biologicals that are currently separately paid under Part D and were proposed to be included in the ESRD PPS base rate (74 FR 50004). Because we are delaying payment under the ESRD PPS for former Part D oral-only drugs, the proposed $14 adjustment will be $0.49 for this final rule, as discussed in section II.E.5. of this final rule.

We did not receive comments on the composition of the portion of the blended rate based on the basic case-mix adjusted composite payment system. Therefore, we are finalizing our proposal that the portion of the blended rate based on the basic case-mix adjusted composite payment system will be comprised of the composite payment rate (which is adjusted by the basic case-mix adjustments and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B. We will include a $0.49 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system during the transition to account for the ESRD-related drugs and biologicals (currently separately paid under Part D), but effective January 1, 2011, will be bundled under the ESRD PPS, (as discussed in section II.E.5. of this final rule).

In the proposed rule, we discussed that for the years during which the transition is applicable, section 1881(b)(14)(F)(ii) of the Act requires the Secretary to annually increase the portion of the ESRD PPS that is based on the composite rate that would otherwise apply if the ESRD PPS had not been enacted (74 FR 50004). In particular, at the time the ESRD PPS proposed rule was published, section 1881(b)(14)(F)(ii)(II) of the Act required the composite rate portion of the blended payment to be updated annually by the ESRDB market basket update minus 1.0 percentage point. Therefore, for each year of the transition, to maintain the 98 percent budget-neutrality amount, we proposed that the composite payment rate portion of the blended amount would be updated by the applicable case-mix adjustments, the drug add-on adjustment, the current wage index, and the ESRDB market basket update minus 1.0 percentage point.

We also proposed that payments for items and services furnished to dialysis patients that are paid separately under Part B under the current composite payment rate methodology, that is, ESRD-related laboratory tests, ESRD-related drugs, and ESRD-related supplies, blood, and blood products would no longer be paid separately. Instead, those items and services would be priced to reflect how they are currently paid (for example, using a fee schedule or ASP amount) (74 FR 50004).

We address comments related to the market basket in section II.J. of this final rule; laboratory tests in section II.A.4; ESRD-related drugs in sections II.A.2. and II.A.3.; ESRD supplies in section II.A.4; and, blood and blood products in section II.A.6. of this final rule. As discussed in these respective sections, for this final rule, ESRD-related blood and blood products will not be included in the ESRD PPS bundle and ESRD-related laboratory tests and ESRD-related drugs will no longer be separately paid. In addition, in accordance with section 3401(h) of the Affordable Care Act, which revised section 1881(b)(14)(F) of the Act, for CY 2011, the full ESRDB market basket update will apply and, for CY 2012, the ESRDB market basket update reduced by a productivity adjustment would apply as discussed in section II.J. of this final rule.

In the proposed rule, we noted that there are ESRD facilities that have existing exception amounts that are used for payment in lieu of the composite rate, drug add-on payment, and basic case-mix adjustments. Any existing exception amounts would not be updated by the ESRDB market basket throughout the transition (74 FR 50004). Finally, in the proposed rule, we discussed that the portion of the blended rate based on the ESRD PPS would include the base rate and all applicable patient-level, facility-level adjustments, and outlier payments as set forth in proposed § 413.231, § 413.232, § 413.235 and § 413.237. We respond to comments regarding exceptions in section II.L.1; the ESRD PPS base-rate in section II.E; patient-level adjusters in section II.F.3; and, facility-level adjusters in section II.F.4. of this final rule.

As noted in the proposed rule, section 1881(b)(14)(E)(ii) of the Act gives an ESRD facility the option to make a one-time election to be excluded from the four-year transition from the current basic case-mix adjusted composite payment system in the form and manner specified by the Secretary (74 FR 50004). Once made, this election may not be rescinded. ESRD facilities may choose to be paid the blended rate under the transition period in order to give them time to determine the impact of the ESRD PPS on their operations and to make necessary adjustments. We indicated in the ESRD PPS proposed rule that we believed ESRD facilities would choose to be excluded from the transition if they concluded that they would benefit financially from the payment amount under the ESRD PPS (74 FR 50004).

Section 1881(b)(14)(E)(ii) of the Act requires that ESRD facilities wishing to be excluded from the transition must make an election to be excluded and their election must be made prior to January 1, 2011, in the form and manner specified by the Secretary. We proposed that ESRD facilities notify their FI/MAC of their election choice in a manner established by the FI/MAC no later than November 1, 2010, regardless of any postmarks or anticipated delivery dates. We proposed that ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services between November 1, 2010 and December 31, 2010, would notify their FI/MAC of their election choice at the time of enrollment. Once an ESRD facility notifies its respective FI/MAC of their election choice, on or before November 1, 2010 (or at the time of enrollment for newly-certified ESRD facilities that begin to provide renal dialysis services between November 1, 2010 and December 31, 2010), the ESRD

facility's election cannot be rescinded (74 FR 50004).

We also proposed that ESRD facilities that fail to affirmatively make an election by November 1, 2010, would be paid based on the blended amount during the transition. We proposed that elections submitted by ESRD facilities that wish to be excluded from the transition that are received, postmarked, or delivered by other means after November 1, 2010, would not be accepted. Thus, we proposed that all ESRD facilities wishing to be excluded from the transition should submit their election choice by the proposed deadline. ESRD facilities electing to be excluded from the transition will receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011 (74 FR 50004).

We did not receive any comments regarding the proposed one-time election process and, therefore, in this final rule we are finalizing § 413.239 with modifications to indicate that the FI/MAC will establish the manner in which an ESRD facility will indicate its intention to be excluded from the transition, consistent with our proposal.

We received the following general comments regarding the transition period.

Comment: Most of the commenters appreciated the transition period and agreed that the time from 2011 through 2014 allows them time to make adjustments to their operations. One commenter requested that we allow the SDOs the time to consider the final rule so that they can make informed decisions regarding transitioning. Another commenter suggested that we eliminate the transition period, continue to pay ESRD facilities based on the current composite rate system, and then implement the ESRD PPS fully in 2014. The commenter explained that this approach would simplify the implementation and remove the need for a complex dual payment system during the transition period.

Response: The statute requires a 4-year transition period for ESRD facilities that do not opt to be excluded from the transition. In addition, after January 1, 2011, the statute requires that a single payment for renal dialysis services be made to ESRD facilities for renal dialysis services furnished to ESRD beneficiaries.

a. New ESRD Facilities

Section 1881(b)(14)(E)(i) of the Act permits a provider of services or a renal dialysis facility to make a one-time election to be excluded from the transition, it also provides that this election must be made prior to January 1, 2011. As a result, we proposed that ESRD facilities that are certified for Medicare participation and begin providing renal dialysis services or home dialysis services on or after January 1, 2011, would not have the option to choose whether to be paid a blended rate under the transition or the payment amount under the ESRD PPS. Rather, we proposed in § 413.239(c) that new ESRD facilities would be paid based on 100 percent of the payment amount under the ESRD PPS (74 FR 50004). As we did not receive any public comments regarding this proposal, we are finalizing § 413.239(c) as proposed.

We proposed to define a new ESRD facility as an ESRD facility that is certified for Medicare participation on or after January 1, 2011 in § 413.171. We did not receive any public comments regarding this proposal. Accordingly, for the reasons we set forth in the proposed rule, we are finalizing § 413.171 as proposed.

b. Limitation on Beneficiary Charges Under the ESRD PPS and Beneficiary Deductible and Co-Insurance Obligations

Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent co-insurance after the deductible (and Medicare pays 80 percent). With respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual) (74 FR 50005).

We proposed the items and services that would be considered renal dialysis services included in the ESRD PPS payment, such as composite rate services, certain separately billable ESRD-related injectable drugs, ESRD-related drugs and biologicals currently covered under Part D, laboratory testing, etc. We acknowledged that certain items and services such as laboratory tests and Part D drugs currently have different beneficiary co-insurance structures. However, we indicated that these items and services would be considered renal dialysis services after the ESRD PPS is implemented when furnished by an ESRD dialysis facility to an ESRD beneficiary. Therefore, we proposed that a 20 percent beneficiary co-insurance would be applicable to the ESRD PPS payment for these services including any adjustments to the ESRD PPS payment such as adjustments for case-mix, wage index, outlier, etc. (74 FR 50005).

We proposed that an ESRD facility receiving an ESRD PPS payment could charge the Medicare beneficiary or other person only for the applicable deductible and co-insurance amounts as specified in proposed § 413.176. Therefore, the beneficiary co-insurance amount under the ESRD PPS would be 20 percent of the total ESRD PPS payment (including payments made under the transition). We noted that the amount of co-insurance is based on the proposed ESRD PPS payment for renal dialysis services and home dialysis in 42 CFR Part 413. We explained that, in general, ESRD facilities are paid monthly by Medicare for the ESRD services they furnish to a beneficiary even though payment is on a per treatment basis. We proposed to continue this practice to pay ESRD facilities monthly for services furnished to a beneficiary beginning January 1, 2011 (74 FR 50005).

During the transition period before January 1, 2014, ESRD facilities that do not elect to go 100 percent into the ESRD PPS in 2011 would receive a blended payment amount. We proposed that the blended monthly payment amount would be subject to a 20 percent beneficiary co-insurance (74 FR 50005).

Additionally, in accordance with section 1881(b)(1) of the Act, we proposed in § 413.172(b) that an ESRD facility may not charge a beneficiary for any service for which payment is made by Medicare. This policy would apply, even if the ESRD facility's costs of furnishing services to that beneficiary are greater than the amount the ESRD facility would be paid under the proposed ESRD PPS (74 FR 50005).

We received about 230 comments on beneficiary co-insurance obligations which are summarized below.

Comment: A number of commenters believed dialysis facilities would be burdened by collecting the beneficiary coinsurance, especially co-insurance associated with the Part D oral drugs. The commenters stated that ESRD facilities are caregivers and not pharmacies and, therefore, their staff does not currently collect co-insurance and that if staff had to collect co-insurance, it would interrupt patient care. Other commenters expressed concern about the burden associated with collecting co-insurance liabilities because they would have to develop new systems.

Response: We do not agree with the commenters that collecting co-insurance would be a new requirement for ESRD

facilities because there has been a beneficiary co-insurance liability on the composite payment system as well as the basic case-mix adjusted composite rate payment. As discussed in section II.A.3. of this final rule, implementation of oral-only drugs will be delayed until January 1, 2014. Therefore, we do not believe that ESRD facilities will experience additional burden as a result of the implementation of the ESRD PPS effective January 1, 2011.

Comment: A number of commenters were concerned about the financial affects on beneficiaries with ESRD due to the copays that would result from the new bundled PPS. The commenters believed the new bundled PPS would increase beneficiary co-insurance and, therefore, would be a financial burden on patients, many who have limited income. Some commenters believed CMS should do an analysis of the impact of the increased beneficiary co-insurance on patients since there is no data available. A number of commenters with ESRD were worried about being able to pay for their dialysis treatment.

Response: Under the current basic case-mix adjusted composite system, there has been an incentive for excess use of separately billable items and services and patients have been responsible for a 20 percent co-insurance liability on most of these separately billable. For this reason, in addressing co-insurance obligations under the current composite payment methodology, it is important to consider not only the co-insurance associated with the composite rate itself, but also the 20 percent co-insurance obligation for most separately billed drugs and biologicals.

Under the ESRD PPS, the base rate (which includes composite rate services as well as items and services that are currently separately billable) reflects the average cost for furnishing dialysis services to patients. For this reason, if patients use less than the average of separately billable items and services (that is, items and services that were separately paid under the current basic case-mix adjusted composite payment system), they can expect an increase in their co-insurance obligation. However, if patients use more than the average of separately billable items and services, they should pay less in co-insurance under the ESRD PPS. The amount of the difference in co-insurance under the current basic case-mix adjusted composite payment system and the ESRD PPS for an individual patient is directly related to how their use of separately billable services compares to the average amount. We acknowledge that this comparison does not reflect that under the ESRD PPS, beneficiaries will assume a 20 percent co-insurance liability for non-routine laboratory tests that was not assumed under the current basic case-mix adjusted composite payment system. However, we note that under the current basic case-mix composite rate system, certain routine laboratory tests are included in the composite rate. Therefore, beneficiaries have been responsible for co-insurance associated with ESRD-related laboratory tests that are included in the composite rate.

A bundled PPS allows patients to pay co-insurance based upon the bundled rate for all items and services needed for their treatment without additional co-insurance costs if more separately billed items or services are needed.

Comment: Many commenters raised concerns about the financial burden for patients under the ESRD PPS because patients would have to pay co-insurance for oral drugs and laboratory tests. The commenters stated that shifting the oral drugs from Part D to Part B could result in significant increases in out-of-pocket costs for beneficiaries. Other commenters indicated that some ESRD patients currently have high out-of-pockets costs for their oral drugs and believed bundling the oral drugs would cause this cost to be even higher. Some commenters indicated that beneficiaries would not have the option to use generics or less expensive drugs in order to save money. Other commenters indicated that some ESRD patients would not reach catastrophic coverage under Part D with the new bundled system because they will be in the coverage gap for a longer time.

Some commenters were concerned that beneficiaries who have the low-income subsidy under Part D will have to pay higher co-pays for these drugs. Some commenters stated that data presented at the recent American Society of Nephrology meeting, showed that 68 percent of dialysis patients are enrolled in Medicare Part D and 76 percent of these patients have the low-income subsidy. A few commenters were concerned that States' Medicaid programs may not cover the 20 percent co-insurance for oral drugs for dual-eligibles, which they would have received under Part D. One commenter stated that including Part D drugs in the bundle could eliminate access to financial programs that assist patients with co-pays, such as Medicare Low Income Assistance programs as well as program such as the American Kidney Fund's Part D Program for Prescription Bone Medication. Some commenters suggested that CMS should delay the inclusion of the oral drugs specifically the ones with no injectable equivalent because of the lack of data available on the use of these drugs so that CMS can obtain data to assess the financial impact on beneficiaries and facilities. A few commenters requested that CMS assess the possible negative effects on beneficiaries who would now be responsible for co-insurance payments for both oral drugs and laboratory tests.

Response: As discussed in section II.A.3.a. of this final rule, we are delaying the implementation of oral-only drugs currently covered under Part D under the ESRD PPS until January 1, 2014. In section II.A.3. of this final rule, we discuss the inclusion of a limited number of ESRD-related oral drugs and biologicals with other forms of administration. Therefore, the oral-only drugs will continue to be covered under Medicare Part D until January 1, 2014. At that time, when oral-only drugs are paid under the ESRD PPS, the same co-insurance structure described in this section will apply for oral-only drugs. We plan to collect data on the oral-only ESRD-related drugs to assess the impact on beneficiaries and ESRD facilities. We will address the implementation of the oral-only drugs in the ESRD bundle in future notice of proposed rulemaking.

Comment: A few commenters were concerned about the negative impact the additional co-insurance would place on beneficiaries which may contribute to decisions to discontinue treatment, medications, etc. The commenters stated that many patients have difficulty in meeting the co-pays under the current system. The comments believe that if there is an increase in beneficiaries' payments, there is the possibility of beneficiaries missing treatments that would affect their quality of care. A few commenters were specifically concerned about patient noncompliance with taking their medications due to higher out-of-pocket costs. One commenter expressed concern that facilities would be held responsible for the drop in the compliance rates under the QIP.

Response: We appreciate the commenters' concerns about the affects of the co-insurance liability on patients. However, as we discussed in the proposed rule (74 FR 50005), section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. We also explained that with respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual). Therefore, we do not have the authority

to eliminate the beneficiary co-insurance liability.

As we have discussed in previous responses, beneficiaries have been responsible for co-insurance under the current basic case-mix adjusted composite payment system. Under the ESRD PPS, beneficiaries will continue to assume the co-insurance liability for the renal dialysis services provided by ESRD facilities. However, rather than a co-insurance for each separately billable item and for the basic case-mix adjusted composite rate under the current system, beneficiaries will pay co-insurance on the ESRD PPS payment amount which includes the ESRD PPS base rate and all applicable payment adjustments under the ESRD PPS.

We discuss the applicable adjustments which would be applied to the ESRD PPS base rate and subject to the beneficiary co-insurance liability in sections II.F.3. of this final rule. As discussed in section II.A.3.a. of this final rule, oral-only ESRD-related drugs will not be implemented under the ESRD PPS until January 1, 2014. Therefore, we do not believe that implementation of the ESRD PPS effective January 1, 2011, will cause patients to make decisions to discontinue any medications or treatment because of their co-insurance liability.

Comment: Many commenters expressed concern that ESRD facilities would need to develop systems for collecting medication co-payments. Other commenters expressed concern for the safety of ESRD facility staff stating that ESRD facilities maintaining cash on hand from patients' medication co-payments would place their staff and patients at risk for crime and theft. The commenters also stated they would need to hire additional security to protect against crime and theft. Another commenter stated that there is currently no billing mechanism in place between ESRD facilities and pharmaceutical companies nor is there a mechanism by which the pharmaceutical company could collect the patient's co-payment obligation for drugs included in the ESRD PPS bundle.

Response: Because ESRD-related drugs are included in the ESRD PPS bundle and, therefore, are in the ESRD base rate, the ESRD facility is responsible for obtaining any applicable co-insurance from their beneficiaries. A beneficiary would not have a co-insurance liability on each prescription, but rather on the bundled ESRD PPS payment amount. Beneficiaries have a co-insurance liability under the current basic case-mix adjusted composite rate. Therefore, we do not understand the concerns being raised about the need to collect co-insurance payments under the ESRD PPS, as this responsibility exists under the current payment system. We expect that ESRD facilities will employ any necessary measures that they require to ensure their staff's safety. We believe that because collection of co-insurance payments exist under the current ESRD payment system, the same safety concerns exist and the same measures to address these concerns are in place.

Comment: A number of commenters expressed concern that under the ESRD PPS, beneficiaries will have to pay co-insurance on laboratory tests. The commenters noted that beneficiaries currently have no financial responsibility to pay for their laboratory tests because Medicare pays 100 percent. The commenters believed the inclusion of laboratory tests in the ESRD PPS bundle would lower Medicare's obligation to only 80 percent of the payment and require beneficiaries to pay the 20 percent co-insurance for associated costs, resulting in increased out-of-pocket costs for beneficiaries. The commenters indicated that both beneficiaries and dialysis facilities would be penalized financially for laboratory services.

A few commenters complained about the burden and cost of collecting co-insurance for laboratory tests because most facilities do not have their own laboratories. One commenter indicated that according to the proposed rule, Medicare beneficiaries with ESRD who require dialysis will not have access to needed laboratory tests, which will be discriminatory. The commenter further believed patients who currently do not have a co-insurance obligation for laboratory tests, will now be responsible for 20 percent which might result in financial burden for many patients who already might be on limited or fixed incomes. Another commenter noted that those with limited or fixed incomes may be subject to an additional $300 to $400 per year for co-insurance on laboratory tests. One commenter believed the additional co-insurance would presumably be covered by Medicare Supplemental plans but could not predict the effects of the bundle for the costs of Medicare supplemental insurance. One commenter noted that Congress in MIPPA did not indicate that the longstanding policy that Medicare paying 100 percent for laboratory tests would change under the ESRD bundled system. Another commenter stated that historically CMS recognized the difficulty of placing a co-insurance on laboratory tests on facilities and patients and excluded diagnostic testing from beneficiary co-insurance obligations.

Response: As we discussed in section II.A.4. of this final rule, ESRD-related laboratory tests are considered renal dialysis services and are included in the ESRD PPS bundled base rate, and therefore, as part of the ESRD base rate after applicable adjustments are applied, would be subject to the 20 percent co-insurance (that is, individual laboratory services would not be subject to a separate beneficiary co-insurance liability). In other words, under the ESRD PPS, beneficiaries will not have a co-insurance liability for each laboratory test, but rather beneficiaries will have a co-insurance liability on the total payment that Medicare makes to an ESRD facility on their behalf. This is analogous to the beneficiary co-insurance liability under the current basic case-mix adjusted composite rate where beneficiaries have a co-insurance liability for the composite payment made to ESRD facilities on their behalf and not co-insurance liability on each composite rate service they receive.

We note that most routine laboratory tests for ESRD-related purposes are currently included in the basic case-mix adjusted composite rate. This means that currently, beneficiaries with ESRD have a co-insurance liability for the composite rate, which includes laboratory tests. We do not see the inclusion of ESRD laboratory tests in the ESRD PPS as being any different than what occurs currently under the basic case-mix adjusted composite rate system.

Comment: One commenter expressed concern that the implementation of the bundled ESRD PPS presents a substantial risk to ESRD facilities because of the potential for non-recovery of co-insurance payments for patients who are dually eligible under Medicare and Medicaid. The commenter recommended that CMS should create a new billing code for the bundle of services under the ESRD PPS and require States to recognize the new Medicare payment system. The commenter stated that CMS could work through the National Association of State Medicaid Directors to educate the States well in advance of the implementation of the PPS to provide ample time for them to adjust their co-insurance amounts, as required.

Response: We have already begun outreach efforts with the States to ensure that State Medicaid Agencies understand their responsibilities to adjust their systems so that co-insurance amounts are properly determined and paid appropriately for dually-eligible

beneficiaries upon implementation of the ESRD PPS.

Although an ESRD PPS billing code may make it easier for States to determine whether they have an obligation to pay co-insurance on behalf of a patient with ESRD, line item billing by date of service (where each renal dialysis service is itemized on the claim) will continue to be necessary in order for blended payments to be made during the transition and for identification of outlier services.

Comment: Several commenters were concerned about dialysis beneficiaries who have Medigap supplemental plans because oral drugs and laboratory tests have not previously been covered under Medigap. The commenters were specifically concerned about how Medigap plans will adjust to the inclusion of oral drugs in the ESRD PPS. A commenter questioned if Medigap plans would consider drugs as renal dialysis services. Several commenters stated that Medigap insurers may deny payment of the beneficiary co-insurance because statute prevents them from coordinating benefits for oral drugs. Several commenters believed that Medigap premiums would increase significantly and would financially burden patients.

One commenter stated that CMS should take into consideration that Medicare is the only insurance available to stage 5 chronic kidney disease patients (that is, ESRD patients). Another commenter believed that the ESRD PPS will target patients with private insurance and their co-insurance for additional revenue which would be an unfair burden on those that pay their insurance and co-insurance out-of-pocket. A commenter with private drug insurance was concerned about the costs and processes to pay two sets of premiums and co-insurance. Another commenter stated that the copayment under Medicare could significantly exceed the current copayments for those with private insurance.

Response: We believe that generally, Medigap and other private insurance plans cover co-insurance and copayment obligations for Medicare Part B services after the beneficiary meets the Part B deductible amount. We do not expect this to change under the ESRD PPS bundle. We are unable to address if these plans will continue to cover the co-insurance under the ESRD PPS. As we discussed in a previous response, ESRD-related oral drugs and laboratory tests included in the ESRD PPS bundle are considered renal dialysis services under the Part B benefit. Therefore, we do not believe there should be issues with Medigap plans because such oral drugs are renal dialysis services. We reiterate that payment under the ESRD PPS for oral-only drugs currently covered under Part D will be delayed until January 1, 2014.

We do not agree with the comments that Medicare will target patients with private insurance and their copays for additional revenue. The ESRD PPS, as a Medicare Part B payment system for outpatient maintenance dialysis, provides payment on behalf of Medicare beneficiaries to ESRD facilities that provide home dialysis and renal dialysis services. Therefore, beneficiary's co-insurance liability is not based on the absence or presence of private insurance.

We also do not anticipate any change with regard to beneficiaries with private drug insurance and the costs and processes to pay two sets of premiums and co-insurance under the ESRD PPS. As we discussed in previous responses, under the current basic case-mix adjusted composite payment, beneficiaries are subject to co-insurance liability for composite and separately billable payments made to ESRD facilities. We acknowledge that this co-insurance obligation changes under the ESRD PPS because the Medicare payment made to ESRD facilities will include items and services that are separately billable under the current basic case-mix adjusted composite payment system.

Comment: A few commenters expressed concern that the wide array of case-mix adjusters would create an inequity for patients, especially the sicker patients, because their bundled payment rate will be higher due to the adjustments with sicker patients having higher co-insurance. Other commenters stated that the proposed adjusters like age, health history, and clinic size would add extra work and complexity to reimbursement and would increase the co-payment. Another commenter was concerned that patients would not withstand the additional out-of-pocket costs associated with the ESRD bundle and the case-mix adjusters. One commenter opposed the application of beneficiary co-payment amounts to outlier payments asserting that this would set a dangerous precedent for discrimination on the basis of patient characteristics. The commenter recommended that CMS limit all patients' co-payment responsibility to 20 percent of the base rate payment amount.

Response: We do not have the authority to determine how the beneficiary co-insurance liability is applied. Section 1881(b)(2)(A) of the Act requires payments for dialysis services furnished by ESRD facilities to individuals with ESRD for which payments may be made under Part B to be equal to 80 percent of the amounts determined. The statute further requires that payments from individuals are to be 20 percent of the amount for such services after the deductible. Therefore, Medicare is required by statute to pay 80 percent and the beneficiary's responsibility is 20 percent of the amounts established for ESRD PPS renal dialysis services. This would include applying the beneficiary co-insurance liability to the ESRD PPS base rate and all applicable adjustments, including the outliers.

We do not agree that applying the beneficiary co-insurance liability based on characteristics is discriminatory. We discuss the patient characteristics that have demonstrated higher usage of separately billable items in section II.F.3. of this final rule. Because these characteristics (such as age, BSA and BMI) result in higher resource utilization and therefore higher costs, ESRD facilities will receive a payment adjustment to the ESRD PPS base rate and beneficiaries will be required to assume 20 percent of the costs. We note that under the current basic case-mix adjusted composite payment system, many of the same patient characteristics have been applied to the composite rate (age, BMI and BSA) and beneficiaries have been required to assume 20 percent of those payments.

Payments under the ESRD PPS reflect the extent to which additional resources are utilized. In situations where a patient with ESRD is sicker and, therefore, utilizes more resources, the payment to the ESRD facility providing renal dialysis services to that patient would reflect the higher resource use. Under the current basic case-mix adjusted composite payment system, greater resource utilization is reflected by greater use of separately billable items that are subject to a beneficiary co-insurance liability. In other words, patients have been subject to paying co-insurance under the current payment system based on the use of resources.

Therefore, based on the comments and the reasons discussed above, we are finalizing the beneficiary co-insurance liability of 20 percent applied to the ESRD PPS payment inclusive of all applicable payment adjustments.

2. Claims Processing

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services and other items and services (for example, supplies and equipment

used to administer dialysis, drugs, biologicals, laboratory tests, and support services) related to home dialysis. In the proposed rule, we noted that implementation of the ESRD PPS will require changes to the way we process claims. Some of the changes we proposed may involve establishing consolidated billing rules and edits and changes to the data elements reported on claims (74 FR 50005).

The consolidated billing approach essentially confers to the ESRD facility the Medicare billing responsibility for all of the renal dialysis services that its patients receive. The consolidated billing rules and edits that are being set forth in this final rule are described further below.

a. Consolidated Billing Rules and Edits

In the proposed rule (74 FR 50005), we explained that since the ESRD PPS payment model represents an all-inclusive payment for renal dialysis services and home dialysis items and services, the ESRD facility is responsible for all of the ESRD-related services that its patients receive. Items and services that are paid separately under the current basic case-mix adjusted composite rate (such as laboratory tests), would no longer be billed for by entities (such as laboratories and DME suppliers), and therefore, payment for these services would be made only to the ESRD facility so that duplicate payment is not made by Medicare. Although DME suppliers and laboratories may not bill Medicare for ESRD-related services paid under the ESRD PPS beginning January 1, 2011, in the event an erroneous bill is submitted, consolidated billing edits will prevent payment for those services under the ESRD PPS.

In the proposed rule, we also discussed the difficulty in differentiating between a renal dialysis service and a service furnished for other non-ESRD conditions (74 FR 50005). In order to ensure proper payment in all settings, we explored the use of modifiers to identify those services furnished that are not ESRD-related (74 FR 50005).

We received one comment regarding consolidated billing.

Comment: One commenter expressed concern that consolidated billing would require entirely new billing and payment arrangements for dialysis facilities and for the suppliers under arrangement. The commenter explained that building these relationships may be particularly challenging for SDOs. Further, the commenter stated that the proposed consolidated billing arrangement is similar to the provisions applicable to skilled nursing facilities (SNF). However there is a large difference in volume of administrative employees that can implement the new set of business practices necessitated by consolidated billing.

Response: We do not expect that the billing requirements under the ESRD PPS will require substantial changes in billing. Under the current basic case-mix adjusted composite payment system ESRD facilities that do not provide laboratory testing services, drugs, DME and supply services directly, would have to provide these items and services under arrangements. However, under the ESRD PPS there may be more services furnished than those under existing arrangements.

With respect to changes to the claims, under the ESRD PPS, there are requirements for ESRD facilities to provide additional information in existing fields. For example, ESRD facilities will be required to (1) itemize all drugs and biologicals provided to each individual patient; (2) itemize all laboratory tests provided to each individual patient; (3) place a modifier for non-ESRD related laboratory tests, drugs and biologicals, and supplies and equipment for the purpose of receiving separate payment; and (4) enter a co-morbidity ICD–9–CM diagnostic code (as described in section II.A.3. of this final rule) recognized for purposes of the co-morbidity payment adjustment. Because ESRD facilities have been required to line itemize under the current basic case-mix adjusted composite payment system and as ESRD facilities had been encouraged to enter co-morbidities on ESRD claims, we do not consider any of these reporting requirements to be an additional burden.

We are not requiring ESRD facilities to itemize supplies and equipment that are ESRD-related and are therefore paid through the bundle. However, in the event that supplies or equipment are not ESRD-related, ESRD facilities will place a modifier for those supplies and equipment signifying that they were used for services that are not ESRD-related and eligible for separate payment.

Comment: One commenter suggested that we consider deferring the consolidated billing edits for laboratory tests, drugs, and DME equipment and supplies until the full implementation of the ESRD PPS. The commenter also requested that we ensure that all interested parties receive adequate provider education regarding the changes implemented with the final rule.

Response: We are unable to delay implementation of the consolidated billing rules and edits because, as mentioned above, the ESRD PPS is an all-inclusive payment for home dialysis and renal dialysis services and ESRD facilities are responsible for all ESRD-related services furnished to their patients. Because it is a bundled payment system for which a single payment is made the ESRD facility, we are required to ensure that payment for these services is made only to the ESRD facility so that duplicate payment is not made by Medicare. We intend to issue educational materials regarding the implementation of the ESRD PPS to all interested parties in the near future.

i. Laboratory Tests

Section 1881(b)(14)(B)(iv) of the Act requires that ESRD-related diagnostic laboratory tests not included under the current basic case-mix composite payment system must be included as part of the ESRD PPS payment bundle. In the proposed rule, we explained that patients with ESRD often have co-morbid conditions which would require many of the same laboratory tests as those required to monitor the patients' ESRD (74 FR 50005). Therefore, we acknowledged that it may be difficult to differentiate between an ESRD-related laboratory test and tests ordered for non-ESRD-related conditions. We indicated that to ensure proper payment in all settings, we were exploring the use of modifiers to identify laboratory tests furnished for ESRD-related conditions from those furnished for non-ESRD-related conditions.

We received numerous comments regarding the proposed inclusion of laboratory tests in the ESRD PPS bundled payment which are set forth below.

Comment: Many commenters expressed concern that it is common for a patient's nephrologist to act as their primary care physician (PCP) and monitor all of the patient's medical conditions. The commenters expressed concern that there would be unintended consequences if the non-ESRD-related laboratory tests ordered by the nephrologists are included in the ESRD PPS bundle. Commenters were concerned that patients would be referred to medical specialists which would fragment care and require additional travel for medical appointments. Commenters were also concerned that patients would require more needle sticks if non-ESRD-related laboratory tests were included in the ESRD PPS bundle.

Some commenters indicated that it is common for physicians other than the

nephrologist to order laboratory tests from the ESRD facility. The commenters explained that the ESRD facility draws the specimen and then either furnishes the testing, if they are qualified to do so, or sends the specimen to a laboratory. The commenters believed that it is helpful for the patient and their continuity of care, if other physicians have this type of service (courtesy draws) available to them. Several patients requested that CMS continue to allow courtesy draws because it protects patients' vascular access site and saves patients from making multiple trips.

Response: As we discussed in a previous response, ESRD facilities will be able to identify laboratory tests, drugs, biologicals, and other items that are not ESRD-related by utilizing a modifier on claims. Therefore, in this final rule, we are finalizing a consolidated billing approach that gives the ESRD facilities and laboratories the ability to identify non-ESRD-related laboratory tests, by using a modifier, which allows for separate payment.

With regard to the commenters who indicated that providers other than the patient's nephrologist may order non-ESRD-related laboratory tests in order to preserve patient's vascular access and to mitigate multiple medical visits, physicians or other practitioners that directly submit orders to the ESRD facility to furnish a laboratory test or draw a specimen to send to an independent laboratory will be able to continue to do so. However, we remind ESRD facilities that they would still be subject to the following rules: (1) ESRD facilities are expected to furnish such services in accordance with the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 provided at § 493; and (2) physicians are required to order the diagnostic tests in accordance with the conditions provided at § 410.32.

Comment: We received numerous comments requesting that we implement a specific listing of routine ESRD-related laboratory tests that are included in the ESRD PPS bundle. Many commenters identified laboratory tests they believed belong in the listing. Some of the commenters referred to the laboratory tests that are currently paid under the composite payment system, while other commenters referred to a list that State and Federal surveyors use as guidance while conducting audits of the ESRD facilities. Two LDOs and two other dialysis advocacy associations provided a listing of approximately 50 laboratory tests. Another commenter suggested that we use a listing of laboratory tests that were developed through the Kidney Disease Outcomes Quality Initiative. We also received requests to omit diagnostic tests used for kidney transplants, bacteriology tests, and tests furnished specifically for travelling patients.

Response: We agree with the commenters that there should be a specific list indentifying laboratory tests that are furnished for ESRD patients. We believe that a listing of laboratory tests can be used as part of a consolidated billings strategy to mitigate duplicate payment. We also believe that ESRD facilities can use this list in developing contractual relationships with laboratories. However, in developing a listing of laboratory tests that are considered to be ESRD-related, we found that there are some laboratory tests that are specifically necessary for monitoring a patient's ESRD condition. We also found that there are numerous laboratory tests that are used by physicians not only for ESRD-related conditions, but also for other reasons. Therefore, a clinical review of the laboratory tests suggested by the commenters was performed by CMS physicians and other medical professionals.

As a result of this review, we have compiled a listing of laboratory tests that are used to diagnosis or monitor ESRD-related conditions which is presented in Table F of the Appendix. The laboratory tests listed, if furnished to ESRD patients by the ESRD facility directly or under arrangement, will be considered renal dialysis services (unless otherwise specified as being performed for non-ESRD-related conditions) and will be covered under the ESRD PPS bundled payment. If a laboratory test is furnished by the ESRD facility or by an independent laboratory for reasons that are not ESRD-related, then that laboratory tests can be billed with a modifier which would allow for separate payment. We acknowledge that the list of ESRD-related laboratory tests displayed in Table E of the Appendix is not an all-inclusive list and we recognize that there are other laboratory tests that may be ESRD-related. We will monitor claims to see if additional laboratory tests should be added.

Comment: Commenters expressed concern that there are many ESRD facilities that do not own their own laboratories and those ESRD facilities would experience high costs implementing new billing systems. The commenters further explained that the laboratories will need to bill the ESRD facilities making the ESRD facilities responsible for additional documentation and claims processing. One commenter argued that the proposed effective date of January 1, 2011, does not allow time to implement the contract changes that will be required.

Response: We do not understand the commenters' concerns. Currently, ESRD facilities that do not own their own laboratories must have contracting arrangements with a laboratory for the laboratory tests included in the current basic case-mix adjusted composite payment system. Section 494.130 provides that, "ESRD facilities must provide, or make available, laboratory services (other than pathology and histocompatibility) to meet the needs of the ESRD patients. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter." Therefore, we do not see the implementation of the ESRD PPS as requiring any changes from existing practices, with the exception of the inclusion of additional laboratory tests under the ESRD PPS.

ii. Drugs and Biologicals

As we discussed in the proposed rule, section 1881(b)(14)(B) of the Act defines renal dialysis services to include, among other things, certain drugs and biologicals, including drugs and biologicals that were separately payable under Part B and Part D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

We proposed to include renal dialysis service drugs formerly covered under Part D under the ESRD PPS. We further proposed that ESRD facilities furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. We explained that regardless of the mechanism by which these drugs would be furnished (directly or under arrangement), we believed that some of the Part D provisions set forth in the 42 CFR Part 423, would become relevant for ESRD facilities. We requested public comments on the extent to which Part D requirements should apply to ESRD-related oral drugs (74 FR 50006).

We also stated in the proposed rule that we expected ESRD facilities to update their grievance processes to account for all self-administered ESRD-related drugs (74 FR 50006). Patients would continue to have access to both

internal and external grievance processes including the ESRD Network and the State survey agency.

We indicated in the proposed rule that in the case of any ESRD facility that would seek to furnish drugs directly, those facilities would have to comply with state pharmacy licensure requirements. We noted that, as an alternative, many ESRD facilities would forego the process of becoming licensed as a pharmacy and instead, furnish renal dialysis service drugs formerly covered under Part D under arrangement with a licensed pharmacy. We indicated that the ESRD facility would provide their patients with a listing of pharmacies with which it would have arrangements with to dispense the renal dialysis service drugs (74 FR 50006).

As indicated in proposed § 413.241, we further expected that the ESRD facilities would establish arrangements with pharmacies in a manner that would facilitate beneficiary access to renal dialysis service drugs. That is to say, at a minimum, we expected that the arrangement would take into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, the usual distances traveled by patients in the area to obtain health care services, and the pharmacy's capability to provide all classes of renal dialysis service drugs to patients in a timely manner. In addition, we expected that ESRD facilities would coordinate the provision of renal dialysis service drugs on behalf of traveling patients to facilitate ongoing compliance with the plan of care during periods of travel (74 FR 50006–50007).

To prevent duplicate payment under both Part D and Part B for bundled drugs and biologicals formerly covered under Part D, we indicated in the proposed rule that we were considering the incorporation of an ESRD indicator on the Part D eligibility information that would prevent Part D drug payments for bundled ESRD drugs and biologicals at the pharmacy. We proposed that the pharmacy would bill the ESRD facility for all renal dialysis service drugs and biologicals included in the proposed ESRD PPS that were dispensed, but would not be permitted to bill the patient for the usual Part B co-insurance amount, nor treat these drugs in accordance with the Part D rules. The ESRD facility would collect applicable beneficiary co-insurance based on the ESRD PPS per treatment payment amount (74 FR 50007).

In the proposed rule, we noted that the cost of the drugs and biologicals currently separately payable under Part D that we proposed to be designated as Part B renal dialysis services for purposes of the proposed ESRD PPS, would be reflected in the ESRD PPS portion of the blended payment (74 FR 50007).

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

Comment: Many commenters requested that oral medications not be bundled but rather, should continue to be obtained through Part D. The commenters believed that bundling the oral drugs into the ESRD PPS would eliminate patient protections that are currently in place under Medicare Part D such as drug utilization review, medication therapy management, beneficiary choice in drugs within each drug class, geographic access standards and reduced co-insurance levels for low-income subsidy eligible patients.

To the extent oral medications are bundled, some commenters believed that we should implement similar Part D protections into the ESRD PPS. Other commenters asserted that bundling oral medications into the ESRD PPS would result in a duplication of the Medicare Part D system, questioning CMS for considering the imposition of a system similar to Part D asserted that doing so would increase inefficiencies and cost.

Response: We appreciate the commenters interest in maintaining patient protections that ensure access to drugs. As discussed in section II.A.3. of this final rule, although ESRD-related oral drugs and biologicals are included in the ESRD PPS bundle as of January 1, 2011, we are delaying payment under the ESRD PPS of ESRD-related oral-only medications until January 1, 2014. Therefore, because the majority of the oral drugs currently paid under Part D are oral-only drugs and payment under the ESRD PPS for oral-only drugs has been delayed until January 1, 2014, we intend to further evaluate beneficiary protections under the ESRD PPS related to oral drugs. We note that we are developing monitoring procedures that we will discuss in the future.

We acknowledge that as discussed in section II.A.3. of this final rule, there are a limited number of ESRD-related oral drugs and biologicals with other forms of administration which will be implemented January 1, 2011 and therefore, ESRD facilities will be required to ensure that patients have access to these drugs. Consequently, ESRD facilities will need to address their concerns in order to be able to furnish ESRD-related oral drugs and biologicals with other forms of administration, prior to January 1, 2011. With regard to the oral drugs that are being bundled in 2011, we believe these concerns can be alleviated and/or gradually addressed because such drugs have some other forms of administration.

Comment: Many commenters opposed the bundling of oral medications citing logistical and operational concerns associated with furnishing drugs either directly or under arrangement. The commenters believed that activities associated with furnishing these drugs directly would necessitate infrastructure and staffing changes that would drive up costs. These commenters stated that developing expertise in meeting pharmacy requirements and in hiring additional personnel, adopting technology and creating space for the storage and distribution of self administered drugs would require a great deal of effort and resources. The commenters stated that pharmacists would need to be hired to comply with dispensing requirements under State and Federal law. Other commenters believed that nursing and social work staff would be expected to distribute the self-administered drugs and that this task would detract from their nursing and social work duties.

Other commenters believed that clinical care staff such as registered nurses and personal care attendants would be cut to fund the additional cost of bringing pharmacy staff on board. Several commenters indicated that ESRD facilities currently in operation will be constrained in their ability to create in-house pharmacies or to store additional bundled drugs in instances where they have already maximized their square footage.

Similarly, commenters were also concerned about the additional burden ESRD facilities that elect to furnish these drugs under arrangement would experience such as establishing and maintaining pharmacy contracts. Commenters identified pros and cons of contracting with a large number of pharmacies versus contracting with a few pharmacies. The commenters believe that large numbers of contracts would promote convenient patient access but ESRD facilities' administrative costs would increase proportionally according to the number of pharmacies with which they contract. Overall, commenters asserted that payment under the ESRD PPS would not cover the additional costs of administrative burdens and increased staffing needs that will result from the bundling of oral drugs.

One commenter supported the option to allow facilities to choose between furnishing oral drugs directly or under arrangement. This commenter further noted that by allowing this choice, CMS

did not directly impose a requirement that a facility become a licensed pharmacy or have a pharmacist on staff. This commenter believed that beneficiary access to drugs would be preserved through facility arrangements with contracted pharmacies much like facilities currently contract with clinical laboratories.

Response: As we discussed in detail in section II.A.3.a. of this final rule, we are delaying payment for oral-only drugs under the ESRD PPS until after the ESRD PPS transition. We agree with the comment that ESRD facilities will have choices regarding whether and how to furnish ESRD-related oral drugs and biologicals that have other forms of administration. For example, an ESRD facility may continue to furnish the injectable and other forms of iron or may elect to furnish the oral forms of these drugs (and biologicals), as determined by the patients' plans of care. ESRD facilities will need to determine how they will obtain and furnish these drugs and biologicals (for example under arrangement or mail order). We note that ESRD facilities currently furnish drugs and biologicals to patients and, therefore, would have experience and arrangements under the current basic case-mix adjusted composite payment system. We acknowledge that these experiences and arrangements may only address the injectable drugs and biologicals and, that given the inclusion of the other ESRD-related drugs and biologicals under the ESRD PPS beginning January 1, 2011, additional arrangements may be needed.

Comment: One commenter was concerned that the bundling of oral drugs would result in an automatic shift of patients' drug coverage to Medicare. The commenter believed that patients who currently rely on drug coverage from private retiree or employer health plans with little or no cost sharing will be disadvantaged under the ESRD PPS. Another commenter believed that the ESRD PPS may benefit uninsured patients who currently either cannot receive these drugs or have difficulty getting to a pharmacy.

Response: We do not agree with the commenter that bundling oral drugs will shift patients' drug coverage to Medicare. Under the ESRD PPS, Medicare coverage for some ESRD-related drugs and biologicals will shift from Medicare Part D to Part B and, therefore, would be included in the ESRD PPS. The statute does not govern private insurance or require that drug coverage shift from private insurance to Medicare Part B. Furthermore, the statute does not change private insurance or incorporate coverage of services paid for by private insurers.

We do not believe that the ESRD PPS will have any effect with regard to benefiting patients who are currently having difficulty getting to a pharmacy. Under the ESRD PPS, patients may still need access to a pharmacy for their ESRD-related oral drugs and biologicals if the ESRD facility provides drugs and biologicals under arrangement.

With regard to the comment that uninsured patients will benefit under the ESRD PPS, we agree that patients who currently do not have drug coverage (either privately or through Part D) will benefit from the inclusion of ESRD-related oral drugs and biologicals under the ESRD PPS. However, as these drugs and biologicals have been included in the ESRD PPS base rate, patients will have a co-insurance liability.

Comment: Several commenters stated that bundling of oral drugs provides an unfair advantage to LDOs which the commenters believed control the market for certain ESRD-related drugs. Commenters also believed that LDOs have a further advantage because they have developed in-house pharmacies.

Other commenters stated that small ESRD facilities would not have the resources to develop in-house pharmacies and would need to contract for oral medications. One commenter asserted that SDOs that opt to furnish drugs under arrangement would not reach the volume necessary to contract with pharmacy benefit managers (PBMs) and would need to contract with smaller pharmacies at less favorable rates. Another commenter asserted that small and rural facilities and their local pharmacy partners will be disadvantaged because they are less capable of aggressively negotiating drug prices.

Several commenters urged CMS to propose a standard national method for dialysis facilities to establish prospective contracts with multiple traditional and mail-order pharmacies for the furnishing of dialysis-related drugs, regardless of the size of the dialysis provider. Other commenters suggested that CMS negotiate with pharmaceutical manufacturers on behalf of ESRD facilities to establish prices for ESRD-related drugs. Another commenter suggested that as an alternative to furnishing medications directly, ESRD facilities could rely on a third party Competitive Acquisition Program (CAP) vendor to purchase and distribute Part B renal dialysis service drugs to ESRD patients.

Response: We thank the commenters for expressing their concerns about the advantages and disadvantages that they believe exist between large and small dialysis organizations and for providing suggestions for ways in which ESRD facilities could obtain ESRD-related drugs and biologicals. However, we are not specifying in this rule how ESRD facilities are to obtain ESRD-related drugs and biologicals.

Thus, we are not adopting a national method for establishing contracts with pharmacies, nor will we negotiate with drug manufacturers on behalf of ESRD facilities to establish ESRD-related drug prices. We note that CAP participation is limited to Medicare physicians who administer drugs in their offices. However, we will take these suggestions into consideration when we implement ESRD-related oral-only drugs under the ESRD PPS. In the meantime, we encourage ESRD facilities to pursue group purchasing arrangements with similarly situated organizations to secure the most favorable drug prices possible.

Comment: One commenter stated that organizations with demonstrated pharmacy capabilities can help ESRD facilities minimize potential operational and administrative burdens of managing pharmacy care. The commenter further stated that mail order pharmacies provide ESRD patients with consistency of care and ease of access to their necessary medications while also saving payers and patients money.

Response: We appreciate the commenter's input and believe that ESRD facilities that elect to furnish drugs under arrangement will seek contracts with pharmacies on the basis of competitive pricing and on the value that contracted pharmacies can offer to the ESRD facilities' patients in terms of convenient access.

Comment: Several commenters requested clarification as to whether the ESRD facility will be required to hire a pharmacist or if the nurses will be required to dispense the oral drugs. An ESRD facility nurse expressed concern that she would be forced to act as a pharmacist, performing duties that would be beyond the scope of nursing practice.

Response: We do not require that ESRD facilities hire a pharmacist nor do we require that ESRD facilites dispense oral drugs. Rather, under the ESRD PPS, ESRD facilities will be required to provide ESRD-related drugs and biologicals (including ESRD-related drugs and biologicals with other forms of administration). ESRD facilities will need to determine how they will obtain and dispense drugs and biologicals (that is, directly or under arrangements). However, ESRD facilities and the

professional staff associated with these facilities will continue to be required to comply with State and Federal laws pertaining to dispensing of prescription drugs and biologicals.

Comment: One commenter requested clarification as to how oral medications would be dispensed and charted; on a per treatment, weekly or monthly basis. Several commenters believed that oral drugs covered under the ESRD PPS (such as phosphate binders), would only be provided on the days that the patient is in the facility and during the dialysis treatment itself. Other commenters stated that phosphate binders should be given with meals and that administering phosphate binders during dialysis could result in patients experiencing nausea, vomiting, choking or altered blood pressure.

Several commenters expressed concern that ESRD facilities may have difficulty recouping the full payment amount for oral medications that are taken outside the ESRD facility, particularly in instances where multiple days, weeks or months-worth of medications are prescribed. The commenter provided an example in which an ESRD facility provided a patient with a month's supply of a drug but, as a result of missed treatments, the facility would only receive payment for a partial month worth of treatments and would not recoup the full cost of the medication furnished.

Other commenters were concerned that patients may encounter additional burden if ESRD facilities do not approve 30 day supplies of drugs. The commenters stated that smaller prescribed quantities of drugs would increase the number of trips that patients would need to make to the pharmacy, which would be particularly burdensome for patients with limited transportation.

Response: ESRD facilities will be required to record the quantity of oral medications provided for the monthly billing period. In addition, ESRD facilities would submit claims for oral drugs only after having received an invoice of payment. We will address recording of drugs on an ESRD claim in future guidance.

We appreciate the commenter's concern that ESRD facilities believe they will be at risk for drug costs incurred but for which payment may not be recouped as a result of missed treatments. Under the ESRD PPS, payments are made on a treatment basis. However, some ESRD-related oral drugs and biologicals may be required to be taken on days that do not correspond with a treatment. We will be providing instruction on how these medications are to be entered on the ESRD claim. We believe that ESRD facilities will need to ensure, to the best of their ability, that patients do not miss treatments. ESRD facilities will need to determine the most appropriate way to furnish drugs and biologicals that ensures that patients receive their required medications, while mitigating the facilities' risk for drug costs.

Comment: One commenter stated that hospital-based ESRD facilities meet their patients' medication needs through the use of intravenous medications prepared by the hospital's on-site pharmacy. One commenter indicated that state pharmacy licensure requirements do not permit the hospital pharmacy to dispense outpatient medications. The commenter further noted that hospital-based ESRD facilities would need to establish a contract with an outside pharmacy to furnish the necessary oral medications.

Response: We want to clarify that in bundling ESRD-related injectable and oral drugs and biologicals with other forms of administration, we are not mandating that ESRD facilities change from intravenous to oral or other forms of these drugs. As indicated in the proposed rule, we would expect that any ESRD facility that provides outpatient maintenance renal dialysis items and services, would either establish their own licensed pharmacies or contract with licensed pharmacies.

Comment: Several commenters asserted that bundling oral medications into the ESRD PPS would create confusion between Part B and Part D for patients, ESRD facilities, pharmacies and Part D sponsors. One commenter supported our proposal to create an ESRD indicator as a way of preventing duplicate payment of drugs under Part B and Part D. Other commenters stated that Part D plans would bear much of the burden of ensuring that ESRD patients do not receive drugs under Part D coverage that have been bundled into the ESRD PPS as ESRD-related services. The commenter stated that because Part D already has effective cost control mechanisms in place, it is not necessary to bundle Part D drugs into the ESRD PPS for purposes of controlling costs. Another commenter believed that where an ESRD-related drug is indicated for non-ESRD-related indications, the ESRD indicator would not provide all the information necessary to prevent duplicate payment.

Response: We intend to implement an ESRD indicator that will store a beneficiary's ESRD status in Part D systems. Part D sponsors would be expected to share the information with their claims processing contractors for purposes of claims adjudication. This indicator will allow contracted pharmacies to correctly bill ESRD-related drugs to the ESRD facility and non-ESRD-related drugs to Part D.

We do not agree with the commenter that it is not necessary to bundle Part D drugs in the ESRD bundle because Part D has mechanisms to control costs. We discuss the interpretation of the definition for renal dialysis services and the inclusion of Part D drugs in the ESRD bundle in section II.A.3. of this final rule.

With regard to the commenter's concern that an ESRD indicator would not provide necessary information to prevent duplicate payment, when a drug is indicated for non-ESRD-related conditions, as we discuss later in this section, ESRD facilities will be able to identify drugs and biologicals used to treat non-ESRD conditions with a modifier and will be paid separately for these items.

Comment: One commenter expressed concern about potential administrative complexities that may be associated with furnishing drugs that are on the Drug Enforcement Agency's (DEA) list of controlled substances. This commenter further specified that the process of securing and renewing a DEA license would add to the administrative complexity of implementing the ESRD PPS.

Response: We expect that ESRD facilities are currently complying with any applicable requirements associated with controlled substance administration if they provide controlled substances to their patients. While there is no requirement under the ESRD PPS for ESRD facilities to administer controlled substances, if an ESRD elects to provide them, they would be required to comply with State and Federal requirements.

Comment: One commenter requested clarification as to how antitrust laws would be applied in the context of ESRD facilities that may seek to contract with one or more pharmacies for the provision of oral drugs. The commenter suggested that to the extent an ESRD facility were to contract with one pharmacy but not another, this may violate antitrust laws.

Response: Antitrust laws are beyond the scope of this final rule. However, to the extent an ESRD facility opts to furnish drugs under arrangement, we would expect that the facility would conduct an independent compliance review of antitrust and any other applicable Federal or State laws.

Comment: One commenter stated that OIG, MedPAC, or the Institute of Medicine should conduct studies two

years after implementation of the ESRD PPS to ensure proper implementation of oral-only drugs into the ESRD PPS bundle has occurred and that Medicare beneficiaries have not been adversely impacted.

Response: We thank the commenter for this recommendation and note that to the extent these entites were to conduct such studies we would support those efforts. As discussed in this final rule, oral-only drugs PPS will not be paid under the ESRD PPS until January 1, 2014. We note that section 10335 of the Affordable Care Act requires the GAO to conduct a study and submit a report to Congress on Medicare beneficiary access to high quality dialysis services, including specific oral drugs (oral-only).

As a result of the public comments and for the reasons discussed above, we are revising § 413.241. The revised § 413.241 will read as follows: "Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis drugs and biologicals to patients in a timely manner."

iii. Home Dialysis

In the proposed rule, we discussed that section 1881(b)(14)(A)(i) of the Act requires the costs of home dialysis supplies and services furnished under Method I and Method II, regardless of home treatment modality, be included in the ESRD PPS bundle. We proposed that the Method II home dialysis approach in its present form would no longer exist under the ESRD PPS effective January 1, 2011, but our proposal did not eliminate Method I in its present form (74 FR 50006). Therefore, a supplier could only furnish, under an arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis patient and the supplier would have to go to the ESRD facility for payment. As discussed in section II.A.4. of this final rule, under the ESRD PPS, all home dialysis items and services are covered under the ESRD PPS payment and no separate payment will be made. In the event supplies or equipment are used for non-ESRD-related purposes, those supplies or equipment could be billed separately by utilizing a modifier which indicates that the supply or equipment is not ESRD-related.

The comments we received regarding Method II can be found in section II.A.7. of this final rule.

b. Expansion of the Data Elements Reported on Claims

In the proposed rule, we explained that currently the services that are billed on the ESRD claim do not provide any detail of the composite rate items and services that are furnished to the patient beyond the treatment itself (74 FR 50006). We did not propose additional reporting requirements in regards to collecting data for composite rate items and services, but we noted that collecting additional data at the patient-level is necessary for refinements to the case-mix adjustments of the ESRD PPS's payment model. We provided examples of items and services, such as time on machine, nutritional services, social work services, and nursing services included in the current basic case-mix adjusted composite payment system, but are not captured on the claim. We requested public comment on possible data elements and other claim-based information that would identify patients who are high cost (74 FR 50006).

We received comments regarding the expansion of the data elements reported on claims as described below. The comments and our responses are set forth below.

Comment: All commenters agreed that it is important to expand the data elements required on ESRD claims in order to effectively make refinements to the ESRD PPS payment model in the future. Some commenters agreed with the examples of services in the proposed rule. Two commenters stated that therapeutic nutritional services are critical for ESRD patients who cannot swallow or digest and absorb adequate nutrition from traditional nutrient formulas. One of the commenters suggested that we specifically collect data from ESRD facilities to assess the frequency and duration of nutrition services. Another commenter suggested that we collect drug data with applicable laboratory results that examine physiological responses to each drug.

Response: We thank the commenters for their suggestions and will consider them when we initiate changes to the data elements required on claims. Further direction will be provided in the future.

3. Miscellaneous Comments

We also received general comments related to the ESRD PPS, which are included below. The comments and our responses are set forth below.

Comment: Several commenters requested that there be a payment adjustment for nursing home staff providing care to beneficiaries with ESRD.

Response: The ESRD PPS will provide a bundled payment for renal dialysis services provided by a Medicare-certified ESRD facility. The case-mix payment adjustments are provided to account for the additional costs associated with separately billable items and services, of providing dialysis related services for patients with certain characteristics. The facility payment adjustments, including the outlier payment, are provided to account for the additional composite costs of providing dialysis related services. A payment adjustment for nursing home staff services would not be available under the ESRD PPS because payment for nursing home staff is covered separately outside of the ESRD PPS and, such services do not meet the definition of renal dialysis services for which ESRD facilities are paid a single rate.

Comment: One commenter was concerned that the proposed ESRD PPS would violate State and Federal anti-kickback and physician self-referral laws. The commenter believed that under the proposed ESRD PPS, an ESRD facility would be required to bill directly for laboratory tests that currently, are billed by the laboratory. The commenter believed that in cases where ESRD facilities have physician ownership, this arrangement would result in the ESRD facility sharing in profits of self-ordered laboratory tests. The commenter was concerned that physician-owned ESRD facilities, may be in violation of physician self-referral rules, and that these facilities would not be permitted to submit bills for laboratory charges. The commenter concluded that under the ESRD PPS, laboratories, as the provider of laboratory services, should continue to bill Medicare to avoid potential anti-kickback or Stark violations. Another commenter expressed concern that to the extent the ESRD facility would omit laboratory services from the ESRD facility claim in an attempt to adhere to physician self-referral rules, the services would not count towards the outlier eligibility calculation rendering the ESRD facility ineligible for potential outlier payment for laboratory services. Another commenter stated that to the extent that hospital-based ESRD facilities choose to enter into arrangements with community pharmacies for self-administered ESRD drugs, the facility would have to initiate a Stark law compliance review in the event that the community pharmacy has physician owners.

Response: Because all renal dialysis services, including ESRD-related laboratory services and drugs (with the exception of oral-only drugs), will be

paid under the ESRD PPS beginning January 1, 2011, these services as described 42 CFR § 411.351, would not be considered designated health services subject to physician self-referral requirements. If ESRD facilities have arrangements that they believe may be subject to the Federal anti-kickback statute, these facilities should contact the OIG. (Information about the Federal anti-kickback statute is available on the OIG's Web site at *http://oig.hhs.gov*.)

Comment: One commenter indicated the importance of monitoring fluid status and the need to develop strategies and practices for effective and safe fluid removal.

Response: We agree that fluid management is important; however, methods for monitoring fluid status are beyond the scope of this final rule.

Comment: Several commenters offered suggestions for additional collection of data and analyses which they believed would be helpful in connection with improving and refining the ESRD PPS. Suggestions were wide-ranging and included additional analyses showing beneficiary out-of pocket expenses under the PPS, collection of data to determine how dialysis practice patterns change under the new system, analyses for additional performance measures that could be integrated into the QIP, analysis on changes in the utilization of drugs subsequent to PPS implementation, refinement of data sources to evaluate race as a potential case-mix adjuster, collection of data on home dialysis training services and analysis of the effect on home dialysis, and collection of data and analysis to incorporate new drugs, technologies, and advances in clinical protocols into the ESRD PPS.

Response: We appreciate all of the commenters' suggestions on the collection of data and recommendations for subsequent analyses we could undertake to monitor and refine the ESRD PPS. As we gain experience with the new system, certain policy issues may emerge requiring more immediate attention for data collection and analysis. We recognize that we must balance the need for additional data and the potential for improvements and revisions to the ESRD PPS with the administrative burden that may be created. We will take all of these suggestions and recommendations under advisement for consideration of future refinements to the ESRD PPS.

Comment: Commenters expressed concern that we did not include information on how we intend to identify ESRD-related items and services after 2011. The commenters requested that we establish a periodic review process to add or remove items and services in the ESRD PPS bundle such as laboratory tests and drugs as well as update the reimbursement allocated to those services as market conditions change. Other commenters pointed out that we made policy determinations related to a number of specific items and services under the ESRD PPS based upon the current clinical practice for ESRD. The commenters requested that we specify an appropriate process for updating policies under the ESRD PPS as clinical treatments evolve and new technologies emerge.

Other commenters expressed concern that there will be little incentive for innovation from the medical products industry for new therapies and that CMS should encourage investment and innovation to improve patient outcomes. One commenter stated they believed we have the flexibility to provide for a separate payment for new and innovative drugs and technologies for a defined period of time while determining the appropriate costs of the new therapies for inclusion in the ESRD PPS bundle.

Response: We do not agree that the ESRD PPS will inhibit the development of new technologies or treatment. The ESRD PPS does not dictate, limit or prescribe any treatment or technologies used for ESRD patients. Rather, the ESRD PPS provides a payment for the average patient as well as adjustments to that payment rate to account for increased resource utilization. We have determined that several aspects of the ESRD PPS will need to be updated annually to keep current with new renal dialysis services. As we discussed in section II.A.3 of this final rule, we have not specified drugs and biologicals that would be renal dialysis services, but rather we specified categories by mode of action to provide for any new drugs or biologicals that may be developed or used in the future. For example, for anemia management, new drugs that constitute renal dialysis services that are approved for the treatment of anemia and are furnished by an ESRD facility, would be reported on the ESRD facility claims and paid under the ESRD PPS. We will use this information to update the list of ESRD-related drugs and biologicals, including the drug categories each January 1 for purposes of the outlier policy (see section II.H. of this final rule).

In a similar manner to drugs, we will need to keep the list of ESRD-related laboratory tests up-to-date for purposes of the outlier policy. The clinical laboratory fee schedule is updated annually to reflect updates in Medicare payment as well as to reflect new tests. We will be reviewing on an annual basis the new tests that are being added to the clinical laboratory fee schedule so that we can determine whether any of them are ESRD-related so they can be recognized under the outlier policy.

With regard to new technology, the payment structure under the ESRD PPS does not specify the type of modality (and therefore, the type of technology) that should be used for dialysis. Rather, the per-treatment payment provides for ESRD facilities to use the modality they believe is best, as determined by the individual plan of care. We believe that under the ESRD PPS, ESRD facilities will have the opportunity to utilize any new technology that arises.

We believe that these mechanisms of updating ESRD-related drugs and biologicals and laboratory tests, will address any changes that may arise in the future. However, should the technologies and treatments for ESRD change significantly at some point in the future, we could consider whether other mechanisms may need to be incorporated through future rulemaking to ensure that Medicare ESRD patients continue to have access to important advances in care.

Comment: One commenter suggested that we update the ESRD PPS base rate, patient-specific adjusters, co-morbidity case-mix adjusters and facility-level adjusters no later than CY 2013 because by that time we should have adequate data. The commenter expressed concern that if the ESRD PPS is not updated annually, the adjusters could remain unchanged over an extended period of time and would not reflect changes in the costs of provided ESRD care.

Response: We plan to implement payment for oral-only ESRD-related drugs under the ESRD PPS base rate after the ESRD PPS transition in 2014. In order to do so, we anticipate that the rulemaking to implement oral-only drugs under the ESRD PPS in 2014 would take place during 2013.

After that refinement, we expect to update periodically the regression analysis using the most recent claims and cost report data to determine if changes to the type and amount of payment adjustments are warranted. In addition, we will update the ESRD PPS annually to reflect the latest market basket forecast with adjustments for productivity, geographical variations in wages to reflect the most current hospital wage data and CBSA definitions, and appropriate changes to the fixed-dollar loss threshold amounts to maintain the 1 percent outlier policy.

As we proposed, we have codified these annual updates in § 413.196

(Notification of changes in rate-setting methodologies and payment rates). However, we have revised the language to reflect that the market basket update could result in a negative update. Therefore, we replaced reference to the market basket percentage increase with the market basket update factors.

Comment: Some commenters expressed concern about the role of the ESRD Networks. The commenters stated that there is a need to implement an ESRD Network Program that will effectively protect and support patients. The commenter suggested that the Network Program include mandatory best practice quality standards for all Networks to ensure that the quality of ESRD care is being judged consistently throughout the country. Other commenters expressed concern that the ESRD Networks are not accessible or attentive to patient concerns. Another commenter stated that the ESRD Networks should be tasked with monitoring and reporting involuntary discharges. Several commenters asked what role the ESRD Networks will have in implementing the ESRD PPS.

Response: We promote high value quality healthcare for beneficiaries and utilizes a variety of approaches to meet this goal. Examples of these approaches include contemporary quality improvement, coverage and payment policy, public reporting, and regulatory enforcement. The 18 ESRD Networks are contracted by us to oversee and facilitate high quality ESRD care, promote quality improvement, evaluate and resolve patient grievances, and assist ESRD facilities in meeting Network goals. The Networks monitor and report information related to complaints and grievances and involuntary discharges. We are currently assessing the role of the ESRD Network Program as it relates to the ESRD PPS and the QIP and how to optimize the expertise of the Networks to accelerate improvements in dialysis care.

Comment: Several commenters suggested a patient representative panel to monitor how the ESRD PPS will affect dialysis treatment and patient care. One commenter stated that there is little mentioned in the proposed rule with regards to patient satisfaction and that patient satisfaction is an important qualifier for future refinements to the system. Other commenters suggested that we establish a review process for evaluating the impact of the new PPS on patients and providers to ensure that the changes in payment do not result in clinical practice changes that adversely affect patients.

Response: We are concerned about how the ESRD PPS affects beneficiaries and has aimed to identify and mitigate potential negative effects. The way beneficiaries experience dialysis care is important to us. The QIP provides a method to ensure quality dialysis care and refers to patient satisfaction (information regarding the QIP is found in section II.M. of this final rule). Because the statute indicates that the quality measures should include patient satisfaction measures to the extent feasible, we are assessing the dialysis facility Consumer Assessment of Healthcare Providers and Systems (CAHPS tool), to determine the feasibility and readiness of use within the QIP in future years. In addition, as an integral part of the QIP, a program monitoring plan is in development to identify indicators useful in determining adverse effects on vulnerable (high risk) populations. Patient input is an important component of our monitoring plan development activities.

Comment: Some commenters expressed concern about non-compliant patients and gave suggestions for initiatives for incentivizing them to comply with their care plans. One example provided by the commenters was a "pay less for performance" incentive under which patients would be rewarded with a deduction in premiums if they follow their care plan. The commenters indicated that non-compliant behavior is very expensive in terms of furnishing healthcare.

Response: We encourage a patient-centered care approach in which the patient is included as a multidisciplinary team member (*see* § 494.80 of the ESRD Conditions for Coverage). We also encourage sharing of best practices among ESRD facilities including best practices regarding patients compliance with their care plans. While we recognize the role a dialysis patient plays into the success of their own care, Medicare is paying dialysis facilities to provide dialysis services and as such, the dialysis facility is ultimately responsible for ensuring that patients participate in their plan of care. We note that we do not have the authority to reduce patient premiums (Part B premium or co-insurance liability) to reflect patient compliance with their care plans.

Comment: One commenter noted that the proposed ESRD PPS did not inform patients adequately about effects on their costs and indicated that patients need to be informed in a clearly understood manner about how the ESRD PPS will affect their costs.

Response: We appreciate the commenter's concern about informing patients about the changes of the new ESRD PPS. We plan to outreach and educate facilities, providers and beneficiaries after this final rule is released.

Comment: One commenter supported including drugs in the bundle and believed that having drugs covered by ESRD facilities will be helpful for many patients. This commenter noted that her drug use decreased since going on home hemodialysis and she was able to stop some medications which helped lower her copayments for drugs.

Response: We thank the commenter for supporting our proposal to include drugs in the bundle.

Comment: We received several comments regarding the need for updating the Medicare cost report for ESRD facilities. Commenters stated that in order to accurately determine how facilities will fare over time under the new payment system and in order to evaluate cost trends, cost report reform is required. The commenters further explained that all of the changes that will occur under the ESRD PPS will not be properly captured in the cost report in its current form. Some commenters argued that Medicare cost reports for ESRD facilities do not offer a resource for an accurate estimation of costs associated with home hemodialysis or other home modalities. One commenter stated that if payment adequacy and other benchmarking of costs associated with current and new ESRD modalities are to be possible, cost report instructions at the modality level will need substantial revision.

Response: We agree that changes to the cost report are necessary to reflect the ESRD PPS and to improve the accounting of ESRD facility costs. Any changes in cost reporting will be addressed in the future.

Comment: Commenters indicated that the proposed ESRD PPS will give dialysis facilities an incentive not to support their dialysis patients' efforts to travel. These commenters indicated that dialysis providers often require transient patients to submit Hepatitis B, Surface Antigen and Surface Antibody results which are more recent than required by the Centers for Disease Control and Prevention (CDC) guidelines. Under current practice, the patient is generally responsible for the cost of the testing; the proposed rule will shift the cost to the home dialysis facility.

Response: Hepatitis B testing is included in the basic case-mix adjusted composite payment rate, and therefore, payments for these tests were included

in the ESRD PPS base rate. As a result, we expect that ESRD facilities will require Hepatitis B testing only when appropriate to meet CDC guidelines. The patient will have a 20 percent co-insurance liability on the ESRD PPS per treatment payment amount and does not have a financial liability specifically for Hepatitis B testing. As a result, we do not believe that the treatment of Hepatitis B under the ESRD PPS will affect or prohibit patients from traveling.

Comment: Commenters indicated that patients who travel represent an administrative burden and economic loss to the patient's home facility and bundling will make traveling patients less attractive. A few commenters had concerns about how payment will be made for the administration of medications to traveling dialysis patients. Commenters believed that dialysis facilities will be cautious of arranging transient treatment if there is no established means of reimbursement between the patient's home facility and the transient facility. One commenter indicated that transient facilities will have no incentive to administer injectable medications or higher dosages of ESAs to traveling patients. The commenter also questioned which dialysis facility would be responsible for administering necessary medications to the traveling patient under the bundled ESRD PPS. Other commenters indicated that laboratory tests required by traveling patients should be specifically excluded from the bundled ESRD PPS. If the laboratory testing required by a destination unit are not separately billable, it will complicate and perhaps, compromise the ability of beneficiaries to travel for work, family and pleasure.

Response: ESRD facilities that accept responsibility for a transient ESRD patient must furnish all necessary ESRD-related care. We expect the home dialysis facility and the transient dialysis facility to work together and exchange patient information regarding co-morbid medical conditions and drug dosing to accommodate dialysis patients who travel because of work, family or for pleasure. Given that beginning January 1, 2011, the bundled ESRD PPS base rate and adjustments include payments for laboratory tests, ESAs and other ESRD-related drugs and biologicals (other than oral-only ESRD-related drugs), dialysis facilities furnishing these services to the traveling patients will receive payment for these services through their bundled ESRD PPS payment.

Comment: Several commenters offered views regarding the imprudence of not having an ESRD PPS demonstration project or pilot testing of the proposed ESRD payment approach before going forward with national implementation.

Response: The MMA included a provision for a demonstration project to test the ESRD PPS prior to full implementation. However, that provision was repealed.

4. Comments Regarding Monitoring

We received many comments, primarily from patients and health care practitioners expressing concerns about monitoring the effects of the ESRD PPS. Comments that pertain to the QIP are addressed in section II.M. of this final rule. Other comments and our responses are discussed below.

Comment: Many commenters expressed concern about the need to monitor the impact of bundling ESRD drugs based on patient outcomes. Others questioned if there will be tracking mechanisms to see how payment changes will affect patient health. Some commenters cited particular areas of concern such as an increase in the number of parathyroidectomies being performed; iron use; bone mineral metabolism; hospitalization and vascular access.

Response: We understand the concerns raised and have indicated throughout this final rule that we will be monitoring the outcomes and effects of the ESRD PPS. While virtually all commenters expressed concerns about the potential negative effects of the PPS, we believe that the ESRD PPS provides opportunities for positive outcomes as well. Therefore, we plan to look at positive effects as well as areas of vulnerabilities. We are in the process of identifying those areas including those expressed by commenters. For example, as we discussed in section II.A.3. of this final rule, we have identified ESRD-related categories of drugs rather than specific drugs that will allow us to identify trends or changes in the drugs utilized by outcome such as anemia management. Also, as discussed earlier in this section, ESRD facilities will be required to indicate ESRD-related drugs and biologicals with other forms of administration on their claims. Because we have information on Part B on the ESRD claims and Part D separately payable drugs and biologicals, we will have a baseline from which to compare future drug usage and can monitor for changes in drug substitutions and dosing. We are also able to monitor for changes in inpatient hospital admissions and outpatient services for ESRD patients to determine if there are increases in ESRD-related procedures such as parathyroidectomies.

Comment: Some commenters questioned how changes from the ESRD PPS will be monitored for errors or fraud attempts.

Response: We have identified a number of measures in this final rule that address potential errors or fraud attempts. For example, in section II.K.2.a. of this final rule, we have described how ESRD facilities and MCPs will be required to utilize a modifier to identify items and services that they attest are not renal dialysis services. In the low-volume facility discussion in section II.F.4. of this final rule, we identified criteria that ESRD facilities will be required to meet in order to be eligible for the low-volume payment adjustment. In section II.A.3. of this final rule, we indicated that specific criteria will be required to be documented for the co-morbidity categories eligible for a payment adjustment. These can be monitored or verified. In addition, as discussed in the previous response to comments, we are in the process of identifying areas of concern (for example, drug utilization). We will be issuing specific instructions and corresponding manual changes in the future.

Comment: Some commenters indicated that oversight is needed to prevent ESRD facilities from "cherry picking" patients. One commenter expressed concern that the ESRD facility conditions for coverage allows patients to be involuntarily discharged for non-payment.

Response: We appreciate the concerns expressed that there may be ESRD facilities that will select patients based on higher payments. We will require information on the ESRD claims that will allow us to identify patient characteristics that result in eligibility for payment adjustments. For example, in the discussion under the onset of dialysis found in section II.F.3. of this final rule, we indicated that we would be looking at the number of beneficiaries who become eligible for Medicare due to a shortened coordination of benefit period. We will monitor very closely, potential access concerns and could make adjustments to the PPS in future years. We expect that ESRD facilities and providers will not "cherry Pick" patients.

We appreciate the commenters' concerns about patients being involuntarily discharged from an ESRD facility and note that, we intend to monitor for changes in the number and characteristics of patients who have been involuntarily discharged from their ESRD facility.

Comment: Several commenters indicated that there could be an increase in negative outcomes because the ESRD PPS does not apply limits on payment for preventable errors or outcomes. One commenter recommended that ESRD facilities not receive payment for preventable negative outcomes.

Response: We agree that other than the QIP discussed in section II.M. of this final rule, there is no payment reduction for negative outcomes. However, as we discuss in section II.F.3. of this final rule, we did not include certain co-morbidities, such as septicemia, as being eligible for a payment adjustment because we believe that it could be an incentive for poor outcomes. By not providing an opportunity to receive additional payment, we believe that we have mitigated payment incentives for poor outcomes.

Comment: A few commenters expressed concern that CMS should be able to determine if patients are not receiving adequate amounts of Epogen®. One commenter recommended that CMS also monitor blood transfusions administered to beneficiaries with ESRD.

Response: The commenters are correct that we collect hemoglobin information on ESRD claims. As we noted earlier, we will require ESRD facilities to indicate all renal dialysis-related drugs such as Epogen®, including dosages on the ESRD claim. We will explain this in more detail in the future. We are also planning to monitor blood transfusions for ESRD patients in our monitoring plans. We note, as discussed in section II.M. of this final rule, hemoglobin is a measure under the QIP.

Comment: One commenter recommended the establishment of an independent panel of stakeholders and experts to evaluate tracking of drugs. Another commenter suggested establishing an external oversight board comprised of dialysis community stakeholders including patients, physicians, nurses and providers to review monitoring reports to ensure transparency of data. The commenter believes the oversight board should have the authority to influence CMS policy to remediate any negative changes in availability or quality of patient care.

Response: We thank the commenters for these suggestions and will take them into consideration as we develop our monitoring plan for the ESRD PPS.

Comment: One commenter believed that it is extremely important to set up a monitoring system that ensures that under the ESRD PPS, patients and physicians maintain access to a wide range of available drugs. The commenter also stated that a process to monitor medication use in real-time using clearly delineated metrics more inclusive than quality measures, to "ensure that no adverse effects of the bundle on patient care and outcomes."

Response: We have discussed that we are requiring ESRD facilities to identify on the ESRD claims, renal dialysis related drugs. We discussed in section II.A.3. of this final rule that we identified categories of renal dialysis related drugs using claims data for drugs which received separate payment. We expect that ESRD facilities will, therefore, ensure that their patients receive the drugs (and biologicals) that they require. At the current time, we are unable to monitor medication use in real time as we are dependent on information on ESRD claims submitted by the ESRD facilities.

Comment: A few commenters were in favor of retaining the ESA Claims Monitoring Policy. These commenters suggested that similar monitoring policies be created for dosage administration and physiological response, for other drug classes (such as antibiotics, thrombolytics, vitamins and minerals).

Response: We thank the commenters and will take the suggestions into consideration as we develop our monitoring policies.

5. Comments Beyond the Scope of This Final Rule

We also received many comments that were beyond the scope of the ESRD PPS final rule, including comments the following topics: Educating patients on the importance of compliance with their prescribed treatment plan and expanding funding for educating people on strategies for the prevention of kidney disease; end of life care for dialysis patients; cost containment or price ceilings on pharmaceuticals and equipment; the need for financial planning for death and financial assistance to bereaved families in need, to deal with outstanding funeral and medical bills; consideration for studying the potential future of stem cell treatments; the need to be more progressive in offering cutting-edge options to beneficiaries; the need to establish criteria such as morbidity, prognosis, age and family support to determine a beneficiary's appropriateness for dialysis; consideration for a payment adjustment for beneficiaries with ESRD who are employed or attending school; concern that the surveyors from the Department of Health are not encouraging best practices and no longer pursue the goal of identifying ways to improve care for patients; and the need for disaster planning for the provision of dialysis treatments.

Other commenters raised issues related to post-transplant coverage of immunosuppressive drugs, stating that coverage of post-transplant immunosuppressive drugs should be extended for the life of the transplant because oftentimes patients have difficulty affording these medications when Medicare coverage runs out. One commenter requested that Medicare preserve access to brand name post-transplant medications. A patient commenter requested help paying for a transplant and for post-transplant medical care. Another patient commenter wanted to know whether they could get a kidney. One commenter stated that it is unfortunate that nephrologists spend minimal time in training on home dialysis modalities. Another commenter stated that greater emphasis should be placed on long-term rehabilitation such that ESRD patients can enjoy active lifestyles, employment and community involvement. Another commenter believed that CMS should develop a plan to encourage and track employment status among patients with ESRD.

Because the above issues are beyond the scope of this final rule, we have not addressed them in this final rule.

L. Evaluation of Existing ESRD Policies and Other Issues

In the proposed rule, we reviewed existing ESRD policies to determine their applicability to the ESRD PPS. We proposed to eliminate the exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities that exist under the basic case-mix adjusted composite payment system (74 FR 50007). We proposed to evaluate the current ESA monitoring policy (EMP) and the operational issues for circumstances in which Medicare is the secondary payer (MSP). We also proposed to maintain the bad debt policy and the 50-cent per treatment deduction to fund the ESRD Networks (74 FR 50007). We also proposed to set forth in § 413.195 the limitation on review with regard to the ESRD PPS (74 FR 50007). In addition, we explained that we were considering the extent to which the laboratory services 50 percent rule would continue to apply under the ESRD PPS (74 FR 50008).

1. Exceptions Under the Case-Mix Adjusted Composite Payment System

Section 1881(b)(7) of the Act and § 413.182 generally address exceptions to the composite payment rates. Section

422(a)(2) of BIPA prohibited the granting of new exceptions to the composite payment rates after December 31, 2000. Section 623(b) of the MMA amended section 422(a)(2) of BIPA to restore composite rate exceptions for pediatric facilities that did not have an exception rate in effect as of October 1, 2002. Section 422(a)(2)(D) of BIPA defined a pediatric facility as a renal dialysis facility at least 50 percent of whose patients are under 18 years of age.

In the proposed rule (74 FR 50007), we noted that in the CY 2005 PFS proposed rule (69 FR 47535), we explained that section 422(a)(2)(C) of BIPA provided that any ESRD composite rate exception in effect on December 31, 2000, would continue as long as the exception rate exceeds the applicable composite payment rate. We further explained the methodology that would be employed to compute the exception amount, and that we were proposing to allow each dialysis facility the option of continuing to be paid at its exception rate or at the basic case-mix adjusted composite rate. On April 1, 2004, we opened the exception window for pediatric facilities and noted that the window would close in September 27, 2004. We further explained that in the CY 2005 PFS final rule with comment period (69 FR 66332), we stated that the exception process was opened each time there is a legislative change in the composite payment rate or when we open the exception window, including our intent to open the pediatric exception windows on an annual basis. We also noted that we would provide for the continuation of the home training exception, to allow for facilities with home training exceptions to retain their current training exception rates as well as take advantage of the case-mix adjusted rates for non-training dialysis (74 FR 50007).

In the proposed rule, we indicated that while section 153 of MIPPA does not directly address exceptions, section 1881(b)(14) of the Act creates an ESRD bundled prospective payment in lieu of payment under previous ESRD payment systems, and given that the ESRD PPS no longer directly addresses changes in the ESRD composite rate, we believe that the exceptions currently in place would no longer apply (74 FR 50007). We also noted we addressed the higher costs relating to case-mix through the patient characteristic adjustments and outlier payments (74 FR 49949 and 49987). We proposed the elimination of the isolated essential facility, self dialysis training costs, atypical service intensity (patient mix) and pediatric facility exceptions, effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the phase-in). In other words, any existing exceptions would terminate effective for ESRD treatment on or after January 1, 2014. Additionally, no further exception windows would be open effective for ESRD treatment furnished on or after January 1, 2011, the effective date of the ESRD PPS. In the event that an ESRD facility elected to receive full payment under the ESRD PPS for renal dialysis services on or after January 1, 2011, any existing exceptions would no longer be recognized. In the event that an ESRD facility elected to receive payment under the transition period, any existing exceptions would be recognized for purposes of the basic case-mix adjusted composite payment system portion of the blended payment through the transition. We proposed to include the periods of exceptions and the elimination of the exceptions to the composite payment rates in § 413.180 of the regulations. With respect to appeals under § 413.194(b), we pointed out that such appeals apply only to exceptions to the composite rate granted before January 1, 2011 (74 FR 50007).

We received comments from three children's hospitals and one from the American Academy of Pediatrics concerning pediatric exceptions and these comments are described below. We did not receive any comments on our proposal to eliminate the isolated essential facility, self-dialysis training costs, and atypical service intensity (patient mix) exceptions.

Comment: One commenter indicated that the proposed pediatric case-mix adjusters and elimination of the pediatric facility exceptions would reduce the costs adjustments needed by many pediatric facilities to remain operational. The commenter believed that the proposed pediatric case-mix adjusters and the elimination of the pediatric exceptions would result in children and adolescents with ESRD not having access to specialized dialysis care. Other commenters believed that these proposals fail to recognize the uniqueness of pediatric facilities that have State mandated higher staff ratios, additional staff required such as teachers and child life specialists, and higher supply costs associated with treating pediatric ESRD patients.

Response: We believe that the changes we have made in this final rule with regard to the pediatric model address the specific needs of pediatric patients and the care that they require. We discuss these changes in detail in section II.G. of this final rule. With regard to the pediatric exceptions, as we discuss in greater detail below, we believe that our proposal to eliminate such exceptions is appropriate and warranted under the statute.

Comment: One commenter indicated that the MIPPA legislation did not specifically eliminate the existing pediatric exceptions to the composite rate and believes that our interpretation of the MIPPA "is a stretch."

Response: We do not agree with the commenter with regard to our interpretation of the MIPPA legislation and section 1881 of the Act. As we discussed in the proposed rule, we continue to believe that the ESRD PPS under section 1881(b)(14) of the Act creates an ESRD prospective payment system in lieu of payments under previous ESRD payment systems. Given that these exceptions pertain to the prior composite rate payment systems under section 1881(b) of the Act, we do not believe that such exceptions would carry forward or be appropriate under the ESRD PPS. After the ESRD PPS transition, no portion of the ESRD PPS payments will be based on the composite rate. As a result, we do not believe it would be appropriate to continue composite rate exception payments after January 1, 2014. We also believe that we have addressed the higher costs of pediatric patients in the final pediatric model discussed in detail in section II.G. of this final rule.

We are finalizing the elimination of the isolated essential facility, self-dialysis training costs, atypical service intensity (patient mix)and pediatric facility exceptions effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the phase-in). We are also finalizing our proposal that no further exception windows would be open after January 1, 2011, the effective date of the ESRD PPS. In the event that an ESRD facility elects to receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, existing exceptions would no longer be recognized. In the event that an ESRD facility elects to receive payment under the transition existing exceptions would be recognized for the purpose of the basic case-mix adjusted composite payment system portion of the blended payment. We are finalizing the inclusion of the periods of exception and the elimination of the exceptions to the composite payment rates in § 413.180 of the regulations. We note that appeals under § 413.194(b) apply only to exceptions to the composite rate granted before January 1, 2011.

2. Erythropoiesis Stimulating Agent (ESA) Claims Monitoring Policy

In the proposed rule, we discussed the historic development of the ESA Claims Monitoring Policy. We noted that we were evaluating the extent to which we could continue the ESA Claims Monitoring Policy for renal dialysis services furnished on or after January 1, 2011. Specifically, at that time it was not known how the reduction in payment that is currently applied to the separately billed ESAs would be applied under the proposed ESRD PPS (74 FR 50008).

In the proposed rule, we noted that we would continue to evaluate how to establish eligibility for outlier payments in instances where the ESA Claims Monitoring Policy is implicated. CMS is adopting the EMP under the ESRD PPS in computing basic case-mix adjusted composite payments amounts during the transition and it will be taken into account when determining eligibility for outlier payments. We have included the comments and responses pertaining to this policy in section II.H. of this final rule.

3. ESRD Facility Network Deduction

In the proposed rule, we indicated that pursuant to section 1881(b)(7) of the Act, to fund the ESRD Networks, 50 cents is deducted from the amount of each payment for each treatment (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). The reduction amount applies to all treatment modalities. We sited the Medicare Claims Processing Manual, Public Law 100–04, Ch. 8, section 110 for information on the methodology for calculating the reduction.

We proposed to continue this deduction under the ESRD PPS with a 50-cent reduction per treatment from the payment made to ESRD facilities under the ESRD PPS for facilities that elect to receive payment under the ESRD PPS. For facilities that elect the ESRD PPS transition, we would apply the 50-cent reduction the blended payment amount (74 FR 50008).

We did not receive any comments opposing the continuation of the ESRD network deduction. Therefore, we are finalizing that we will continue the 50-cent deduction under the ESRD PPS.

4. Bad Debt

In the proposed rule, we explained that § 413.89 and Chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM)(CMS Pub. 15–1) set forth the general requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and coinsurance amounts. Additional requirements for ESRD facilities are set forth at § 413.178. We further explained that under the basic case-mix adjusted composite payment system Medicare pays ESRD facilities 80 percent of a prospectively set composite rate for outpatient dialysis services. The Medicare beneficiary is responsible for the remaining 20 percent as co-insurance, as well as any applicable deductible amounts as set forth in § 413.176 of the regulations. If the ESRD facility makes reasonable collection efforts, as described in section 310 of the PRM, but is unable to collect the deductible or coinsurance amounts for items or services associated with the composite rate, we consider the uncollected amount to be a "bad debt", if the facility meets the requirements at proposed § 413.178 and proposed § 413.89 of the regulations. We also explained that at the end of the ESRD facility cost reporting period, Medicare recognizes a facility's Medicare bad debts. However, § 413.178(a) requires CMS to reimburse ESRD facilities for its allowable bad debt up to the facility's costs as determined under Medicare principles (74 FR 50008).

We explained in the proposed rule that in developing the proposed changes to the ESRD payment system, section 153(a)(4) of MIPPA states, as a Rule of Construction, that, "nothing in this subsection or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act." Therefore, we stated that bad debt payments would continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the proposed single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we proposed to use only the composite rate portion of the proposed single ESRD payment rate to determine bad debt payments. We also proposed that bad debt payments for ESRD facilities would continue to be capped as required under § 413.178(a). We also indicated that the Medicare cost report and instructions in the PRM, Part 2 (CMS Pub. 15–2) might be revised to report the case mix adjusted composite rate payment and associated cost data necessary to compute the ESRD facility bad debt payments.

In addition, we proposed to make a conforming change to regulation text at § 413.178(d) regarding ESRD bad debt payment under the proposed ESRD payment system and include a cross-reference to § 413.178 in § 413.89(h) and (i).

We received several comments on bad debt. The comments and our responses are set forth below.

Comment: One commenter questioned how dialysis-related bad debts would be determined under the ESRD PPS. The commenter also questioned if unreimbursed co-payments for laboratory services and Part D drugs would be reimbursed. The same commenter believes that if these services are in the bundle, then they should be included in the bad debt reimbursement and if they are not, then this would result in a financial burden for providers.

Response: As we discussed above, section 153(a)(4) of MIPPA states, as a Rule of Construction, that, "nothing in this subsection or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and co-insurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act." Therefore, we stated that bad debt payments would continue to be made for the unpaid Medicare deductibles and co-insurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we would use only the composite rate portion of the single ESRD payment rate to determine bad debt payments. As oral drugs were not included in basic case-mix adjusted composite rate, they would not be subject to bad debt reimbursement.

In order to determine bad debt amounts for only the basic case-mix adjusted composite rate portion of the

bundled ESRD PPS payment, we will utilize data from the Medicare ESRD cost report to determine the percentage of basic composite rate costs to total costs on a facility-specific basis. The current ESRD cost report Form CMS 265–94 for freestanding facilities and Form CMS 2552–96 for hospital-based facilities, contain data that can be used to compute a facility's percentage of composite costs to total costs. We will apply that facility-specific composite rate percentage to the facility's total bad debt amount associated with the bundled ESRD PPS payment. The resulting bad debt amount will be used to determine the allowable Medicare bad debt payment in accordance with § 413.89 and § 413.178. During the transition period, a facility will apply the facility-specific composite cost percentage to the bad debt amounts associated with only the transition composite rate portion of the bundled ESRD PPS payment. The resulting bad debt amount will be added to the bad debt amount associated with the transition portion of the facility's ESRD reasonable costs to determine the total allowable Medicare bad debt payment in accordance with § 413.89 and § 413.178.

Comment: One commenter believed that section 153(a)(4) of MIPPA is silent with regard to bad debt reimbursement for ESRD services and that the statute does not imply that bad debts for non-composite rate related services should or should not be covered. The commenter further believed that under the ESRD PPS, ESRD bad debts should be reported in the same manner as bad debts for other outpatient PPS services.

Response: We believe that the Rule of Construction included in section 153(a)(4) of MIPPA, as stated above, would allow for the payment of bad debt amounts that are only associated with the basic case-mix adjusted composite rate. Thus, any bad debt amounts associated with drug and laboratory tests or with any non-composite rate amounts will not be allowed. We also note that under § 413.89(i) and § 413.178(d), bad debts arising from covered services paid under a reasonable charge-based methodology, or a fee schedule are not reimbursable under Medicare. Thus, if a Medicare PPS or a portion of a Medicare PPS has its basis in reasonable charges or a fee schedule then, any associated bad debt amounts are not reimbursable.

Comment: One commenter believed that certain proposals, specifically the inclusion of laboratory services in the co-insurance calculation, contravenes the MIPPA statute which, prohibits opening the bad debt issue and increases bad debt costs for ESRD facilities. The commenter further suggested that until oral drugs are accurately accounted for, they should not be in the bundle, to ensure that additional bad debt is not imposed on facilities. The commenter recommended that CMS use caution until meaningful tracking and compliance tools for States, secondary insurers, and beneficiaries be in place. The commenter also recommended that ESRD facilities not be left with additional bad debt resulting from a new payment system.

Response: We believe that the method described above of applying a facility-specific composite rate percentage to the bad debt amounts associated with the ESRD PPS allows us to compute a facility's allowable bad debt payments in accordance with the Rule of Construction included in section 153(a)(4) of MIPPA.

Comment: One commenter noted that it was burdensome to require hospitals to calculate bad debt under a composite rate definition that will no longer exist. The commenter urged CMS to have this policy modified to relate bad debt payments to the new payment system.

Response: We believe that utilizing data that are already reported on the facility's current Medicare cost report to compute the allowable bad debt payment under the ESRD PPS, will mitigate the reporting burden to the provider. ESRD facilities will be required to continue to complete the appropriate cost report worksheets with the data necessary to compute the composite cost percentage and compute the allowable bad debt payment under the ESRD PPS.

Based on the comments received, we are finalizing that bad debt payments will continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we will use only the bad debt amounts associated with the composite rate portion of the single ESRD payment rate to determine a facility's allowable bad debt payments. We will use the methodology described above to apply a facility-specific composite cost percentage to the total bad debt amount associated with the bundled ESRD PPS payment to compute the bad debt amount for only the basic case-mix adjusted composite rate. Bad debt payments for ESRD facilities will continue to be made in accordance with § 413.89 and § 413.178 of the regulations, including the requirement to cap ESRD bad debt payments under § 413.178(a). We will revise and publish the appropriate cost reporting worksheets and instructions in the PRM, Part 2 (CMS Pub. 15–2) along with any other necessary administrative issuances, to implement the computation of Medicare ESRD bad debt payments through to the cost report, as described above, for services rendered on or after January 1, 2011.

In addition, we are finalizing the conforming change to regulation text at § 413.178(d) regarding ESRD bad debt payment made under the ESRD payment system described in this final rule. We are also including a cross-reference to § 413.178 in § 413.89(h). In the proposed rule, we erroneously indicated that we were proposing to add a cross-reference in § 413.89(i). However, we did not make any proposed revisions to § 413.89(i). Therefore, for this final rule, we are not revising § 413.89(i).

5. Limitation on Review

As discussed in the proposed rule, section 153(b) of MIPPA amends section 1881(b) of the Act to provide for a limitation on review. Specifically, section 1881(b)(14)(G) of the Act provides the following: "There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act or otherwise of the determination of payment amounts under [section 1881(b)(14)(A)], the establishment of an appropriate unit of payment under [section 1881(b)(14)(C)], the identification of renal dialysis services included in the bundled payment, the adjustments under [section 1881(B)(14)(D)], the application of the phase-in under [section 1881(b)(14)(E)], and the establishment of the market basket percentage increase factors under [section 1881(b)(14)(F)]." We proposed to codify this limitation on review in § 413.195 of the regulations (74 FR 50008).

We received several comments concerning the limitation on review. The comments and responses are set forth below.

Comment: Given the limitation of review clause, one commenter was concerned that it would impose a limit on payment for dialysis services of three treatments per week. The commenter believed that payment should be given for any treatments beyond the three treatments per week without requiring medical justification.

Response: The limitation of review clause would prohibit review of our determination of the number of treatments that would be eligible for payment. We explain how the number of ESRD treatments eligible for Medicare

payment (that is, three treatments per week), was derived in section II.E. of this final rule. We do not agree that we should abolish the medical justification requirement for treatments that exceed the threshold because this process provides a mechanism to allow additional payment beyond the established treatment threshold.

Comment: Several commenters requested we issue an ESRD PPS interim final rule to allow for additional comments or to challenge payments for Part D drugs, because the limitation on review would not allow for administrative or judicial review of the final rule.

Response: Given that we have issued a proposed rule containing a detailed proposal for an ESRD PPS, allowed for an extended 90-day public comment period, and carefully considered the comments received, we believe that a final rule is appropriate. The ESRD PPS bundle is discussed in section II.A. of this final rule and we note that oral-only drugs currently covered under Part D will not be paid under the ESRD PPS until January 1, 2014.

As we proposed, we are codifying the limitation on review in § 413.195 of the regulations. However, we have revised the language to reflect that the market basket update could result in a negative update. Therefore, we replaced reference to the market basket percentage increase with the market basket update factors.

6. 50 Percent Rule Utilized in Laboratory Payments

In the proposed rule (74 FR 50008), we discussed that as specified in CMS Pub 100–04, Chapter 16, Sect. 40.6, for a particular date of service to a beneficiary, if 50 percent or more of the covered laboratory tests within an Automated Multi-Channel Chemistry (AMCC) test are included under the composite rate payment, then all submitted tests are included within the composite payment and no separate payment is made for any of the AMCC tests. If less than 50 percent of the covered laboratory tests within the AMCC are composite rate tests, then all AMCC tests submitted are separately payable. We also described how ESRD facilities were to identify each test that is included in the composite rate and each test that is not included. We further explained that during the transition period, the 50 percent rule would continue to apply to the basic case mix adjusted composite payment system portion of the blended payment. We also stated that under the proposed consolidated billing provisions, the ESRD facility would assume the responsibility for all of the renal dialysis services that its patients receive, including laboratory tests. As a result, the ESRD facilities would apply the 50 percent rule billing procedures including application of the relevant modifiers. Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment (74 FR 50008).

In the proposed rule, we noted that preliminary analyses revealed a small impact upon removing from eligibility for outlier services the AMCC tests to which the 50 percent rule applies. As a result, we considered excluding AAMC tests from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS (74 FR 50009). We also noted that we planned to continue to evaluate the impact of this approach and include further discussion in the final rule. We requested public comments on whether or not to include the AMCC tests in the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS.

Because we are finalizing the use of the 50 percent rule with regard to determining eligibility for outlier payments, we have included our discussion of this issue, along with the comments and responses that we received pertaining to the 50 percent rule, in section II.H. of this final rule.

7. Medicare as a Secondary Payer

In the proposed rule, we stated that Medicare may be a secondary payer (MSP) when the primary payer is a group health plan for ESRD items and services furnished to Medicare beneficiaries during the 30-month Medicare coordination of benefit period (74 FR 50009). We further stated that at that time, we were unable to identify the systems operations and billing procedures impact of this relationship under the current basic case-mix adjusted composite payment system, and we were exploring how it would be utilized and managed under the proposed ESRD PPS. We stated that we believed that while there may need to be system changes in order to process MSP claims under the proposed ESRD PPS, there should be no impact on ESRD providers and on primary payers. We stated our intent to issue through administrative issuance, any changes in the manner of reporting information, should that be required. We solicited public comments on the operational issues of MSP under the proposed ESRD PPS.

We received a few comments on MSP. The comments and our responses are set forth below.

Comment: One commenter questioned what would prevent his secondary payer from dropping him or increasing his premiums. Another commenter suggested changing the MSP period for employed, child-rearing, in-school, or under 25 years of age dialysis patients from 30 months to a continuous period.

Response: Questions concerning premiums or other issues pertaining to secondary insurers are beyond the scope of this final rule. In addition, recommendations concerning changes to the coordination of benefits period are beyond the scope of this final rule.

We believe that the implementation of the ESRD PPS will have no effect on MSP rules. We will continue to evaluate the need for changes to MSP systems, operations and billing procedures under the ESRD PPS and we will issue through administrative issuance any changes in the manner of reporting information should that be required.

8. Conforming Regulation Changes

We proposed to amend 42 CFR Chapter IV. Specifically, we proposed conforming changes to existing regulations to reflect the current basic case-mix adjusted composite payment system and the ESRD PPS. We did not receive any public comment on these changes. Therefore, we are finalizing these conforming changes, along with the technical changes noted in the final rule, as follows:

- Section 413.170(a)—setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system;
- Section 413.170(b)—providing procedures and criteria under which a facility may receive a pediatric exception;
- Section 413.171—defining base rate, composite payment system, basic case-mix adjusted composite payment system, ESRD facility;
- Section 413.172(a)—setting forth that payment for renal dialysis services and home dialysis services are based on prospective payment rates:
- Section 413.172(b)—requiring that all prospective payments to approved ESRD facilities as payment in full and defines approved ESRD facility;
- Section 413.174(a)—establishing prospective payment rates for hospital-based and independent ESRD facilities prior to January 1, 2009;
- Section 413.174(f)—establishing payment for separately billable ESRD-related drugs and biological prior to January 1, 2011;

- Section 413.176(a) and (b)—establishing the beneficiary deductable;
- Section 413.178(d)—establishing bad debt under reasonable charge-based methodology or fee schedule are not reimbursable;
- Section 413.180(1),(2), and (3)—establishing the periods of exceptions to payment rates;
- Section 413.231(a)—establishing the adjusted labor portion of the base rate to account for geographic differences in area wage levels;
- Section 413.231(b)—defining urban and rural areas;
- Section 414.330(a)(2)—establishing exception for equipment and supplies furnished prior to January 1, 2011;
- Section 414.330(b)(2)—establishing exception for home support services furnished prior to January 1, 2011;
- Section 414.330(c)—establishing payment limits for support services, equipment and supplies furnished prior to January 1, 2011; and
- Section 414.335(a)—establishing payment home EPO use prior to January 1, 2011.

M. Anemia Management and Dialysis Adequacy Measures

In the September 29, 2009 proposed rule (74 FR 50009), we proposed to adopt three measures by which the quality of dialysis services furnished by ESRD providers participating in Medicare would be measured.

Section 1881(h)(2)(A) of the Act requires that the measures specified for the Quality Incentive Program (QIP) include measures on anemia management that reflect the labeling approved by the Food and Drug Administration (FDA) for such management, measures on dialysis adequacy, and such other measures the Secretary specifies. To implement this section, we proposed (74 FR 50011) that for the first QIP performance period we would adopt the two anemia management measures and one hemodialysis adequacy measure that are currently used for Dialysis Facility Compare (DFC). Data needed to calculate these measures can be collected from Medicare claims submitted by ESRD providers/facilities on a patient-specific basis.

The anemia management measures used for DFC assess the percentage of patients at a facility whose anemia was not controlled at both the high and low ends of the FDA-recommended hemoglobin levels. Specifically, these measures are: (1) The percentage of patients treated at a provider/facility with a Hemoglobin Less Than 10 g/dL and treated with erythropoiesis stimulating agents (ESAs), and (2) the percentage of patients at a provider/facility with a Hemoglobin Greater Than 12 g/dL and treated with erythropoiesis stimulating agents (ESAs).

The current FDA labeling guideline released November 8, 2007 for the administration of ESAs to patients with chronic kidney disease, including ESRD patients, states, "The dosing recommendations for anemic patients with chronic renal failure have been revised to recommend maintaining hemoglobin levels within 10 g/dL to 12 g/dL."

As we stated in the proposed rule (74 FR 50011), we believe that the proposed anemia management measures reflect the approved FDA labeling for anemia management because they assess the number of patients whose hemoglobin levels are at the low and high end of the FDA label recommendation. In addition, we believe that it is more appropriate to adopt two measures which together assess the high and low ends of the FDA recommended hemoglobin level range, rather than a single measure that reflects the percentage of patients who have hemoglobin levels within the 10 through 12 g/dL range, because two measures will provide a richer picture of provider/facility performance. Additionally, the low and high ends for anemia management have been of particular concern for the treatment of vulnerable patients and these measures will allow for monitoring for this potential outcome. These data will also allow us to calculate the percentage of patients who have hemoglobin levels within the 10 through 12 g/dL range. Therefore, we proposed to adopt these two anemia management measures for the QIP (74 FR 50011).

Anemia data have been reported on DFC since January 2001. As we noted above, we updated the reporting of anemia data for DFC in November of 2008 to be consistent with the new FDA labeling guideline released in November 2007; however, the methodology for calculating the provider/facility, State, and national averages for anemia measures has not changed since the initial release of DFC. We proposed to use the same methodology we use to calculate the anemia management measures for purposes of DFC to calculate the measures for purposes of the QIP because the methodology is consistent with how we have calculated that data since 2001 (74 FR 50011). Under this methodology, we will calculate the measures using hemoglobin data for Medicare patients who have been diagnosed with ESRD for at least 90 days and whose Medicare claims submitted by providers/facilities indicated the use of an ESA during that 90-day period. Data from patients whose first ESRD maintenance dialysis starts before day 90 or who have hemoglobin values of less than 5 g/dL or greater than 20 g/dL will be excluded from the measure calculation. In addition, there must be for the same patient at least 4 claims meeting this criteria for that data to be included in the data for a specific provider or facility.

Technical details on the methodology used to calculate the anemia measures are available on the Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center Web site: *http://www.dialysisreports.org/Methodology.aspx.*

The Hemodialysis Adequacy Measure (urea reduction ratio (URR)) that we proposed to adopt (74 FR 50011) is also used for DFC and assesses the percentage of patients at a provider or facility that get their blood cleaned adequately (blood urea is removed during in-center hemodialysis). Specifically, this measure assesses the percentage of in-center hemodialysis patients at a provider or facility whose urea reduction ratio (URR) is 65 percent or greater, a standard based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines (NKF–KDOQI). These guidelines are widely used and generally accepted throughout the ESRD community. More information on the calculation of the URR is available at *http://www.dialysisreports.org/Methodology.aspx.*

The methodology for calculating the provider/facility, State, and national averages for the in-center hemodialysis measure has been used since January 2001 with the initial release of DFC; we proposed to use the same methodology to calculate the measure for purposes of the QIP to be consistent with how that data has been calculated since 2001 (74 FR 50012). Under this methodology, we will calculate URR data only for Medicare patients who have been diagnosed with ESRD and received in-center maintenance hemodialysis for at least 183 days from the date that they received their first maintenance dialysis treatment, and whose Medicare claims submitted by providers/facilities included a value for the URR. In addition, there must be for the same patient at least four claims meeting the criteria above for that data to be included in the data for a specific provider or facility. Technical details about the methodology we proposed to use to calculate the hemodialysis adequacy measure are available on the University of Michigan Kidney Epidemiology and Cost Center Web site

at: *http://www.dialysisreports.org/Methodology.aspx.* We note that the data we need to calculate the proposed anemia management and hemodialysis adequacy measures described above can be collected through ESRD claims, which is the only complete provider/facility level data set available to CMS at this time. For this reason in the September 29, 2009 proposed rule published in the **Federal Register** (74 FR 50012), we proposed to adopt only the two anemia management measures and one dialysis adequacy measure described above.

Although we recognize that section 1881(h)(2)(A)(i)(ii) states that the measures shall include "measures on dialysis adequacy," only one dialysis adequacy measure is collected nationally and available to determine provider/facility-specific values. For this reason, we proposed to adopt only one dialysis adequacy measure. We also note that section 1881(h)(2)(A)(iii) of the Act states that the measures shall include, to the extent feasible, other measures as the Secretary specifies, including measures on iron management, bone mineral metabolism, and vascular access (intended to maximize the placement of arterial venous fistula). CMS did not propose in the September 29, 2009 proposed rule, to adopt any measures in these categories for the QIP payment consequence year 2012 since we are not currently collecting data in a manner that would allow determination of provider/facility-specific performance with respect to these categories of measures (74 FR 50012). We are working to identify appropriate sources from which we can adequately capture data to support the future adoption of additional measures. Finally, as we stated in the ESRD PPS proposed rule (74 FR 50012), it is not feasible to propose a patient satisfaction measure at this time because the data collection tool has not been fully validated for the collection of relevant and industry accepted patient satisfaction data. Therefore, we believe it is not feasible to propose more than the aforementioned measures for the QIP payment consequence year 2012 because of the lack of complete and accurate data. We will address other measures in future rulemaking.

In the September 29, 2009 proposed rule (74 FR 50012 through 50016), we also outlined a conceptual model describing various components of the QIP under consideration, such as the weighting of measures and scoring methodology for determining payment reductions. The purpose of the conceptual model was to notify the public regarding what we believe to be essential components of the QIP and obtain detailed comments on those components for purposes of future rulemaking. Our previous discussion of the measures and the conceptual model may be found in the ESRD PPS proposed rule (74 FR 50009).

We received approximately 194 comments on the proposed measures. Many commenters agreed that we should adopt the three proposed measures, although many also suggested that additional measures be included in the ESRD QIP to ensure a robust measurement of the quality of services furnished by dialysis providers/facilities. Commenters also noted the importance of including measures for pediatric, peritoneal and home hemodialysis patients to assure that quality care is provided to these populations.

In response to public comments received about the inclusion of younger patients, we have decided that patients < 18 years of age will not be included in the final calculation of the anemia measures because at this time there is no consensus on the appropriate hemoglobin range for this age group. Further, using this exception makes these measures more consistent with the target age used in the clinical performance measures (CPMs) which have been used by providers/facilities for several years. Therefore, we will use the same methodology for data collection and analysis as used for calculation of the anemia measures reported to the DFC with the exception of not including patients < 18 years of age in the final calculation of provider/facility performance on the measures.

In response to a number of public comments received on these measures and in recognition of a number of concerns related to the exclusion of home hemodialysis patient data from the Hemodialysis Adequacy measure, we are clarifying that home hemodialysis patient data will be included in the calculation of the anemia management measures. Home hemodialysis patients have been included in the anemia management measures currently reported; however, there are different frequencies of treatment for the Home Hemodialysis population that makes the currently accepted measure of Hemodialysis Adequacy of a URR Greater than 65 percent invalid at this time. CMS is currently working with stakeholders to establish a measurement of the adequacy of a hemodialysis treatment that is accurate for this population. This is CMS' basis for excluding this population from the initial year of the QIP. Below we provide a brief summary of each measure proposed, a summary of the public comments received, and our responses to the comments.

We also received comments on the weighting and scoring of measures and the setting of the national performance standard described in the conceptual model. Comments received on components of the conceptual model not related to these measures will not be addressed in this rule. As stated in the proposed rule, we intend to use these comments to inform future rulemaking.

1. Anemia Management Measures: Hemoglobin Less Than 10 g/dL and Hemoglobin Greater Than 12 g/dL

As stated above, we proposed to use the anemia management measures as used in the current DFC database since January 2001 and as required by section 1881(h)(2)(A)(i) of the Act. The anemia management measures proposed for the QIP include two measures on anemia management that reflect the labeling approved by the FDA for such management (74 FR 50011). Data for these measures can be collected from Medicare claims currently submitted by ESRD providers/facilities as required in the initial year. The anemia measures that were proposed are as follows:

- Percentage of Medicare patients at a provider/facility who have an average hemoglobin value less than 10.0 g/dL (referred to in this final rule as the "Hemoglobin Less Than 10 g/dL").
- Percentage of Medicare patients at a provider/facility who have an average hemoglobin value greater than 12.0 g/dL (referred to in this final rule as the "Hemoglobin Greater Than 12 g/dL").

We proposed to calculate these measures using hemoglobin data for Medicare patients who have been diagnosed with ESRD for at least 90 days and whose Medicare claims submitted by providers/facilities indicated the use of an ESA during that 90-day period. Data from patients whose first ESRD maintenance dialysis starts before day 90 or who have hemoglobin values of less than 5 g/dL or greater than 20 g/dL will be excluded from the measure calculation. In addition, there must be, for the same patient, at least 4 claims meeting this criteria for that data to be included in the data for a specific provider or facility. However, as described, ESRD patients less than 18 years of age will not be included in the measure calculation. (Technical details on the methodology we proposed to use to calculate the anemia measures are available on the Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center Web site: *http://*

www.dialysisreports.org/Methodology.aspx.)

Comment: A few commenters voiced concern about the lack of measures specific to home hemodialysis. Because this modality is being advanced within the ESRD community and Medicare, commenters wished to ensure that measures for this patient population are incorporated in the QIP.

Response: We agree that inclusion of home dialysis modalities (that is, home hemodialysis and peritoneal dialysis) data is important to ensure providers/facilities are incentivized to include these populations in quality improvement efforts. To that end, home hemodialysis patient data will be used to calculate provider/facility scores on the anemia management measures in the QIP payment consequence year 2012. However, due to the varying frequencies of treatments for the home hemodialysis population the use of the currently accepted measure of Hemodialysis Adequacy of a URR greater than 65 percent is invalid at this time. For this reason we will not include home hemodialysis patient data in the calculation of the Hemodialysis Adequacy measure at this time. We are currently working with stakeholders to establish a measurement of the adequacy of a hemodialysis treatment that is accurate for this population. Beyond anemia management and dialysis adequacy, we are continuing to work with the ESRD stakeholders to develop new quality measures for use in future years of the QIP that are applicable, relevant, and provide a means to assess the quality of care that is being delivered to the home hemodialysis population.

Comment: Some commenters questioned the value of the Hemoglobin Greater Than 12 g/dL measure because they believe that the bundled payment should reduce the incidence of overutilization of erythropoiesis stimulating agents (ESAs). The commenters also stated that the percentage of patients with hemoglobin in the range of >10 g/dL and <12 g/dL would be a more effective measure for the QIP.

Response: Hemoglobin values at either end of the spectrum have adverse consequences for the ESRD patient population. We believe that focusing on the population that falls within the range of 10–12 g/dL will not provide the necessary information to evaluate the percentage of patients whose anemia is either inadequately treated or overtreated.

A Hemoglobin Less Than 10 g/dL may be the result of inadequate administration of ESAs, inadequate iron stores, blood loss (gastrointestinal bleeding), an infectious process, or other clinically significant causes. Hemoglobin Less Than 10 g/dL can result in poor oxygenation, decreased activity, increased hospitalizations, need for blood transfusions, and death. We believe that the threat of such adverse consequences should prompt ESRD facilities to take steps to increase patients' average Hemoglobin to greater than 10 g/dL.

On the other hand, a Hemoglobin Greater Than 12 g/dL may result from the overtreatment of anemia with ESAs. A Hemoglobin Greater Than 12 g/dL while a patient is being treated with ESAs has been associated with an increased incidence of death in the ESRD population.

By focusing solely on the percentage of patients that fall between 10–12 g/dL, we believe that important clinical indicators of inadequate or overaggressive treatment of anemia would be lost. A summary of evidence regarding the importance of these measures may be accessed at: *http://www.cms.gov/CPMProject/Downloads/ESRDAnemiaSummary05212008.pdf.*

Comment: Two commenters noted that patients who are active or younger may have higher average hemoglobin levels because higher hemoglobin supports their energy levels. Using the Hemoglobin Less Than 10 g/dL and Hemoglobin Greater Than 12 g/dL for the first QIP performance period, according to the commenters, will force dialysis centers to prescribe less erythropoietin and maintain these patients' average hemoglobin levels closer to 10 g/dL, thereby reducing these patients' ability to continue working and greatly affecting their quality of life. Another commenter stated that patients who live at high altitudes may have higher average hemoglobin levels which should be accounted for in the QIP.

Response: Section 1881(h)(2)(A)(i) of the Act requires that the measures on anemia management specified for the QIP reflect the labeling approved by the Food and Drug Administration (FDA) for such management. The current FDA guidance may be found at: *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126481.htm.*

We also note that due to the lack of scientific evidence indicating that anemia management for the pediatric population should be the same as the adult population, we do not believe it is appropriate to include the ESRD population under the age of 18 years in the final calculation of the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) that we are finalizing for the QIP payment consequence year 2012. However, the data collection and measure calculation will remain consistent with that used for the DFC since 2001 as described in the current methodology at: *http://www.dialysisreports.org/Methodology.aspx.*

Lastly, guidelines for the administration of ESAs, along with dose adjustments are included along with the ESA packaging that is approved by the FDA. Dose adjustments are made at the discretion of the clinician, based on the needs of the individual patient in order to achieve the desired hemoglobin. This rationale is equally applicable to the population that lives at higher altitudes mentioned by the other commenter and is reported in Brookhard M.A., *et al. Journal of American Society of Nephrology* 19(7): 1389. 2008. In considering the commenters concerns for patients living in high altitude areas, we have determined, based on clinical studies, that while patients living at high altitudes may require less or lower doses of ESA to maintain hemoglobin levels at the appropriate level, they should not be excluded from the measure.

Comment: One commenter recommended that patients not on ESAs be excluded from the Hemoglobin Greater Than 12 g/dL.

Response: Patients who are not receiving ESAs are excluded from the Hemoglobin Greater Than 12 g/dL measure. The purpose of this measure is to monitor high hemoglobin that may be directly attributed to the use (possible overutilization) of ESAs and not attributed to other causes. Therefore, patients not receiving ESAs are excluded from Hemoglobin Greater Than 12 g/dL. Specifications for this measure may be found at: *http://www.dialysisreports.org/Methodology.aspx.*

Comment: Two commenters had a concern about the specifications for the anemia management measures, particularly the time window for measurement. One of the commenters had concerns about the proposal to use the DFC specifications for the Hemoglobin Less Than 10 g/dL because, under those specifications, we calculate a yearly average for the hemoglobin level. The commenter recommended that CMS calculate a 3-month average and then average these 3-month averages over a 12-month period (for example, create a 12-month average using 4 averaged patient quarters). The other commenter believed that the use of 12-month averaging to calculate the anemia management measures would

decrease the public's ability to separate good performers from poor performers. According to this commenter, when 12-month averages are used, clinical performance in most providers/facilities approximates the national average for performance on the anemia management measures. The commenter recommended that for purposes of the QIP, we calculate a 3-month average based on a monthly assessment of lab results.

Response: We proposed to calculate the proposed anemia management measures using the same specifications that we currently use for DFC because the methodology is consistent with how we have calculated those measures since 2001. Details and an explanation for the use of and planned continued use of the existing calculation used for the calculation of the anemia percentages are available on the following Web site: *http://www.dialysisreports.org/Methodology.aspx*.

We believe that using the specifications currently in use for these measures will create minimal data collection disruptions for providers/facilities because they are already submitting data in accordance with these specifications. However, as we review the data from the initial year of the ESRD QIP, we will use findings from this data review to determine whether or not specifications for this measure should be changed. We believe we have the authority to update specifications of quality measures in appropriate cases, such as when selected specifications do not result in useful or accurate information in comparing ESRD providers/facilities. However, we will use the rulemaking process to adopt any changes to measures or new measures into the QIP.

After consideration of the comments received on the Anemia Management Measures and for the reasons stated above, we are finalizing the two anemia measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) as proposed for the QIP payment consequence year 2012 with one change to these measures. As noted above, patients < 18 years of age will not be included in the final measure calculation of the two anemia measures because of lack of scientific evidence to support the appropriate hemoglobin range for this population and concerns voiced through public comment. Further, excluding the population less than 18 years of age is consistent with the target age for the Anemia Management CPMs in current use. However, we are finalizing the data collection process and calculation of the facility level measures consistent with what has been used for the DFC since 2001. Once testing of data collection for additional measures is completed and such measures prove to be feasible and reliable measures, we will consider adding those measures in future years of the QIP.

2. Hemodialysis Adequacy Measure: Urea Reduction Ratio (URR)

The Hemodialysis Adequacy Measure—Urea Reduction Ratio (URR)—is a nationally reported measure used in the DFC database since January 2001 and can be calculated from claims data currently submitted by ESRD providers/facilities. The hemodialysis adequacy measure that we proposed to adopt (74 FR 50011) is the percent of hemodialysis patients with URR ≥ 65 percent (referred to in this final rule as the "Hemodialysis Adequacy Measure"). We proposed to calculate URR data only for Medicare patients who have been diagnosed with ESRD and received maintenance dialysis for at least 183 days from the date that they received their first maintenance dialysis treatment, and whose Medicare claims submitted by providers/facilities included a value for the URR. In addition, there must be for the same patient at least 4 claims meeting the criteria above for that data to be included in the data for a specific provider or facility. In the proposed rule (74 FR 50013), we proposed that this measure would only apply to facility-based hemodialysis and patients > 18 years of age. As we explain in detail below, peritoneal and home hemodialysis patients will not be included in this measure because, based on the clinical evidence, we have determined that the existing Hemodialysis Adequacy Measure of (URR) > 65 percent is not applicable to these patients.

Comment: Several commenters stated that the Hemodialysis Adequacy Measure is not an accurate measure of dialysis adequacy and that the measure Kt/V is the more accurate and better measure. Additionally, one commenter stated that URR specifications should be adjusted for patients receiving short, daily dialysis (that is, dialysis received 5 or more times per week for 2 to 3.5 hours as required to ensure adequate dialysis).

Response: We currently use ESRD claims for quality data and the URR is one of the measures on the claims. However, the collected URR is only reported for patients receiving in-center hemodialysis and those above the age of 18 years (approximately 96 percent of hemodialysis patients). Accordingly, we believe it is appropriate to use this measure initially for the QIP. The use of URR ≥ 65 percent for the measurement of adequacy with peritoneal dialysis, home hemodialysis, and pediatric dialysis is not a valid measurement of dialysis adequacy because of the unique variations that exist with each different type of dialytic modality and patient population (that is, pediatric patients or adults). Starting July 2010, however, providers are required to submit both URR (in-center hemodialysis patients) and Kt/V (all modalities) on all ESRD claims as reported through CMS Change Request (CR 6782). Given that Kt/V will soon be submitted on claims and that it has become a more widely accepted measurement of the adequacy of dialysis and the National Quality Forum has endorsed quality measures using Kt/V for hemodialysis and peritoneal dialysis, we anticipate that the URR may be replaced by Kt/V in future program years.

Comment: One commenter expressed concern about the Hemodialysis Adequacy Measure proposed for the QIP payment consequence year 2012 as a valid measure of quality. The claims data used for this measure reports the Hemodialysis Adequacy Measure as a range and does not require the number of treatment sessions. The commenter recommended that CMS require that providers/facilities report the specific URR value and the number of treatments to ensure that the measure captures only those patients receiving three treatments per week. Additionally, a commenter recommended that we calculate the measure using patient quarters rather than a 12-month average.

Response: ESRD providers/facilities are required to submit the number of treatments and the specific URR value on each claim submitted for payment. The measure is currently calculated for purposes of DFC using data from patients that have three treatment sessions per week. Patients included in the measures are those receiving in-center hemodialysis. As noted previously, peritoneal and home hemodialysis patients are excluded as well as pediatrics because clinical evidence demonstrates that this is not a valid measure for these patients; however it is an accepted measure for in-center hemodialysis patients. Patients included in this measure must be greater than 18 years of age, have at least 4 claims and have been on dialysis for at least 183 days. Full details and technical specifications for this measure can be accessed at: *http://www.dialysisreports.org/Methodology.aspx*. It is important to note that initially for the QIP all

measures will be claims-based since that is the only complete facility level source of data available for this population. URR is being used in the QIP payment consequence year 2012 because it is a standard measure used in ESRD practice for in-center hemodialysis and has been publicly reported in the DFC since January 2001. We believe this will avoid confusion in the data collection process. We have analyzed the existing claims data to see if there was a significant variance in calculating the URR based on patient quarters rather than a 12-month average and found that there is no difference that would warrant a change in the current methodology that uses a 12-month average.

Comment: A few commenters agreed that the proposed Hemodialysis Adequacy Measure should continue to exclude patients on peritoneal dialysis or home hemodialysis because this measure is not an accurate reflection of the effectiveness of these two modalities. Additionally, some of the commenters recommended that Kt/V be implemented to include peritoneal dialysis and home hemodialysis. Other commenters expressed concerns about the timing of laboratory testing for dialysis adequacy. Another commenter recommended that both the number of treatments prior to measurement of URR and when tests should be taken should be made clear. Lastly, there was concern among the commenters about the impact of residual renal function, which contributes to overall renal clearance and thus, would increase the measure score.

Response: We agree with the commenters that the existing Hemodialysis Adequacy Measure of URR >65 percent should be excluded for home hemodialysis, pediatric dialysis and peritoneal dialysis patients, since it is not a valid measurement of the adequacy of treatment for those modalities based on treatment characteristics. We are in the process of working with the stakeholder community to develop consensus based measurements of adequacy for these modalities.

With regard to the URR measure and number of treatments per week, the specifications state that the measure is based on thrice-weekly hemodialysis treatments. Those receiving more than three treatments per week are excluded from the current measure. Measure specifications may be accessed at: *http://www.dialysisreports.org/Methodology.aspx*. Additionally, we anticipate dialysis providers/facilities to use recommended KDOQI guidelines for laboratory testing for the calculation of Dialysis Adequacy. Guidelines can be accessed at: *http://www.kidney.org/professionals/kdoqi/pdf/12–50–0210_JAG_DCP_Guidelines-HD_Oct06_SectionA_ofC.pdf*.

In terms of patients with residual renal function, residual renal function usually drops off after about 6 months on hemodialysis therefore, dialysis adequacy (URR) for patients are excluded until patients have been on hemodialysis for 6 months. As we indicated, starting July 2010, providers/facilities are required to submit both URR (hemodialysis patients) and Kt/V (all modalities) on all ESRD claims. Given that Kt/V will be submitted on all ESRD claims, and that Kt/V has become a more widely accepted measurement of the adequacy of dialysis and the National Quality Forum has endorsed quality measures using Kt/V for hemodialysis and peritoneal dialysis, we anticipate that the URR may be replaced by Kt/V in future program years which will allow for inclusion of these modalities as well as pediatric patients.

Comment: One commenter noted that the use of 12-month averaging for the Hemodialysis Adequacy Measure diminishes the public's ability to discern performance differences between providers/facilities because, when 12-month averages are used, clinical performance in most providers/facilities approximates the average. The commenter recommended that we calculate the measure by using a three-month average based on a monthly assessment of lab results.

Response: We appreciate the comment. To avoid any confusion in data collection, in the initial year of the QIP we will use the technical specifications used for the DFC. To date, the current specifications and data publicly reported on DFC have been viewed as accurate. However, if data in the initial year of the QIP demonstrate that specifications should be changed, we will take this recommendation under consideration.

After consideration of the comments received on the Hemodialysis Adequacy measure (URR) and for the reasons discussed above, we are finalizing the Hemodialysis Adequacy measure for the QIP payment consequence year 2012. Once testing of data collection for Kt/V is completed and if Kt/V proves to be a feasible and reliable measure, we will consider replacing the URR measure with Kt/V in the future.

3. Additional Comments

In the September 29, 2009 proposed rule (74 FR 50009), we did not propose to include any additional measures beyond the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) and the Hemodialysis Adequacy Measure (URR) both of which will exclude ESRD patients less than 18 years of age for the QIP payment consequence year 2012. Section 1881(h)(2)(A)(iii)of the Act states that the measures shall include, to the extent feasible, such other measures as the Secretary specifies, including measures on iron management, bone mineral metabolism, vascular access (intended to maximize the placement of arterial venous fistula) and patient satisfaction measures. CMS did not propose to adopt any measures in these categories since we are not currently collecting data that would allow determination of provider/facility-specific performance with respect to these categories of measures. We are working to identify appropriate sources from which we can adequately capture data to support the future adoption of additional measures. We anticipate that measures such as Kt/V, vascular access and vascular access infections will be included in future program years when data sources prove valid. Finally, we believe it is not feasible to include a patient satisfaction measure at this time because there is no fully validated data collection tool available to collect relevant and industry accepted patient satisfaction measure data. Additional measures will be addressed in future rulemaking.

Comment: A significant number of commenters expressed concern about the lack of mineral metabolism measures in the list of measures proposed for 2012, with particular concern for the monitoring of parathyroid hormone levels (PTH), Phosphate (PO4) and calcium levels. Commenters noted that the inclusion of calcimimetics and phosphate binders in the bundled payment could result in the underutilization of these effective medications, and some commenters were also concerned about the potential for overutilization of parathyroidectomies as a less expensive option to the medications.

Response: On April 15, 2008, we published in the **Federal Register** the Medicare Conditions for Coverage (CfC) for End-Stage Renal Disease Facilities final rule (73 FR 20370). These Medicare CfCs are enforced by periodic site visits by state survey agencies and specifically require the development and execution of Patient Plans of Care to "provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease." (*See* 42 CFR § 494.90(a)(3).) In addition, § 494.110(a)(2)(iii) requires dialysis facilities to include bone and mineral

metabolism outcomes as part of their ongoing Quality Assessment and Performance Improvement Programs. We consider the mineral metabolism and renal bone disease measure as measures that will be considered for future years of the QIP; however, for the reasons we discussed above, these measures will not be included for 2012.

Comment: We received several comments stating that the three performance measures we proposed for the QIP payment consequence year 2012 were not adequate for evaluating the quality of care offered by ESRD providers/facilities. Several commenters recommended that we also adopt outcome measures for the QIP specifically dealing with hospitalizations, infections, vascular access and iron management. A few commenters also suggested that measures on transfusion and transplant rates be included.

Response: We agree that the measure topics suggested by these commenters would allow us to more fully assess the quality of care provided to Medicare ESRD beneficiaries. As stated above, we are in the process of developing additional quality measures that we will consider for use in future years of the QIP. At this time, ESRD Medicare claims are the only complete provider/facility-level data set available to us. The three measures that we are finalizing for the first year of the QIP—two anemia management measures (Hemoglobin less than 10 g/dL and Hemoglobin more than 12 g/dL) and one Hemodialysis Adequacy Measure (URR)—focus on core aspects of the medical management of ESRD Medicare beneficiaries and have significant implications for their quality of life, morbidity and mortality. Further, observational studies and practice pattern analyses have shown that providers/facilities that perform well on these three measures also experience better patient outcomes in terms of reduced hospitalizations and reduced risk of heart attack, stroke and other adverse events.

Comment: Recognizing that CMS is not proposing at this time to include other measures in the QIP such as iron management, bone mineral metabolism, and vascular access and that CMS has concluded that it is not feasible to propose a patient satisfaction measure at this time, one commenter requested a detailed plan for incorporating these measures into the ESRD QIP. Additionally, the commenter emphasized the importance of establishing a tracking system to ensure baseline values for bone and mineral metabolism markers because these may be significantly impacted by the incorporation of oral medications in the bundled payment.

Response: We are dedicated to the ongoing process of developing additional quality measures, refining existing quality measures and identifying complete and accurate data sources for use in future years of QIP including measures addressing the commenter's concerns regarding bone mineral metabolism and the potential impact with bundled payment. Currently, ESRD claims provide the only complete set of facility level quality data to support the existing measures. We will be monitoring the data to ensure that the ESRD QIP is achieving the desired quality clinical outcomes. We plan to use the rulemaking process as the way to propose the incorporation of new measures currently under development such as hospitalizations, mineral metabolism, vascular access infections, iron management and fluid volume weight management as well as pediatric measures. In addition, we will have a comprehensive monitoring plan in place when the new PPS begins that ensures access and quality care are furnished to ESRD beneficiaries.

Comment: Several commenters expressed support for inclusion of patient-centered measures in the QIP, such as patient quality of life, ability to return to work or whether patients are in rehabilitation. One commenter supported the implementation of a measure of patient awareness of ESRD treatment options (such as transplant and different dialysis modalities). The commenter also noted that for patients, these types of measures may often be more useful to patients in their decision making than clinical measures.

Response: We agree that patient-centered measures, such as awareness of treatment options, are important for the ESRD population in making decisions such as where they wish to seek care. We appreciate the recommendation to incorporate measures evaluating patient outcomes from a patient's perspective, including patient awareness of treatment options, percentage of patients working or in rehabilitation, and quality of life surveys into the QIP. The NQF has endorsed measures of this type, and we are actively seeking a data source for such data as well as developing a means to collect these data. We intend to use such measures in future payment years and will do subsequent rulemaking on these additional measures.

Comment: One commenter recommended the inclusion of a Practice-related Risk Score (PRS) and a patient-level all Clinical Performance Measure (CPM) index as QIP measures, stating that these types of measures may be better for establishing a facility or provider's quality of care. Composite measures are made up of discrete quality measures that, when calculated together, provide a score that assesses more than one aspect of patient care. According to the commenter, the recommended PRS would be a composite, facility-level index of four key dialysis quality measures, including the percent of patients with: (1) Kt/V >1.2; (2) Hemoglobin >11g/dL; (3) Albumin >4.0g/dL; and (4) A central venous catheter for dialysis access. The commenter noted that the score for the PRS may be a good predictor of mortality. The commenter also recommended a patient-level CPM index that would be similar to the PRS and would be composed of dialysis adequacy (single-pooled Kt/V urea of >1.2); Anemia (Hemoglobin >11g/dL); albumin (>40g/L with bromcresol green or >37g/L with bromcresol purple); and access (that is, use of an arteriovenous fistula). The commenter noted that patient risk for hospitalization and/or death increases, according to their studies, with each unmet target (component) of the CPM index.

Response: We appreciate this recommendation. Measures development is already underway in the areas the commenter recommends such as vascular access measures. Technical Expert Panels (TEP) were convened in Spring 2010 to begin development of these additional measures, and subsequent to these initial TEPs, more work on measures development will take place. As stated above, we intend to fully test all measures before proposing to adopt them for the QIP in order to assure that they are reliable indicators of the quality of care and feasible for data collection. Because measures we are adopting at this time are limited to data available on ESRD claims, we would not have the specificity needed to calculate the composite measures presented by the commenter. However, we will continue to consider and evaluate component measures such as those suggested by the commenter as more data resources become available.

Comment: One commenter wrote that CMS must understand and create a category for mortality rates within long term care hospital (LTCH) settings separate from outpatient clinics and other home dialysis settings. Commenters stated that a facility may have greater than 50 percent of its patients with an end of life care option, such as hospice, when such patients can

no longer care for themselves and are thus compromised on many levels. Commenters stated that the other 50 percent of patients may be in LTCH rehabilitation settings and are admitted only a short time, but come to the facility after a lengthy hospitalization in a compromised condition that in many cases includes life threatening morbidity.

Response: We appreciate the recommendation. For the initial year of the QIP, we have decided to limit the measures to the Anemia Management and the Dialysis Adequacy Measures because they go to the core of ESRD patient care, are feasible to collect, and reliably reflect the quality of patient care. However, as we evaluate and refine the mortality measures currently used for the DFC, these issues will be considered.

Comment: Two commenters recommended that there should be measures of fluid balance (overload) in the measure set.

Response: Appropriate and effective fluid management reduces the risk of congestive heart failure, hospitalizations and premature death, and therefore we believe that measures of fluid management are important for evaluating another aspect of ESRD patient care. We are in the process of developing additional quality measures for possible use in future years of the QIP and will be researching the feasibility of including fluid balance as a measure.

Comment: One commenter recommended that the QIP should include measures of treatments, laboratory testing, medications and other clinical care services included in the new bundled payment to evaluate potential impact on patient care (for example, phosphate binders for mineral metabolism).

Response: The selection of the anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) and the Hemodialysis Adequacy Measure (URR) was driven by what is required in section 153(c) of MIPPA, as well as the limitations of complete facility-level data currently available to us. Patient outcomes are a key focus of the ESRD QIP. Therefore, we are developing or identifying performance measures that will assess the quality of care delivered to the ESRD patients under the bundled payment. For example, we are currently developing measures of bone mineral metabolism, an important clinical issue with ESRD patients. Implementation of the ESRD bundled payment system may have the impact of providers/facilities decreasing use of medications used to treat clinical conditions associated with the appropriate management of bone mineral metabolism therefore measures to address these issues are important.

Comment: One commenter recommended an approach to monitoring quality by analyzing the drug utilization data that providers/facilities report on Part B claims submitted for Medicare payment. It was further recommended that CMS continue to collect information on the volume and use of drugs and other services included in the broader bundled ESRD payment.

Response: We will monitor drug utilization data to the extent that reliable data is available. However, we note that the linkage between drug utilization patterns and patient quality outcomes needs further exploration. Therefore, we are in the process of identifying possible quality measures related to drug utilization and identifying pertinent drug utilization data sources for potential use in future years of the QIP.

Comment: One commenter suggested that CMS develop quality measures that use a real-time system for reporting rates of hospitalization, emergency department use, and mortality for the dialysis population. The commenter further suggested that such information could help CMS and researchers monitor unintended effects of the new bundled payment method.

Response: We agree that real-time data would be beneficial for tracking in a timely manner, clinical outcomes and the quality of care being delivered, and that more timely access to data would further advance the goals of the QIP to improve the quality of care delivered to ESRD patients. While this type of data source is not currently available, we plan to have a comprehensive monitoring strategy in place that will provide the necessary information to evaluate the quality of care being delivered to Medicare patients with ESRD as the bundled payment system is implemented. Along with the development of additional measures, we are seeking data sources that will allow for more timely assessment and reporting of the data.

Comment: Two commenters requested that CMS add venous access flow surveillance to the measure set. One of the commenters offered that, in addition to the three measures proposed in the ESRD QIP conceptual model, vascular access surveillance metrics be added to include metrics for: (1) Assessment of patient condition; (2) treatment interventions; and (3) thrombotic events. Commenters recommended use of electronic surveillance devices for venous access flow monitoring.

Response: We appreciate the comment and agree that the development of venous access monitoring strategies and the development of measures are important for optimizing outcomes within the ESRD population because decreased venous access flow has implications for hospitalizations, potential stroke and other adverse patient outcomes. We are dedicated to the ongoing process of developing additional quality measures, refining existing quality measures and identifying complete and accurate data sources for use in future years of QIP.

Comment: One commenter recommended the development and use of a list of "Never Events" in the ESRD QIP.

Response: We appreciate the recommendation because these types of events are ones that are avoidable. We will consider the potential development and use of sentinel events (never events)—in future years of the ESRD QIP.

Comment: A commenter requested that CMS act with all due speed to ensure that quality of care for vulnerable patients may be measured and facilities may be held accountable.

Response: We agree that monitoring the quality of care for vulnerable populations under the QIP is critical. A program monitoring and evaluation program is being developed to track impact on vulnerable populations and will be addressed in future rulemaking. The current measures, to the extent that relevant data are available (for example, socio-demographics), will be evaluated for potential disparities in future years. Data on the socio-demographics of the ESRD population might be collected from patient, facility/provider enrollment forms; however, we would need to ensure that data analysis methodologies in use would be able to accurately identify these populations and monitor effectively.

Comment: One commenter urged CMS to verify that all quality data aggregated through the ESRD Clinical Performance Measurement Project and used to calculate the QIP performance measures is case-mix and severity adjusted; further, the commenter asked that special consideration be given for hospital-based units.

Response: We acknowledge that some patients may present additional challenges for the treatment of anemia and achieving adequate dialysis because of existing co-morbid conditions, but we do not believe that the anemia management or dialysis adequacy measures should be risk-adjusted for the

ESRD population. The specifications for these measures may be found in the Dialysis Facility Report instructions and descriptions. Patients with hemoglobin <5 g/dL and >20 g/dL are excluded from the measured population as are patients who are less than 18 years of age. Further, to be included in the measurement population (for both anemia management and dialysis adequacy) patients must have received dialysis for at least 90 days and have had four claims submitted. Additionally, these claims must indicate the use of erythropoiesis-stimulating agents (ESAs) for at least 90 days. These exclusions and inclusions from the measurement population act to adjust the measures for certain patient aspects. However, regardless of the type of unit or patient acuity, all patients should receive the appropriate level of care.

Comment: One commenter noted that, because nursing home patients have a higher patient acuity, the national standards may not be achievable by these facilities, resulting in unfair payment reductions.

Response: We agree that this patient population may have multiple co-morbid conditions that make achieving the national standard difficult. However, given the practice guidelines recommended for all ESRD patients, we would expect a majority of ESRD patients in nursing homes to meet or exceed the national average.

Comment: One commenter noted that by using Kt/V in the CPM program and URR in the QIP, Medicare is targeting the mortality rates from a model that was developed over thirty years ago that has also proven no more predictive of morbidity and mortality than patient self-reported physical and mental functioning scores. The commenter recommended that CMS consider mix adjusted physical and mental functioning scores from patient self-report data and expect dialysis providers to improve the scores that indicate higher risk of hospitalization or death.

Response: We will consider this comment as we develop new measures for use in the QIP in the future. We agree that there are challenges related to different levels of patient acuity within the ESRD population that may have an impact on morbidity and mortality beyond URR. Even though these measures are not risk-adjusted, the specifications for the three measures we are finalizing provide exclusions that act as a level of risk-adjustment. Exclusions remove from the denominator a population with a higher than normal severity of illness or have conditions that prevent them for receiving "normal" treatment and therefore, may unfairly impact on performance measurement scores.

Comment: One commenter noted that the quality baseline year should be aligned with the payment baseline year for calculating the payment rate. The commenter recommended that to prevent "gaming" the agency should provide clear and unambiguous requirements surrounding the manner and timing of laboratory measurements (that is, when during the dialysis process laboratory samples are collected for analysis).

Response: The baseline year for performance measurement the commenter referred to is the performance period for the QIP payment consequence year 2012 which is being proposed in the QIP proposed rule published on **August 12, 2010** in the **Federal Register**. Currently, ESRD claims provide the only complete set of facility level quality data to support the existing measures. With regard to the timing of laboratory testing (time of specimen collection on day of patient visit), KDOQI provides guidelines for the timing of laboratory testing. The guidelines may be accessed at: *http://www.kidney.org/professionals/kdoqi/pdf/12-50-0210_JAG_DCP_Guidelines-HD_Oct06_SectionA_ofC.pdf.* We support the KDOQI guidelines and measure specifications which provide the parameters for the timing of testing. Additionally, there will be monitoring and evaluation of the QIP to track and, where, necessary, take action to prevent "gaming" of data.

Comment: One commenter voiced concern that the three proposed measures may not be an accurate reflection of the quality of care. The commenter further stated that the proper goal for the anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin Greater Than 12 g/dL) and the Dialysis Adequacy Measure (URR) may change over time, and that having the measures written in regulations may make it difficult to update to new standards. The commenter also offered that the skill of dialysis staff (measured through turnover rates) may be a better measure of quality of care and that measures of importance to patients (for example, dialysis-induced hypotension) should be used rather than measures such as urea kinetics.

Response: The selection of the proposed measures was driven by what is required in section 153(c) of MIPPA 2008 as well as the limitations of the complete facility-level data currently available to us. In addition, appropriate anemia management and providing adequate dialysis are important to the assessment of care provided to the ESRD population because these measures evaluate the core clinical issues for ESRD patients especially those on in-center hemodialysis. However, we are in the process of developing additional quality measures and identifying data sources for use in future years of QIP. Lastly, we acknowledge that the skill of a facility's staff can have an impact on the quality of care provided to dialysis patients and look forward to gathering more evidenced-based information that we can use to develop appropriate and valid measures in this area.

Comment: One commenter recommended that, for measures related to immunization and vascular access, a one-month, end-of-year value should be considered since these facility outcomes are cumulative.

Response: We are in the process of considering additional quality measures and potentially including measures of immunization and vascular access. We will consider the validity of using a one-month, end of the year value as these measures are developed and tested.

Comment: One commenter voiced concern that the two-year lag between data collection for the performance measures and measure reporting will not allow for facilities to be measured on improvements that may occur during that lag time. The commenter recommended that the QIP measures use Elab data as a source of more current data.

Response: We are seeking data sources that will allow for more timely assessment and reporting of the data in future years of QIP. We are working towards the timely assessment and reporting of data sources that will close the two-year lag in the data. However, we will use the data collection methodology used by the DFC since 2001 for the first year of the QIP.

Comment: One commenter suggested that facilities and providers be rewarded for proactive, real-time monitoring of plasma water volume, vascular compartment refilling and use of techniques that assure optimal fluid volume management.

Response: MIPPA section 153(c) does not grant us the authority to reward providers/facilities on their performance. At most, the statute allows us to provide full ESRD payments to providers/facilities that satisfy the QIP. We view quality as the standard of care that all provider/facilities should strive for and not as an extra that needs to be rewarded. The ESRD QIP will provide those providers/facilities that meet or exceed the performance standard full ESRD payment. With regard to the

commenter's suggestion to measure plasma water volume, vascular compartment refilling and use of techniques assuming optimal fluid volume management, this is an area that experts in the renal community are currently evaluating in the ESRD population because of poor fluid management's implications for hospitalizations, development of congestive heart failure and other avoidable adverse events.

Comment: One commenter requested a detailed outline of the process for measure development.

Response: We use a standardized process for developing measures which can be found at: *http://www.cms.hhs.gov/QualityInitiativesGenInfo/downloads/QualityMeasuresDevelopmentOverview.pdf.* Tested measures are then submitted to the NQF for endorsement.

After careful consideration of the comments, we have decided that for the QIP payment consequence year 2012, we are finalizing the three proposed measures; the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL) and the Dialysis Adequacy Measure (Urea Reduction Rate (URR) ≥65 percent) as proposed with one change. As described above, we will not include ESRD patients less than 18 years of age in the measure calculation of the two anemia management measures (Hemoglobin Less Than 10 g/dL and Hemoglobin More Than 12 g/dL).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

A. ICRs Regarding a Low-volume adjustment. (§ 413.232(f))

As discussed in section VIII.A.2.b. of the proposed rule (74 FR 49975), to receive the low-volume adjustment, we proposed that an ESRD facility must provide an attestation to the Medicare administrative contractor or fiscal intermediary that it has met the criteria to qualify as a low-volume facility. The Medicare administrative contractor or fiscal intermediary would verify the ESRD facility's attestation of their low-volume status using the ESRD facility's final-settled cost reports.

In the proposed rule, we indicated that the burden associated with the requirement would be the time and effort necessary for an ESRD facility attesting as a low-volume facility to develop an attestation and submit it to the Medicare administrative contractor or fiscal intermediary (74 FR 50016). In the 2006 data analysis conducted by our contractor, UM–KECC, 489 ESRD facilities were identified as below the low-volume threshold of 3,000 treatments per year. Of these 488 facilities, 166 met the additional low-volume criteria as specified in § 413.232 of this proposed rule. We estimated that it would require an administrative staff member from each low-volume facility 5 minutes to develop the attestation and a negligible amount of time to submit it to the Medicare administrative contractor or fiscal intermediary (74 FR 50016). We further estimated several dozen additional ESRD facilities may meet the criteria of a low-volume facility prior to implementation of the ESRD PPS and therefore, we rounded the total number of estimated low-volume facilities to 200 (74 FR 50016). Therefore, we estimated that the total initial ESRD facility burden would be 16.6 hours (74 FR 50017).

We did not receive any public comments related to this information collection. However, as discussed in section II.F.4. of this final rule, we are finalizing a threshold of 4,000 instead of 3,000 treatments. Therefore, we identified 857 ESRD facilities as below the updated low-volume threshold of 4,000 treatments per year. Of these 857 facilities, 351 meet the low-volume criteria specified in § 413.232 of this final rule. We continue to believe that the estimated administrative staff time burden of 5 minutes to develop the attestation and a negligible amount of time to submit it to the FI/MAC is appropriate. Therefore, we are finalizing our estimated administrative staff time burden of 5 minutes per facility. We estimate several dozen additional ESRD facilities may meet the criteria of a low-volume facility based on the 4,000 treatment threshold prior to implementation of the ESRD PPS and therefore, we rounded the total number of estimated low-volume facilities to 400. Therefore, we are finalizing the total initial ESRD facility burden to be 33.2 hours.

B. ICRs Regarding Transition Period (§ 413.239)

As discussed in section XIII.A. of the proposed rule, prior to January 1, 2011, an ESRD facility may make a one-time election to be excluded from the four-year transition to the ESRD PPS (74 FR 50003). That is, a facility may elect to be paid entirely based on the proposed ESRD PPS beginning January 1, 2011. Under proposed § 413.239(b), an ESRD facility may make a one-time election to be paid for items and services provided during transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section. The section specified that such election must be submitted to the facility's FI/MAC no later than November 1, 2010.

We estimated in the proposed rule that it would require an accountant or financial management staff member from each of the 4,921 ESRD facilities 1 hour to simulate average aggregate payments under the proposed ESRD PPS and compare them to average aggregate payments under the current basic case-mix adjusted composite payment system, for a total of 4,921 hours (74 FR 50016). In addition, for those facilities electing to be excluded from the four-year transition, we estimated that the burden associated with the requirement in proposed § 413.239(b) would be the time and effort necessary to develop an election and submit it to the FI/MAC (74 FR 50016). We estimated that it would require an administrative staff member from each facility 15 minutes to develop the notice and a negligible amount of time to submit it. We estimated that 36 percent of the estimated 4,921 ESRD facilities, or 1,794 ESRD facilities, would make the election no later than November 1, 2010. Therefore, we estimated that the total one-time ESRD facility burden would be 448.5 hours (74 FR 50017).

The comments pertaining to this information collection, the updated facility data included in the impact analysis and our responses are set forth below.

Comment: One commenter pointed out that we projected that it would take one hour per patient, per month for billing costs related to the proposed ESRD PPS. The commenter indicated that facilities should be compensated for the administrative costs associated with implementing the new payment system including the additional billing related ESRD PPS costs. The commenter further believed that one hour was an insufficient amount of time for this task.

Response: The one-hour timeframe to which the commenter referred pertained to the time that would be spent by ESRD facilities in making a determination to opt out of the 4-year ESRD PPS transition. Specifically, we estimated that each ESRD facility would spend one hour simulating average aggregate payments under the proposed ESRD PPS as compared to the average aggregate payments under the current basic case-mix adjusted composite payment system. With regard to the comment that ESRD facilities should be compensated for billing costs associated with the ESRD PPS and that the projected one-hour timeframe is insufficient to account for their per patient per month billing costs, we note that we computed the ESRD PPS base rate using ESRD facility 2007 costs updated to 2011 which include billing costs. As discussed in more detail in section II.K.2. of this final rule, we have not made significant changes to the current billing requirements. Under the ESRD PPS, facilities will continue to identify the renal dialysis items and services they furnish as well as other non-renal related services for each day of service. The only new additional reporting is related to the use of oral equivalents of injectable drugs. Thus, we believe that the ESRD PPS base rate adequately accounts for providers' billing costs.

Comment: One commenter indicated that they have exceeded the estimated 1-hour timeframe for deciding whether to opt out of the transition and stated that they have spent hundreds of hours attempting to assess the bundle's impact on their 14 facilities.

Response: We believe that the impact of the final ESRD PPS will be easier for ESRD facilities to assess than the proposed system because we are not implementing oral-only ESRD drugs effective January 1, 2011 and the final ESRD PPS has fewer adjustments. However, we disagree that the analysis will take ESRD facilities hundreds of hours to complete. We believe that ESRD facilities have been aware of and planning for the ESRD PPS for several years and have gained insight as to the factors that will go into their decisions regarding the transition. However, based on the public comments, we believe it is more appropriate to estimate two hours for an ESRD facility to complete an analysis of the significant changes made to the ESRD PPS in this final rule and determine whether to opt out of the ESRD PPS transition.

As reflected in section IV.B. of this final rule, there are 4,951 ESRD facilities. We have increased the number of hours necessary to simulate average aggregate payments under the current basic case-mix adjusted composite payment system from one hour to two hours, for a total of 9,902 hours. We are finalizing the estimated administrative staff member burden at 15 minutes per facility to develop and submit the election notice to elect to be excluded from the transition. We are finalizing that 43 percent of the estimated 4,951 ESRD facilities (or 2,120 ESRD facilities), will make the election no later than November 1, 2010. Therefore, we are finalizing the total one-time ESRD facility burden to be 530 hours. The final collection of information burden hours are indicated below in Table 34.

Table 34: ESRD Facility Burden

Regulation Section(s)	OMB Control Number	Respondents	Responses	Burden Per Response (hours)	Total Annual Burden (hours)
413.232	None	857	400	.083	33.2 hours
413.239(b)	None	4,951	2120	.25	530 hours

We have submitted a copy of this final rule to OMB for its review and approval of the aforementioned information collection requirements.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule is an economically significant rule because we estimate that the requirement under section 1881(b)(14)(A)(ii) of the Act—that the estimated total payments for renal dialysis services in CY 2011 equal 98 percent of the estimated total payments that would have been made if the ESRD PPS were not implemented—equates to an approximate $200 million decrease in payments to ESRD facilities in CY 2011. In addition, given this estimated impact, this final rule also is a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the final rule. We requested comments on the economic analysis.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, approximately 22 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's size standards, which considers small businesses those dialysis facilities having total Medicare

revenues of $34.5 million or less in any 1 year, and 19 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, *see* the Small Business Administration's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf*

(Kidney Dialysis Centers are listed as 621492 with a size standard of $34.5 million). For purposes of the RFA, we estimate that approximately 22 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in the impact Table 35. Using the definitions in this ownership category, we consider the 614 facilities that are independent and the 470 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains would have total revenues more than $34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain). Overall, a hospital based ESRD facility (as defined by ownership type) is estimated to receive a 1.7 percent increase in payments under the new ESRD PPS for 2011. An independent facility (as defined by ownership type) is estimated to receive a −0.3 percent decrease in payments under the ESRD PPS for 2011. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The claims data we use to estimate payments to ESRD facilities in this RFA and RIA does not identify which dialysis facilities are part of an LDO, regional chain, or other type of ownership. As each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFAs and RIAs presented in proposed and final rules that updated to the basic case-mix adjusted composite payment system, we considered each ESRD to be a small entity for purposes of the RFA. However, we conducted a special analysis for this final rule that enabled us to identify the ESRD facilities that are part of an LDO or regional chain. The results of this analysis are presented in the type of ownership category of impact Table 35.

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations 50,000 or less and therefore, they are not enumerated or included in this final RFA. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule has a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 187 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 187 rural hospital-based dialysis facilities will experience an estimated 4.4 percent increase in payments. As a result, this rule will not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2010, that threshold is approximately $135 million. While dialysis facilities will be paid approximately $200 million less, we do not believe that this rule includes any mandates that would impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $133 million.

Executive Order 13132 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 do not believe this final rule will have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

Payment for ESRD Bad Debt

The changes to the ESRD bad debt payment in this final rule are not changes to the existing ESRD bad debt payment methodology and, therefore, there is no impact on ESRD payments from implementing the Rule of Construction described in Section 153(a)(4) of MIPPA and described elsewhere in this final rule.

B. Anticipated Effects

1. 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 2011 under the current basic case-mix adjusted composite payment system (current payments) to estimated payments in CY 2011 under the final ESRD PPS, including payments to ESRD facilities paid a blended rate under the transition (new payments). To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of current payments and new payments contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both current payments and new payments.

ESRD providers were grouped into the categories based on characteristics provided in the Online Survey and Certification and Reporting (OSCAR) file and the most recent cost report data from the Healthcare Cost Report Information System (HCRIS). We also used the June 2008 update of CY 2007 National Claims History file as a basis for Medicare dialysis treatments and separately billable drugs and biologicals.

Table 35 shows the impact of the ESRD PPS compared to current payments to ESRD facilities under the basic case-mix composite payment system, including all separately billable items. Column A of impact Table 35 indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions).

Table 35 Impact of Final Changes in Payments to ESRD Facilities for CY 2011 ESRD

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

Facility Type	Number of Facilities	Number of Treatments (in millions)	2011 Impact Assuming Blended and 100% PPS Payments[1]	2011 Impact Assuming All Facilities Paid Under 100% PPS Payments
All Facilities	4,951	36.7	-2.0%	-2.0%
Type				
Freestanding	4,361	32.9	-2.4%	-2.6%
Hospital based	590	3.8	1.8%	3.9%
Ownership Type				
Large dialysis organization	3,069	23.5	-3.0%	-3.7%
Regional chain	787	5.9	-0.9%	0.1%
Independent	614	4.1	-0.3%	0.7%
Unknown	11	0.1	-3.4%	-4.4%
Hospital based[2]	470	3.1	1.7%	3.7%
Geographic Location				
Urban	3,826	30.5	-2.1%	-2.0%
Rural	1,125	6.2	-1.6%	-2.1%
Census Region				
East North Central	785	5.8	-2.4%	-2.4%
East South Central	387	2.8	-3.0%	-4.2%
Middle Atlantic	582	4.6	-2.5%	-2.4%
Mountain	268	1.6	3.1%	6.0%
New England	156	1.2	-1.8%	-0.4%
Pacific	559	4.6	0.7%	3.1%
South Atlantic	1,119	8.4	-4.1%	-6.2%
West North Central	378	2.0	0.0%	1.3%
West South Central	683	5.2	-2.2%	-2.1%
Puerto Rico and Virgin Islands	34	0.4	2.8%	5.0%
Facility Size				
Less than 4,000 treatments[3]	857	1.8	5.4%	6.9%
4,000 to 9,999 treatments	1,949	10.3	-2.4%	-2.9%
10,000 or more treatments	2,084	24.4	-2.4%	-2.3%
Unknown	61	0.2	-1.5%	-2.3%
Percentage of Pediatric Patients				
Less than 2%	4,840	36.3	-2.0%	-2.1%
Between 2% and19%	55	0.4	1.0%	2.2%
Between 20% and 49%	13	0.0	7.5%	10.1%
More than 50%	43	0.0	2.3%	2.8%

[1] Assumed that 2120 out of 4951 Facilities choose to be excluded from the transition based on comparison of payments under current system to payments under the final ESRD PPS.

If payments under a 100% fully implemented ESRD PPS are higher than payments under current system, we assumed that the facility would elect to be excluded from the transition.

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

[3] Of the 857 Facilities with less than 4,000 treatments, only 351 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 15.2% increase in payments.

Section 1881(b)(14)(E)(ii) of the Act provides all ESRD facilities with the option to make a one-time election to be excluded from the transition from the current payment system to the ESRD PPS. Electing to be excluded from the 4-year transition means that the ESRD facility receives payments for renal dialysis services provided on or after January 1, 2011, based on 100 percent of the payment rate under the final ESRD PPS, rather than a blended rate based in part on the payment rate under the current payment system and in part on the payment rate under the ESRD PPS.

In order to estimate which ESRD facilities would and would not elect to opt out of the transition and receive payment based on 100 percent of the payment amount under the ESRD PPS, we estimated both the aggregate payments for each ESRD facility under the ESRD PPS (based on 100 percent of the payment amount under ESRD PPS) and payments in the first year of the transition (based on a blend of 25 percent of payments under the ESRD PPS and 75 percent of payments under the current basic case-mix adjusted composite payment system). We then assume that facilities that would receive higher aggregate payments under the ESRD PPS would elect to be paid based on 100 percent of the payment amount under the ESRD PPS, and facilities that would receive higher aggregate payments under the first year of the transition (based on a blend of 25 percent of payments under the ESRD PPS and 75 percent of payments under the current basic case-mix adjusted composite payment system) will elect to be paid under the transition. Based on these assumptions, we are estimating that 43 percent of ESRD facilities would choose to be excluded from the transition and we estimate that 57 percent of ESRD facilities would choose to be paid the blended rate under the transition.

Additionally, in accordance with section 1881(b)(14)(E)(iii) of the Act and as described in section VII.E of this final rule, we intend to apply a transition budget-neutrality adjustment factor to all payments. The purpose of this factor is to make the estimated total payments under the ESRD PPS equal the estimated total payments that would have been made if there had been no transition. We estimate this factor to be 0.969. Since the same factor would be applied to all payments, including the blended payment rates under the transition, the effect of the transition budget neutrality adjustment factor is the same for all impact categories.

The overall effect of the final ESRD PPS, in the first year of the transition, is shown in column C. This effect is determined by comparing total estimated payments under the ESRD PPS, which includes blended payments and payments that are computed using our assumption that 43 percent of ESRD facilities would elect to be paid 100 percent ESRD PPS and 57 percent of ESRD facilities would elect to go through the transition. These payments have also been adjusted to reflect the transition budget neutrality adjustment factor. Total payments are then compared to payments that would have been made to facilities for renal dialysis services provided during CY 2011 under the basic case-mix adjusted composite payment system plus items and services separately billable under Title XVIII, including ESRD-related Part D drugs.

In column C, the aggregate impact on all facilities is a 2.0 percent reduction in payments, which reflects the statutory 98 percent budget neutrality provision. Hospital-based ESRD providers of services show a 1.8 percent increase because as a group they receive higher payments under the ESRD PPS than they would receive under the current system. We believe that the model used to create the ESRD PPS adjustment factors more accurately predicts costs for this provider category. Facilities with less than 4,000 treatments show a 5.4 percent increase in payments under the ESRD PPS because many of these facilities are eligible to receive the low-volume adjustment, which is a 18.9 percent adjustment per treatment. As with hospital-based ESRD providers of services, we believe that the model more accurately predicts costs for this category. Facilities that chose to retain a composite rate exception in the current system will have an 11.3 percent increase in payments under the ESRD PPS. This may be explained by the fact that the current basic case-mix adjusted composite payment system does not completely account for their higher costs and that the ESRD PPS more accurately accounts for the higher costs of these facilities as a group. The largest decrease in payments under the ESRD PPS is for facilities in the South Atlantic census region which will experience a 4.1 percent decrease. We believe this decrease is a result of the current over usage of separately billable drugs.

Column D shows the effect if all ESRD facilities were paid 100 percent of the ESRD PPS. In this column, we are showing a hypothetical effect, as the statute provides for a 4-year transition to a fully implemented ESRD PPS. We show this column as a comparison to column C, in order to show how each impact category would have been effected if the ESRD PPS had been fully implemented in 2011. In column D, the overall effect for all facilities in aggregate is a 2.0 percent reduction, which reflects the statutory 98 percent budget neutrality provision. As with column C, we see the same categories of ESRD facilities most impacted by the ESRD PPS. However, in column D the changes are generally more pronounced as those providers do not have the mitigating effect of the transition. Since column D shows the hypothetical effect if all ESRD facilities were to be paid 100 percent of the ESRD PPS in the first year of the transition, there would be no need for a transition budget neutrality adjustment to account for the cost of the ESRD PPS transition. Therefore, we did not apply the transition budget neutrality factor to column D.

We believe that the comparison of columns C and D shows that the statutory option to transition does

provide a more gradual affect for provider categories that receive lower payments under the ESRD PPS, as well as the effect of the transition budget neutrality factor. Generally, providers that do well under the ESRD PPS show larger increases in column D compared to column C because column D does not reflect the transition budget neutrality adjustment. However, many provider categories include a combination of providers that are estimated to receive higher payments under the ESRD PPS and providers that are estimated to receive lower payments under the ESRD PPS. We believe the comparison of columns C and D also shows that application of the transition budget neutrality factor to all payments does not penalize any one group, but rather it evenly distributes the effect of this transition budget neutrality factor among all provider types.

2. Effects on Other Providers

Under the expanded bundle in the ESRD PPS, other provider types such as laboratories, DME suppliers, and pharmacies would have to seek payment from ESRD facilities rather than Medicare. This is because under the ESRD PPS, Medicare is paying ESRD facilities one combined payment for services that may have been separately paid by Medicare in the past. We noted that other provider types noted above may continue to provide certain ESRD-related serves; however, beginning January 1, 2011, they may no longer bill Medicare directly and instead must seek payment from ESRD facilities.

3. Effects on the Medicare and Medicaid Programs

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in 2011 will be approximately $8.0 billion. This estimate is based on various price update factors discussed in section II.E.2. of this final rule. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 3.6 percent in CY 2011. Consistent with the requirement for 98 percent budget neutrality in the initial year of implementation, we intend for estimated aggregate payments under the ESRD PPS to equal 98 percent of the estimated aggregate payments that would have been made if the ESRD PPS were not implemented. Our methodology for estimating payment for purposes of the budget neutrality calculation uses the best available data.

4. Effects on Medicare Beneficiaries

The principal effect of the ESRD PPS on beneficiaries is that implementation of the system will change beneficiary financial liability for co-insurance. Under the current basic case-mix adjusted composite payment system, beneficiaries pay 20 percent of the basic case-mix adjusted payment amount plus 20 percent of ESRD-related separately billable drugs; however they do not pay co-insurance on separately billable laboratory tests. Under the ESRD PPS, beneficiaries will be responsible for paying 20 percent of the ESRD PPS payment amount or blended payment amount for patients treated in facilities that choose the ESRD PPS transition. As the beneficiary will be responsible for the co-insurance on the laboratory tests, we estimate they will have a 1.2 percent increase in their payments. Additional information regarding beneficiary co-insurance is in section II.K.1.b. of this final rule.

C. Alternatives Considered

In developing this final rule, we considered a number of alternatives. We considered other adjustments, including race, modality, and site of service. We considered alternative adjustments to explain variation in cost and resource usage among patients and ESRD facilities. For example, we considered alternatives in the outlier policy, such as outlier percentages of 1.5, 2, 2.5, to 3 percent, rather than the 1 percentage policy. We also considered a monthly payment, but instead are finalizing a per treatment payment.

The statute requires a low-volume adjustment of at least 10 percent and an outlier policy. However, the statute did provide the Secretary with discretion in defining low-volume facilities and establishing the details of the outlier policy. Throughout this final rule, we discuss our rationale for the policy decisions we have made for each adjustment that we are finalizing. Although we have discretion on some of the adjustments we are finalizing, there is no impact on the aggregate amount of spending in the first year of the ESRD PPS (CY 2011) because we have standardized the base rate. The base rate is standardized to account for the overall positive effect of the case-mix and other adjustments.

D. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement showing the classification of the expenditures associated with the provisions of this final rule.

Table 36, below provides our best estimate of the decrease in CY 2011 Medicare payments under the ESRD PPS as a result of the changes presented in this final rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of $230 million dollars (or as a savings to the Medicare Program) and as a transfer to provider from the beneficiaries of $30 million.

Table 36

Category	Primary Estimate
Transfers Annualized monetized transfers: “on budget”	-$200 million
From whom to whom?	Federal Government & Beneficiaries to ESRD Facilities

Note: In CY 2011, the -$200 million from the Federal Government and Beneficiaries to ESRD Providers is distributed as -$230 million from the Federal Government to the ESRD Provider, and +$30 million from the Beneficiaries to the ESRD Provider.

We received the following comments regarding the impact of the proposed rule on small dialysis organizations and independent dialysis facilities.

Comment: One commenter stated that CMS should include within the RFA, an analysis of the impact of the compliance requirements of the proposed rule on SDOs and an analysis of options for

regulatory relief. Other commenters expressed concern about the increase in administrative costs that will occur due to implementing the infrastructure to collect information to support the case-mix adjusters, specifically the co-morbidity adjustments.

Response: As discussed throughout this preamble, we have made numerous changes to the proposed ESRD PPS in response to public comments and further analysis. The principle change we have made that reduces the burden on ESRD facilities is to delay implementation of oral-only ESRD-related drugs currently paid under Part D. The inclusion of ESRD-related oral drugs is limited and should have minimal impact. We believe that many ESRD facilities already have contractual arrangements with a pharmacy to obtain Part B injectable drugs. Thus, we believe the inclusion of a limited number of oral drugs will not pose a significant burden on any ESRD facilities.

Many of the other adjustments reflect the adjustments in the current basic case-mix adjusted composite payment system (that is, age, BSA, and BMI) and therefore, should not pose new burden on ESRD facilities. In addition, we have not made significant changes in the information that ESRD facilities will be required to report on claims in order to be eligible for payment adjustments. The only new billing requirement is that facilities will be required to line item report ESRD-related oral drugs currently covered under Part D. Consistent with the policy under the current basic case-mix adjusted composite payment system, ESRD facilities will have to report non-ESRD-related services (that is, services that are not renal dialysis services) and the appropriate modifier on their claims in order to receive payment for these services outside the ESRD PPS payment. We have reduced the number of co-morbidity adjustment factors and limited the number of acute co-morbidity diagnostic categories which will minimize the effort needed to track and report co-morbid medical conditions that would be eligible for an adjustment.

Comment: Several commenters did not agree with the impacts provided in the proposed rule. One commenter conducted an independent analysis and asserted that LDOs were more likely than other dialysis providers to serve patients disadvantaged by poverty. While the commenter believes this finding would support a case-mix adjuster to better compensate LDOs for disproportionately servicing areas of high poverty, the commenter urged CMS to avoid implementing a case mix adjuster that is based on facility type. Other commenters indicated that CMS lacks the authority to adjust payments to facilities based on whether they are owned by a dialysis organization of a particular size. The commenters indicated that distinguishing facilities based on ownership status would be an unprecedented extension of CMS' authority to determine Medicare payments. One commenter stated that creating a tiered reimbursement on the basis of facility size or ownership type would create incentives for centers to pursue or retain a certain ownership status to receive higher reimbursement.

Other commenters advocated for an adjustment that would apply to small independent and hospital-based facilities, asserting that these providers have higher costs and lower margins than LDOs. One commenter disputed a finding by MedPAC that the spread in Medicare margin for LDOs compared to small dialysis organizations (SDOs) is about 6 percent and stated that SDOs are incurring even further losses from Medicare, maybe 3 percent more per treatment.

One commenter suggested that we revise the facility-level adjustments or develop a new case-mix adjustment to account for the administrative and financial burden for SDOs. Other commenters stated that the SDOs do not have the economies of scale and resources to implement the ESRD PPS and, therefore, will be forced to provide substandard care or close. The commenters expressed concern that competition allows patient choice and access to care and that we should support small businesses and work to "level the playing field for providers of all sizes."

Response: We have not provided a facility-level adjustment to reflect the size of the chain of dialysis facilities with which an ESRD facility is affiliated because our analysis does not indicate that such adjustments are warranted. In the final impact table (Table 35), facilities that are part of LDOs are projected to experience a -3.0 percent decrease in payment under the PPS compared to what they would have received in the absence of the PPS; medium-sized dialysis organizations (which are captured under the heading regional chains) are projected to experience a -0.9 percent decrease; SDOs are projected to experience a -0.3 percent decrease; and hospital-based facilities are projected to experience a 1.7 percent increase. Given that the impact percentages include the -2.0 percent decrease mandated by section 1881(b)(14)(A)(ii) of the Act, we do not believe these projected impacts indicate a need for adjustments based on the size of the facility or chain organization.

In addition, although there may currently be differences in the spread in Medicare margin for LDOs compared to small dialysis organizations (SDOs), the estimate indicated by the commenter is based upon the current basic case-mix adjusted composite payment system. As stated above, our analysis based on the payment adjustments in this final rule indicate that SDOs are projected do better under the ESRD PPS than larger organizations. We will be monitoring the effects of the ESRD PPS and will consider the commenters' suggestions as we refine the ESRD PPS.

With regard to the need for an adjustment for SDOs due to the administrative and financial burden of the ESRD PPS, we believe the decision to delay the implementation of oral-only Part D drugs under the ESRD PPS until after the transition as discussed in section II.A.3. of this final rule and the reduction in the number of co-morbidity adjustments described in section II.F.3. of this final rule will reduce substantially the administrative and financial burden on all ESRD facilities, including SDOs.

Comment: Many commenters stated that SDOs provide essential services to ESRD beneficiaries and requested that we take steps to ensure the survival of small ESRD facilities, thus preserving beneficiary choice. Commenters identified additional services such as dressing changes, staple removal and other basic nursing related tasks that small and independent ESRD facilities provide to patients who reside in remote areas to alleviate some of the burden associated with traveling to multiple healthcare providers for the provision of basic services. Commenters asserted that the calculations and adjusting of the base rate have reduced it to a value that will not allow SDOs and independents to survive. The commenters believed that the closure of these facilities would compromise beneficiary access to life sustaining dialysis and other basic services. The commenters stated that a higher base rate and fewer adjusters would be more beneficial to the SDOs and MDOs.

Response: We agree that ESRD facilities located in remote areas provide essential services to their patients and are interested in preserving beneficiary choice and access in these areas. As discussed further in sections II.F.3. and 4. of this final rule, we are finalizing a more targeted set of payment adjustments and reducing the standardization factor that is applied to the base rate. As a result, as discussed in section II.E.3. of this final rule, the

adjusted base rate has increased from $198.64 in the proposed rule to $229.63.

Comment: One commenter believed that section 150(d)(iv) of MIPPA provides CMS with the authority to make an annual update to account for the cost differential of ESRD facilities that do not qualify for the low-volume adjustment. This commenter further stated that such an adjustment would balance the incentives for efficiency and budget neutrality with the needs of patient care and a more competitive marketplace.

Response: We believe the commenter is referring to section 1881(b)(14)(D)(iv) of the Act which provides authority for other payment adjustments. Although we have the authority to establish other payment adjustments, we do not believe creating adjustments to create a more competitive marketplace is an appropriate use of this authority.

Comment: Several commenters did not believe that the market basket update would address the low margins for SDOs especially in the context of a two percent reduction in payments under the bundle. The commenters believed that at baseline, the SDO payments would be reduced while many of the cost inputs would continue to increase from inflation resulting in further reduction in SDOs' margins. The commenters asserted that SDOs have less room than other facilities to adjust under the PPS. These commenters concluded that even with new systems and processes in place, the adjustments that the SDOs will receive under the proposed ESRD PPS may not be sufficient to cover the additional costs and burdens of the ESRD PPS.

Response: As we indicated previously, the final impact analysis does not indicate that an adjustment for SDOs is warranted. In addition, to the extent facilities affiliated with SDOs expect to receive financial benefits from the ESRD PPS transition, that option is available to them.

Comment: Several commenters stated that they did not believe that the proposed facility adjustments and outlier policy adequately addresses the many needs of isolated essential facilities.

Response: We disagree with these commenters as the final impact analysis shows that all rural facilities (including those facilities that received IEF exceptions) would see only a slight decrease under the ESRD PPS in 2011 (−2.1 percent decrease). The impact on those few facilities that received a composite rate exception as isolated essential facilities is expected to be positive as those facilities are projected to receive an increase in payment over the current composite payment system.

Comment: One commenter stated that certain drugs used in the treatment of ESRD, particularly ESAs, have no competition within their drug class because they represent a manufacturer's monopoly. Because of the lack of competitive bidding, the commenter maintained that rural ESRD facilities would not be able to compete in price due to their smaller buying power compared to the larger chains. The commenter recommended an adjustment factor for small rural facilities to address this disadvantage.

Response: We do not believe that we should provide a special subsidy to facilities based on size or ownership because of a perceived disadvantage in buying power. We point out that facilities that believe that they are at a competitive disadvantage in purchasing required drugs or supplies due to size or location have the option of forming purchasing consortia in order to leverage their ability to buy products at discounted rates. In addition, in this final rule we have provided for a low-volume adjustment for qualifying ESRD facilities that furnish a small number of treatments and meet other requirements in order to preserve access to dialysis care, where operational costs due to economies of scale might otherwise jeopardize that access. Finally, we note that the impact analysis does not show that small or rural ESRD facilities are particularly disadvantaged under the new system.

E. Conclusion

The impact analysis shows an overall decrease in payments to all ESRD facilities for renal dialysis services of 2.0 percent. This is because of the statutory requirement that payments under the ESRD PPS in 2011 equal 98 percent of what ESRD facilities would have received were the ESRD PPS not implemented (or 98 percent of payments to ESRD facilities under the current payment system).

The analysis above, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

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

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

■ 1. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

■ 2. Section 410.50 is amended by revising paragraph (a) to read as follows:

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

* * * * *

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

* * * * *

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

■ 3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113 (133 stat. 1501A–332)

Subpart F—Specific Categories of Costs

■ 4. Section 413.89 is amended by adding a new paragraph (h)(3) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(h) * * *

(3) *ESRD facilities*—

(i) *Limitation on bad debt.* The amount of ESRD facility bad debts otherwise treated as allowable costs described in § 413.178.

(ii) *Exception.* Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program. Additional exceptions for ESRD bad debt payments are described in § 413.178(d).

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

■ 5. Section 413.170 is amended by revising the introductory text, paragraph (a) and paragraph (b) to read as follows:

§ 413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility (an ESRD facility with at least a 50 percent pediatric patient mix as specified in § 413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

* * * * *

■ 6. Section 413.171 is added to read as follows:

§ 413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in § 413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under § 410.50 and § 410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered "renal dialysis services," and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals 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),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

■ 7. Section 413.172 is amended by revising paragraph (a), paragraph (b), and paragraph (b)(1) to read as follows:

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

* * * * *

■ 8. Section 413.174 is amended as follows:

■ a. By revising paragraph (a).

■ b. By revising paragraphs (f) introductory text, (f)(3), and (f)(4).

■ c. By adding a new paragraphs (f)(5) and (f)(6). The revisions and additions read as follows:

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

* * * * *

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

* * * * *

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis.

Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in § 414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in § 405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biological furnished by independent ESRD facilities is based on the methodology specified in § 414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in § 413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2014, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

■ 9. Section 413.176 is revised to read as follows:

§ 413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

■ 10. Section 413.178 is amended by revising paragraph (d) to read as follows:

§ 413.178 Bad debts.

* * * * *

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

(2) For services furnished on or after January 1, 2011, bad debts arising from covered ESRD items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

■ 11. Section 413.180 is amended by adding a new paragraph (l) to read as follows.

§ 413.180 Procedures for requesting exceptions to payment rates.

* * * * *

(l) *Periods of exceptions.* (1) Prior to December 31, 2000, an ESRD facility may receive an exception to its composite payment rate for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities.

(2) Effective December 31, 2000, an ESRD facility not subject to paragraph (l)(3), is no longer granted any new exception to the composite payment rate as defined in § 413.180(1).

(3) Effective April 1, 2004 through September 27, 2004, and on an annual basis, an ESRD facility with at least 50 percent pediatric patient mix as specified in § 413.184 of this part, that did not have an exception rate in effect as of October 1, 2002, may apply for an exception to its composite payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in § 413.239 of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are used as the payment amount in place of the composite rate, and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with § 413.239(b) of this part, elect to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.220, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are terminated for ESRD services furnished on or after January 1, 2011.

■ 12. Section 413.195 is added to read as follows:

§ 413.195 Limitation on Review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following is prohibited: The determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the establishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

■ 13. Section 413.196 is amended by adding new paragraphs (c) and (d) to read as follows:

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

* * * * *

(c) Effective for items and services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

■ 14. Section 413.210 is added to subpart H to read as follows:

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and

services defined in § 413.217 of this part either directly or under arrangements.

■ 15. Section 413.215 is added to subpart H to read as follows:

§ 413.215 Basis of payment.

(a) Except as otherwise provided under § 413.235 or § 413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in § 413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in § 413.215(a) of this part, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.178 of this part.

■ 16. Section 413.217 is added to subpart H to read as follows:

§ 413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

■ 17. Section 413.220 is added to subpart H to read as follows:

§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

■ 18. Section 413.230 is added to subpart H to read as follows:

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in § 413.232 and § 413.235 of this part;

(b) Any outlier payment under § 413.237; and

(c) Any training adjustment add-on under § 414.335(b).

■ 19. Section 413.231 is added to subpart H to read as follows:

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

■ 20. Section 413.232 is added to subpart H to read as follows:

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that:

(1) Furnished less than 4,000 treatments in each of the 3 years preceding the payment year; and

(2) Has not opened, closed, or had a change in ownership in the 3 years preceding the payment year.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) 25 miles or less from the ESRD facility in question.

(d) The determination under paragraph (c) of this section does not apply to an ESRD facility that was in existence and certified for Medicare participation prior January 1, 2011.

(e) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(f) To receive the low-volume adjustment, an ESRD facility must provide an attestation statement to their Medicare administrative contractor that the facility has met all the criteria as established in paragraphs (a), (b), (c), and (d) of this section.

(g) The low-volume adjustment applies only for dialysis treatments provided to adults (18 years or older).

■ 21. Section 413.235 is added to subpart H to read as follows:

§ 413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14) (D)(iv)(I) of the Act, to account for patient age and treatment modality.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

■ 22. Section 413.237 is added to subpart H to read as follows:

§ 413.237 Outliers.

(a) The following definitions apply to this section.

(1) *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 effective January 1, 2014.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage:* This term has the meaning set forth in § 413.220(b)(4).

(b) Eligibility for outlier payments.

(1) *Adult beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP amount plus the adult fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for an adult beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the adult beneficiary by the number of dialysis treatments furnished to the adult beneficiary in the relevant month. A beneficiary is considered an adult beneficiary if the beneficiary is 18 years old or older.

(2) *Pediatric beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to a pediatric beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the pediatric predicted ESRD outlier services MAP amount plus the pediatric fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for a pediatric beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the pediatric beneficiary by the number of dialysis treatments furnished to the pediatric beneficiary in the relevant month. A beneficiary is considered a pediatric beneficiary if the beneficiary is under 18 years old.

(c) *Outlier payment amount:* CMS pays 80 percent of the difference between:

(1) The ESRD facility's per-treatment imputed MAP amount for the ESRD outlier services, and

(2) The adult or pediatric predicted ESRD outlier services MAP amount plus the adult or pediatric fixed dollar loss amount, as applicable.

■ 23. Section 413.239 is added to subpart H to read as follows:

§ 413.239 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* ESRD facilities not electing under paragraph (b) of this section to be paid based on the payment amount determined under § 413.230 of this part, will be paid a per-treatment payment amount for renal dialysis services (as defined in § 413.171 of this part) and home dialysis, provided during the transition as follows—

(1) For services provided on and after January 1, 2011 through December 31, 2011, a blended rate equal to the sum of:

(i) 75 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 25 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(2) For services provided on and after January 1, 2012 through December 31, 2012, a blended rate equal to the sum of:

(i) 50 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 50 percent of the payment rate determined in accordance with section 1881(b)(14) of the Act;

(3) For services provided on and after January 1, 2013 through December 31, 2013, a blended rate equal to the sum of:

(i) 25 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 75 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(4) For services provided on and after January 1, 2014, 100 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act.

(b) *One-time election.* Except as provided in paragraph (b)(2) of this section, ESRD facilities may make a one-time election to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based

on the payment amount determined under paragraph (a) of this section.

(1) Except as provided in paragraph (b)(3) of this section, the election must be received by each ESRD facility's Medicare administrative contractor (MAC) by November 1, 2010. Requests received by the MAC after November 1, 2010, will not be accepted regardless of postmarks, or delivered dates. MACs will establish the manner in which an ESRD facility will indicate their intention to be excluded from the transition and paid entirely based on payment under the ESRD PPS. Once the election is made, it may not be rescinded.

(2) If the ESRD facility fails to submit an election, or the ESRD facility's election is not received by their MAC by November 1, 2010, payments to the ESRD facility for items and services provided during the transition will be based on the payment amounts determined under paragraph (a) of this section.

(3) ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services, as defined in § 413.171 of this part, between November 1, 2010 and December 31, 2010, must notify their designated MAC of their election choice at the time of enrollment.

(c) *Treatment of new ESRD facilities.* For renal dialysis services as defined in § 413.171, furnished during the transition period, new ESRD facilities as defined in § 413.171, are paid based on the per-treatment payment amount determined under § 413.215 of this part.

(d) *Transition budget-neutrality adjustment.* During the transition, CMS adjusts all payments, including payments under this section, under the ESRD prospective payment system so that the estimated total amount of payment equals the estimated total amount of payments that would otherwise occur without such a transition.

■ 24. Section 413.241 is added to subpart H to read as follows:

§ 413.241 Pharmacy arrangements.

Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis service drugs and biologicals to patients in a timely manner.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 25. The authority citation for part 414 continues to read as follows:

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

Subpart E—Determination of Reasonable Charges Under the ESRD Program

■ 26. Section 414.330 is amended by—

■ A. Removing "§ 413.170" and adding in its place "§ 413.210" in paragraph (a)(1) and paragraph (b)(1).

■ B. Revising the heading of paragraph (a)(2).

■ C. Revising the heading of paragraph (b)(2).

■ D. Removing the paragraph heading and adding in its place new introductory text in paragraph (c).

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* * * *

* * * * *

(b) * * *

(2) *Exception for home support services furnished prior to January 1, 2011.* * * *

* * * * *

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

* * * * *

■ 27. Revise § 414.335 to read as follows:

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

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

Dated: July 15, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 22, 2010.

Kathleen Sebelius,

Secretary.

Note: The following tables will not appear in the Code of Federal Regulations.

BILLING CODE P

Table A: Payment Multipliers for an Expanded Bundle of Services, ages 18 and older, 2006-08

Base Rate - $229.63

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]
	Composite rate services[1]	Separately billable services[2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics			
Age			
18-44	1.254	0.996	1.171
45-59	1.023	0.992	1.013
60-69	1.000	1.000	1.000
70-79	1.033	0.963	1.011
80+	1.063	0.915	1.016
Body surface area (per 0.1 m^2)	1.023	1.014	1.020
Underweight (BMI <18.5)	1.000^	1.078	1.025
Time since onset of renal dialysis < 4 months	1.539	1.450	1.510
Pericarditis (acute*)	1.000^	1.354	1.114
Bacterial pneumonia (acute*)	1.000^	1.422	1.135
Gastro-intestinal tract bleeding (acute*)	1.000^	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic*)	1.000^	1.225	1.072
Myelodysplastic syndrome (chronic*)	1.000^	1.309	1.099
Monoclonal gammopathy[5] (chronic*)	1.000^	1.074	1.024
Low volume facility adjustment Facility size < 4,000 treatments during each year from 2006-08	1.347	0.975	1.189

^A multiplier of 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability in the estimated multipliers.

[1]The CR payment multipliers ($PmtMult_{CR}$) are based on a facility level log-linear regression model of the average composite rate cost/session for 2006-08 (n=12,974 facility years). This model also included facility characteristics (an indicator of low volume facilities as a potential payment variable and control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate exception, % of patients in the facility with URR<65%, and % of home dialysis training treatments in the facility) and the percent of pediatric patients as additional covariates (R-sq=41.0%).

[2]Based on a patient-month level log-linear regression model of separately billable Medicare Allowable Payments/session for 2006-08 (n=8,603,325 patient months) that included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates. An R-squared value of 5.1% was calculated at the patient level based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R-squared value for the patient-month level log-linear SB model was 3.3%.

[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable MAP. Based on total estimated costs of $177.72 per session for composite rate services, $83.97 per session for separately billable services, and $261.69 per session for composite rate and separately billable services ($177.72+$83.97), the relative weights are $Weight_{CR}$=0.6791 for composite rate services ($177.72/$261.69) and $Weight_{SB}$=0.3209 for separately billable services ($83.97/$261.69). The combined low volume multiplier was calculated relative to all other facilities.

[4]To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression models (which correspond to the CR and SB multipliers of 1.347 and 0.975, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.189. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

[5]Excludes multiple myeloma.

*Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

Table B: Payment Multipliers for Pediatric Patients Based on Adjustments for Age and Modality

Base Rate - $229.63

Cell	Patient characteristics		Separately billable (SB) payment multiplier[1]	Expanded bundle payment multiplier
	Age	Modality		
1	<13	PD	0.319	1.033
2	<13	Hemo	1.185	1.219
3	13-17	PD	0.476	1.067
4	13-17	Hemo	1.459	1.277

[1]Based on a pediatric patient month level regression model of SB MAP/session for 2006-08 (n=17,142 pediatric patient months) that included age (<13 vs. 13-17) and modality (PD vs. HD). An R-squared value calculated at the patient year level was 34.8%. This calculation was based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed SB MAP per treatment for the patient year. In estimating this R-squared value, a log transformation was applied to both the average predicted and average observed SB values. The R-squared value for the patient month regression model was 32.8%. Subgroup-specific smearing adjustments were applied to the estimated multipliers from the model. The SB payment multipliers presented above were calculated relative to the average SB multiplier among pediatric patients, such that the average pediatric SB payment multiplier is 1.000.

Table C: Part B Drugs Included in the Proposed and Final ESRD PPS Base Rate

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
Access management	J1642	INJ HEPARIN SODIUM PER 10 U	Yes	Yes
	J1644	INJ HEPARIN SODIUM PER 1000U		
	J1945	LEPIRIDUN		
	J2993	RETEPLASE INJECTION		
	J2997	ALTEPLASE RECOMBINANT		
	J3364	UROKINASE 5000 IU INJECTION		
	J3365	UROKINASE 250,000 IU INJ		
Anemia management	J0882	DARBEPOETIN	Yes	Yes
	J0886	EPO		
	J1751[1]	IRON DEXTRAN		
	J1752[1]	IRON DEXTRAN		
	J1756	IRON SUCROSE INJECTION		
	J2916	NA FERRIC GLUCONATE COMPLEX		
	J3420	VITAMIN B12 INJECTION		
	Q4055[1]	EPO		
Antiemetic	J0780	PROCHLORPERAZINE INJECTION	Yes	Yes
	J1260	DOLASETRON MESYLATE		
	J1626	GRANISETRON HCL INJECTION		
	J2405	ONDANSETRON HCL INJECTION		
	J2550	PROMETHAZINE HCL INJECTION		
	J2765	METOCLOPRAMIDE HCL INJECTION		
	J2950	PROMAZINE HCL INJECTION		
	J3230	CHLORPROMAZINE HCL INJECTION		
	J3250	TRIMETHOBENZAMIDE HCL INJ		
	J3310	PERPHENAZINE INJECITON		
Anxiolytic	J2060	LORAZEPAM INJECTION	Yes	Yes
	J2250	INJ MIDAZOLAM HYDROCHLORIDE		
	J3360	DIAZEPAM INJECTION		
Bone and mineral metabolism	J0610	CALCIUM GLUCONATE INJECTION	Yes	Yes
	J0630	CALCITONIN SALMON INJECTION		
	J0635	CALCITRIOL		
	J0636	INJ CALCITRIOL PER 0.1 MCG		
	J0895	DEFEROXAMINE MESYLATE INJ		
	J1270	INJECTION, DOXERCALCIFEROL		
	J1740	IBANDRONATE SODIUM		
	J2430	PAMIDRONATE DISODIUM /30 MG		
	J2500[1]	PARICALCITOL		
	J2501	PARICALCITOL		
Cellular management	J1955	INJ LEVOCARNITINE PER 1 GM	Yes	Yes
Pain management	J1170	HYDROMORPHONE INJECTION	Yes	Yes
	J1885	KETOROLAC TROMETHAMINE INJ		
	J2175	MEPERIDINE HYDROCHL /100 MG		
	J2270	MORPHINE SULFATE INJECTION		
	J2271	MORPHINE SO4 INJECTION 100MG		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J2275	MORPHINE SULFATE INJECTION		
	J2300	INJ NALBUPHINE HYDROCHLORIDE		
	J2310	INJ NALOXONE HYDROCHLORIDE		
	J3010	FENTANYL CITRATE INJECITON		
	J3070	PENTAZOCINE INJECTION		
Anti-infective	J0278	AMIKACIN SULFATE	Yes	Yes
	J0285	AMPHOTERICIN B		
	J0290	AMPICILLIN 500 MG INJ		
	J0295	AMPICILLIN SODIUM PER 1.5 GM		
	J0456	AZITHROMYCIN		
	J0530	PENICILLIN G BENZATHINE INJ		
	J0560	PENICILLIN G BENZATHINE INJ		
	J0580	PENICILLIN G BENZATHINE INJ		
	J0637	CASPOFUNGIN ACETATE		
	J0690	CEFAZOLIN SODIUM INJECTION		
	J0692	CEFEPIME HCL FOR INJECTION		
	J0694	CEFOXITIN SODIUM INJECTION		
	J0696	CEFTRIAXONE SODIUM INJECTION		
	J0697	STERILE CEFUROXIME INJECTION		
	J0698	CEFOTAXIME SODIUM INJECTION		
	J0713	INJ CEFTAZIDIME PER 500 MG		
	J0715	CEFTIZOXIME SODIUM / 500 MG		
	J0743	CILASTATIN SODIUM INJECTION		
	J0744	CIPROFLOXACIN IV		
	J0878	DAPTOMYCIN		
	J1335	ERTAPENEM SODICUM		
	J1364	ERYTHRO LACTOBIONATE /500 MG		
	J1450	FLUCONAZOLE		
	J1580	GARAMYCIN GENTAMICIN INJ		
	J1590	GATIFLOXACIN INJECTION		
	J1840	KANAMYCIN SULFATE 500 MG INJ		
	J1890	CEPHALOTHIN SODIUM INJECTION		
	J1956	LEVOFLOXACIN INJECTION		
	J2020	LINEZOLID INJECTION		
	J2185	MEROPENEM		
	J2280	MOXIFLOXACIN		
	J2510	PENICILLIN G PROCAINE INJ		
	J2540	PENICILLIN G POTASSIUM INJ		
	J2543	PIPERACILLIN/TAZOBACTAM		
	J2700	OXACILLIN SODIUM INJECTION		
	J3000	STREPTOMYCIN INJECTION		
	J3260	TOBRAMYCIN SULFATE INJECTION		
	J3370	VANCOMYCIN HCL INJECTION		
Composite rate drugs that were billed separately	A4802	PROTAMINE SULFATE PER 50 MG	Yes	No
	J1200	DIPHENHYDRAMINE HCL INJECTIO		
	J1240	DIMENHYDRINATE INJECTION		
	J1940	FUROSEMIDE INJECTION		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J2001	LIDOCAINE HCL 10MG		
	J2150	MANNITOL INJECTION		
	J2720	INJ PROTAMINE SULFATE/10 MG		
	J2795	ROPIVACAINE HCL INJECTION		
	J3410	HYDROXYZINE HCL INJECTION		
Hepatitis B vaccine	90371	HEP B IG, IM	No	No
	90740	HEPB VACC, ILL PAT 3 DOSE IM		
	90743	HEP B VACC, ADOL, 2 DOSE, IM		
	90744	HEPB VACC PED/ADOL 3 DOSE IM		
	90746	HEP B VACCINE, ADULT, IM		
	90747	HEPB VACC, ILL PAT 4 DOSE IM		
	90748	HEP B/HIB VACCINE, IM		
Flu vaccine	90655	FLU VACCINE	No	No
	90656	FLU VACCINE		
	90657	FLU VACCINE, 6-35 MO, IM		
	90658	FLU VACCINE, 3 YRS, IM		
	90660	FLU VACCINE, NASAL		
Pneumoccocal vaccine	90732	PNEUMOCOCCAL VACCINE	No	No
Other vaccine	90471	IMMUNIZATION ADMIN	Yes	No
	90585	BCG VACCINE, PERCUT		
	90632	HEP A VACCINE, ADULT IM		
	90633	HEP A VACC, PED/ADOL, 2 DOSE		
	90636	HEP A/HEP B VACC, ADULT IM		
	90648	HIB VACCINE, PRP-T, IM		
	90700	DTAP VACCINE, IM		
	90703	TETANUS VACCINE, IM		
	90707	MMR VACCINE, SC		
	90714	TETANUS AND DIPTHERIA TOXOIDS		
	90715	ACCELULLAR DPT		
	90716	CHICKEN POX VACCINE, SC		
	90717	YELLOW FEVER VACCINE, SC		
	90718	TD VACCINE > 7, IM		
	90723	DTAP-HEP B-IPV VACCINE, IM		
	90733	MENINGOCOCCAL VACCINE, SC		
	90734	MENINGOCOCCAL CONJUGATE VACCINE SEROGROUPS A,C,Y AND W-135 (TETRAVALENT), IM		
	90735	ENCEPHALITIS VACCINE, SC		
Immune system	J1440	FILGRASTIM 300 MCG INJECTION	Yes	No
	J1441	FILGRASTIM 480 MCG INJECTION		
	J1566	IMMUNE GLOBULIN		
	J1567	IMMUNE GLOBULIN		
	J2504	PEGADEMASE BOVINE		
	J7500	AZATHIOPRINE ORAL 50MG		
	J7502	CYCLOSPORINE ORAL 100 MG		
	J7506	PREDNISONE ORAL		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J7507	TACROLIMUS ORAL PER 1 MG		
	J7515	CYCLOSPORINE ORAL 25 MG		
	J7517	MYCOPHENOLATE MOFETIL ORAL		
	J7518	MYCOPHENOLIC ACID ORAL		
	J7520	SIROLIMUS, ORAL		
	J9216	INTERFERON GAMMA 1-B INJ		
	Q4088	IMMUNE GLOBULIN		
	Q4092	IMMUNE GLOBULIN		
Non-ESRD drug	J0150	INJECTION ADENOSINE 6 MG	Yes	No
	J0152	ADENOSINE		
	J0170	ADRENALIN EPINEPHRIN INJECT		
	J0180	INJECTION, AGALSIDASE BETA, 1 MG		
	J0270	ALPROSTADIL FOR INJECTION		
	J0280	AMINOPHYLLIN 250 MG INJ		
	J0282	AMIODARONE HCL		
	J0330	SUCCINYCHOLINE CHLORIDE INJ		
	J0360	HYDRALAZINE HCL INJECTION		
	J0460	ATROPINE SULFATE INJECTION		
	J0475	BACLOFEN 10 MG INJECTION		
	J0583	BIVALIRUDIN		
	J0670	INJ MEPIVACAINE HCL/10 ML		
	J0702	BETAMETHASONE ACET&SOD PHOSP		
	J0706	CAFFEINE CITRATE INJECTION		
	J0735	CLONIDINE HYDROCHLORIDE		
	J0760	COLCHICINE INJECTION		
	J0835	INJ COSYNTROPIN PER 0.25 MG		
	J1040	METHYLPREDNISOLONE 80 MG INJ		
	J1070	TESTOSTERONE CYPIONAT 100 MG		
	J1080	TESTOSTERONE CYPIONAT 200 MG		
	J1100	DEXAMETHASONE SODIUM PHOS		
	J1160	DIGOXIN INJECTION		
	J1165	PHENYTOIN SODIUM INJECTION		
	J1245	DIPYRIDAMOLE INJECTION		
	J1250	INJ DOBUTAMINE HCL/250 MG		
	J1265	DOPAMINE HCL		
	J1410	INJ ESTROGEN CONJUGATE 25 MG		
	J1570	GANCICLOVIR SODIUM INJECTION		
	J1600	GOLD SODIUM THIOMALEATE INJ		
	J1610	GLUCAGON HYDROCHLORIDE/1 MG		
	J1630	HALOPERIDOL INJECTION		
	J1631	HALOPERIDOL DECANOATE INJ		
	J1645	DALTEPARIN SODIUM		
	J1650	INJ ENOXAPARIN SODIUM		
	J1670	TETANUS IMMUNE GLOBULIN INJ		
	J1700	HYDROCORTISONE ACETATE INJ		
	J1720	HYDROCORTISONE SODIUM SUCC I		
	J1730	DIAZOXIDE INJECTION		

Category	HCPCS	Title	Category Included in ESRD PPS Base Rate	
			Proposed Rule	Final Rule
	J1785	INJECTION IMIGLUCERASE /UNIT		
	J1790	DROPERIDOL INJECTION		
	J1815	INSULIN INJECTION		
	J1817	INSULIN FOR INSULIN PUMP USE		
	J1950	LEUPROLIDE ACETATE /3.75 MG		
	J2320	NANDROLONE DECANOATE 50 MG		
	J2321	NANDROLONE DECANOATE 100 MG		
	J2322	NANDROLONE DECANOATE 200 MG		
	J2360	ORPHENADRINE INJECTION		
	J2370	PHENYLEPHRINE HCL INJECTION		
	J2440	PAPAVERIN HCL INJECTION		
	J2515	PENTOBARBITAL SODIUM INJ		
	J2560	PHENOBARBITAL SODIUM INJ		
	J2597	INJ DESMOPRESSIN ACETATE		
	J2710	NEOSTIGMINE METHYLSLFTE INJ		
	J2780	RANITIDINE HYDROCHLORIDE INJ		
	J2794	RISPERIDONE		
	J2910	AUROTHIOGLUCOSE INJECITON		
	J2920	METHYLPREDNISOLONE INJECTION		
	J2930	METHYLPREDNISOLONE INJECTION		
	J3030	SUMATRIPTAN SUCCINATE / 6 MG		
	J3105	TERBUTALINE SULFATE INJ		
	J3120	TESTOSTERONE ENANTHATE INJ		
	J3130	TESTOSTERONE ENANTHATE INJ		
	J3240	THYROTROPIN INJECTION		
	J3301	TRIAMCINOLONE ACETONIDE INJ		
	J3430	VITAMIN K PHYTONADIONE INJ		
	J3487	ZOLEDRONIC ACID		
	J7192	FACTOR VIII RECOMBINANT		
	J7197	ANTITHROMBIN III INJECTION		
	J7611	ALBUTEROL, INHALATION SOLUTION		
	J7613	ALBUTEROL, INHALATION SOLUTION		
	J7614	LEVALBUTEROL, INHALATION SOLUTION		
	J9090	CYCLOPHOSPHAMIDE 500 MG INJ		
	J9310	RITUXIMAB CANCER TREATMENT		
	J9340	THIOTEPA INJECTION		
	Q4084	HYALURONAN OR DERIVATIVE SYNVISC, IA		
Unknown	J3490	DRUGS UNCLASSIFIED INJECTION	Yes	No

[1] Code terminated

Table D: List of Former Part D Drugs National Drug Codes Bundled in the ESRD PPS

Ingredient Name	NDC	Strength	Trade Name
Calcitriol	260530051	0.25 MCG	Calcitriol Capsules
	000540007	0.25 MCG	Calcitriol Capsules
	000930657	0.25MCG	Calcitriol Capsules
	000930658	0.5MCG	Calcitriol Capsules
	001791578	0.25MG	Calcitriol Capsules
	001791603	0.5MCG	Calcitriol Capsules
	004800657	0.25 MCG	Calcitriol Capsules
	004800658	0.5 MCG	Calcitriol Capsules
	110140011	0.25 MCG	Calcitriol Capsules
	142880007	0.25 MCG	Calcitriol Capsules
	178560007	0.25 MCG	Calcitriol Capsules
	548684584	0.25 MCG	Calcitriol Capsules
	551548251	0.25 MCG	Calcitriol Capsules
	647250048	0.25 MG	Calcitriol Capsules
	647250049	0.5 MG	Calcitriol Capsules
	000543120	1 MCG/ML	Calcitriol Oral Solution
	682589030	0.5 MCG	Calcitriol Capsules
	548683461	0.25 MCG	Rocaltrol Capsules
	604910562	0.5 MCG	Rocaltrol Capsules
	000049115	1 MCG/ML	Rocaltrol Oral Solution
	633040241	1 MCG/ML	Calcitriol Oral Solution
Paricalcitol	000744314	2 MCG	Zemplar Capsules
	000744315	4 MCG	
	000744317	1 MCG	
	110140056	2 MCG	
	110140057	4 MCG	
	242360664	1 MCG	
	511294272	1 MCG	
	551540001	1 MCG	
	551546971	1 MCG	
Doxercalciferol	110140017	0.5 MCG	Hectorol Capsules
	110140018	2.5 MCG	
	511293550	2.5 MCG	
	584680120	0.5 MCG	
	584680122	2.0 MCG	
	584680121	2.5 MCG	
Levocarnitine	544800145	1GM/10ML	Carnitor Solution Oral
	544800144	330MG	Carnitor Tablets
	586090144	330MG	Carnitor Tablets
	503830170	1GM/10ML	L Carnitine Solution Oral
	503830171	10%	Levocarnitine Oral Solution
	003745030	1G/10ML	Levocarnitine Oral Solution
	649800503	1G/10ML	Levocarnitine Oral Solution
	649800130	330MG	Levocarnitine Tablets
	647200160	330MG	Levocarnitine Tablets

Table E: ICD-9 CM Codes Recognized for a Co-morbidity Payment Adjustment

Bacterial Pneumonia

ICD-9-CM	Descriptor
00322	Salmonella pneumonia
4820	Pneumonia due to Klebsiella pneumnoniae
4821	Pneumonia due to Pseudomonas
4822	Pneumonia due to Hemophilus influenzae
48230	Pneumonia due to Streptococcus, unspecified
48231	Pneumonia due to Streptococcus, Group A
48232	Pneumonia due to Streptococcus, Group B
48239	Pneumonia due to Streptococcus, other Streptococcus
48240	Pneumonia due to Staphylococcus, unspecified
48241	Methicillin susceptible pneumonia due to Staphylococcus aureus
48242	Methicillin resistant pneumonia due to Staphylococcus aureus
48249	Other Staphylococcus pneumonia
48281	Pneumonia due to Anaerobes
48282	Pneumonia due to Escherichia coli (E. coli)
48283	Pneumonia due to other gram-negative bacteria
48284	Pneumonia due to Legionnaires' disease
48289	Pneumonia due to other specified bacteria
5070	Pneumonitis due to inhalation of food or vomitus
5078	Pneumonitis due to other solids and liquids
5100	Empyema, with fistula
5109	Empyema. without mention of fistula
5130	Abscess of lung

Gastrointestinal Bleeding

ICD-9-CM	Descriptor
53021	Ulcer of esophagus with bleeding
53100	Acute gastric ulcer with hemorrhage without mention of obstruction
53101	Acute gastric ulcer with hemorrhage with obstruction
53120	Acute gastric ulcer with hemorrhage and perforation without obstruction
53121	Acute gastric ulcer with hemorrhage and perforation with obstruction
53140	Chronic or unspecified gastric ulcer with hemorrhage without mention of obstruction
53141	Chronic or unspecified gastric ulcer with hemorrhage with obstruction
53160	Chronic or unspecified gastric ulcer with hemorrhage and perforation without mention of obstruction
53161	Chronic or unspecified gastric ulcer with hemorrhage and perforation with obstruction
53200	Acute duodenal ulcer with hemorrhage without mention of obstruction
53201	Acute duodenal ulcer with hemorrhage with obstruction
53220	Acute duodenal ulcer with hemorrhage and perforation without mention of obstruction
53221	Acute duodenal ulcer with hemorrhage and perforation with obstruction
53240	Chronic or unspecified duodenal ulcer with hemorrhage without mention of obstruction
53241	Chronic or unspecified duodenal ulcer with hemorrhage with obstruction
53260	Chronic or unspecified duodenal ulcer with hemorrhage and perforation without mention of obstruction
53261	Chronic or unspecified duodenal ulcer with hemorrhage and perforation with obstruction
53300	Acute peptic ulcer with hemorrhage without mention of obstruction
53301	Acute peptic ulcer with hemorrhage with obstruction
53320	Acute peptic ulcer with hemorrhage and perforation without mention of obstruction
53321	Acute peptic ulcer with hemorrhage and perforation with obstruction
53340	Chronic or unspecified peptic ulcer with hemorrhage without mention of obstruction
53341	Chronic or unspecified peptic ulcer with hemorrhage with obstruction
53360	Chronic or unspecified peptic ulcer with hemorrhage and perforation without mention of

	obstruction
53361	Chronic or unspecified peptic ulcer with hemorrhage and perforation with obstruction
53400	Acute gastrojejunal ulcer with hemorrhage without mention of obstruction
53401	Acute gastrojejunal ulcer with hemorrhage with obstruction
53420	Acute gastrojejunal ulcer with hemorrhage and perforation without mention of obstruction
53421	Acute gastrojejunal ulcer with hemorrhage and perforation with obstruction
53440	Chronic or unspecified gastrojejunal ulcer with hemorrhage without mention of obstruction
53441	Chronic or unspecified gastrojejunal ulcer with hemorrhage with obstruction
53460	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation without mention of obstruction
53461	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation with obstruction
53571	Eosinophilic gastritis, with hemorrhage
53783	Angiodysplasia of stomach and duodenum with hemorrhage
56202	Diverticulosis of small intestine with hemorrhage
56203	Diverticulitis of small intestine with hemorrhage
56212	Diverticulosis of colon with hemorrhage
56213	Diverticulitis if colon with hemorrhage
56985	Angiodysplasia of intestine with hemorrhage

Hereditary hemolytic and sickle cell anemia

ICD-9-CM	Descriptor
2820	Hereditary spherocytosis
2821	Hereditary elliptocytosis
2822	Anemias due to disorders of glutathione metabolism
2823	Other hemolytic anemias due to enzyme deficiency
28241	Sickle-cell thalassemia without crisis
28242	Sickle-cell thalassemia with crisis
28249	Other thalassemias
28261	Sickle-cell disease, Hb-SS disease without crisis
28262	Sickle-cell disease, Hb-SS disease with crisis
28263	Sickle-cell disease, Sickle-cell/Hb-C disease without crisis
28264	Sickle-cell disease, Sickle-cell/Hb-C disease with crisis
28268	Sickle-cell disease, Other sickle-cell disease without crisis
28269	Sickle-cell disease, Other sickle-cell disease with crisis

Monoclonal gammopathy (in the absence of multiple myeloma)

ICD-9-CM	Descriptor
2731	Monoclonal paraproteinemia [includes monoclonal gammopathy]

Myelodysplastic syndrome

ICD-9-CM	Descriptor
23871	Essential thrombocythemia
23872	Low grade myelodysplastic syndrome lesions
23873	High grade myelodysplastic syndrome lesions
23874	Myelodysplastic syndrome with 5q deletion
23875	Myelodysplastic syndrome, unspecified
23876	Myelofibrosis with myeloid metaplasia

Pericarditis

ICD-9-CM	Descriptor
4200	Acute pericarditis in diseases classified elsewhere
42090	Other and unspecified pericarditis, acute pericarditis, unspecified
42091	Other and unspecified pericarditis, acute idiopathic paricarditis
42099	Other acute pericarditis

Table F: ESRD-Related Laboratory Tests

CPT/ HCPCS	Short Description
82040	Assay of serum albumin
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82310	Assay of calcium
82330	Assay of calcium, Ionized
82374	Assay, blood carbon dioxide
82379	Assay of carnitine
82435	Assay of blood chloride
82565	Assay of creatinine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin
82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83735	Assay of magnesium
83970	Assay of parathormone
84075	Assay alkaline phosphatase
84100	Assay of phosphorus
84132	Assay of serum potassium
84134	Assay of prealbumin
84155	Assay of protein, serum
84295	Assay of serum sodium
84466	Assay of transferrin
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85014	Hematocrit
85018	Hemoglobin
85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.
85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
85041	Automated rbc count

CPT/ HCPCS	Short Description
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040[1]	Blood culture for bacteria
87070[1]	Culture, bacteria, other
87071[1]	Culture bacteria aerobic othr
87073[1]	Culture bacteria anaerobic
87075[1]	Cultr bacteria, except blood
87076[1]	Culture anaerobe ident, each
87077[1]	Culture aerobic identify
87081[1]	Culture screen only
87340	Hepatitis b surface ag, eia
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

[1] Only ESRD-related when testing is related to the dialysis access site

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BILLING CODE C