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42 CFR Parts 410, 413 and 414

Medicare Programs; End-Stage Renal Disease Prospective Payment System; Town Hall Meeting on End-Stage Renal Disease Prospective Payment System; Proposed Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413 and 414

[CMS–1418–P]

RIN 0938–AP57

Medicare Programs; End-Stage Renal Disease Prospective Payment System

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

ACTION: Proposed rule.

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

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 16, 2009.

ADDRESSES: In commenting, please refer to file code CMS–1418–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.*

Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*1418*–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*1418*–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

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

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

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

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

FOR FURTHER INFORMATION CONTACT: William Cymer, (410) 786–4533. Lynn Riley, (410) 786–1286, (ESRD Quality Incentive Program.)

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

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

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Acronyms

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
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
BN Budget neutrality
BSA Body surface area
CBSA Core-Based Statistical Area
CDC Centers for Disease Control and Prevention
CFR Code of Federal Regulations
CMS Centers for Medicare & Medicaid Services
CPM Clinical performance measure
CR Composite rate
CROWN Consolidated Renal Operations in a Web-Enabled Network
CY Calendar year
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
HD Hemodialysis
IHS Indian Health Service
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
MAC Medicare Administrative Contractor
MAP Medicare allowable payment
MCP Monthly capitation payment
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)
MSA Metropolitan Statistical Area
NEC Not elsewhere classified
NIH National Institutes of Health
NOS Not otherwise specified
NQF National Quality Forum
OMB Office of Management and Budget
OSCAR Online State Certification and Reporting System
PD Peritoneal dialysis
PFS Physician fee schedule
PPS Prospective payment system
PDE Prescription drug event
PVD Peripheral vascular disease
REMIS Renal Management Information System
RRB Railroad Retirement Board
RRT Renal replacement therapy
SB Separately billable
SIMS ESRD Standard Information Management System
SSA Social Security Administration
UM–KECC University of Michigan, Kidney Epidemiology & Cost Center
URR Urea reduction ratio

I. Background

A. Origins of the Composite Payment System

Section 299I of the Social Security Amendments of 1972, Public Law 92–603, established the end-stage renal disease (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. On July 1, 1973, the Medicare program extended benefits to about 11,000 beneficiaries with ESRD. In calendar year 1974, the program paid benefits of about $229 million for dialysis, transplant, and other services. By 1979, the number of beneficiaries had grown to 42,500, with payments reaching $985 million.

Because of concern over the rapid escalation in expenditures for the ESRD program, the Congress enacted legislation in 1978 (Pub. L. 95–292, ''ESRD Program Amendments of 1978''), which amended title XVIII of the Social Security Act (the Act) to add new section 1881, which governs Medicare payment for ESRD benefits. In particular, section 1881(b)(2)(B) of the Act directed us to publish regulations establishing methods and procedures to determine the costs incurred by ESRD providers and renal dialysis facilities in

furnishing covered services to individuals with ESRD, and to determine, on a cost-related or other equitable and economically efficient basis, payment amounts for part B services furnished by such providers and facilities to individuals with ESRD. Section 1881(b)(2)(B) of the Act also provided that we establish a prospective reimbursement method for those services with incentives for encouraging facilities to be more efficient and provide cost-effective care.

The enactment of the Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, resulted in a further directive for implementing 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 supplier to obtain the supplies and equipment needed.) For further information on the distinctions between Method I and Method II, see section III.E of this proposed 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, a substantial portion of expenditures for renal dialysis services are excluded from the composite payment system and reimbursed in accordance with the respective fee schedules or other payment methodologies. For example, payment 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), is 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. The present 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 applied 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. We believe that a fully bundled 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 a bundled ESRD PPS would have several objectives. These include eliminating 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.

B. Statutory Authority for a Bundled ESRD PPS

1. BIPA

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), Public Law 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 a bundled 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 Secretary's May 2003 report contained recommendations and conclusions drawn from research, which CMS had initiated on its own prior to the enactment of the law. In September 2000, the Kidney Epidemiology and Cost Center of the University of Michigan (UM–KECC) was awarded a multi-phased research contract. That research led to UM–KECC's August 2002 report, *An Expanded Medicare Outpatient End Stage Renal Disease Prospective Payment System, Phase I Report.* This report provided useful information on many of the issues that would need to be addressed before a bundled ESRD PPS could be implemented, and formed the foundation for the Secretary's May 2003 report.

2. MMA

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, body surface area, and low body mass index, 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 derived from UM–KECC's research 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_Expanded_ESRD_Bundle.pdf.* Individuals requiring special assistive technology may contact CMS at 410–786–4533 between the hours of 8:30 a.m. and 5 p.m. e.d.t. for assistance. 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, as added by section 623(d)(1) of the MMA, 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). Accordingly, we briefly describe below the basic case-mix adjustment under the current composite payment system before turning to the relevant provisions of MIPPA and the development of the proposed ESRD PPS.

3. The Basic Case-Mix Adjustment

Resources required to furnish routine dialysis such as staff and equipment time vary by patient. For example, all other things being equal, larger patients cost more to deliver the same dose of dialysis than do smaller patients. Also, severely debilitated or aged patients may require more staff time than do younger healthier patients. 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. Such an adjustment also would reduce the disincentives to treat or provide the optimal dose of dialysis to such patients.

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). Patient-specific data related to the costs of furnishing composite rate services are not collected because these costs are included as part of the composite rate and are not separately billed. However, earlier UM–KECC research revealed considerable variability in costs and patient characteristics among dialysis facilities, and that several patient characteristics predicted facility costs. See Wolfe, R. *et al., An expanded Medicare outpatient end stage renal disease prospective payment system, Phase I report,* University of Michigan, Kidney Epidemiology and Cost Center, August 2002; Hirth, R.A., *et al., Is case-mix adjustment necessary for an expanded dialysis bundle?* Health Care Financing Review, Summer 2003, 24, pp. 77–88; *Kidney Epidemiology and Cost Center: Methodology for developing a basic case-mix adjustment for the Medicare ESRD prospective payment system,* May 19, 2004 report and April 1, 2005 addendum, prepared under contract no. N–12004–11–504200 for the Centers for Medicare and Medicaid Services.

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 independent and hospital-based ESRD facilities for 2000 to 2002, patient characteristics/co-morbidity data from CMS's Medical Evidence Form 2728 for 1995 through 2002, and Medicare claims for approximately 360,000 ESRD patients. See Hirth, R.A., *et al., Economic impact of case-mix adjusting the dialysis composite rate,* Journal of the American Society of Nephrology, 16, 2005, pp. 1172–1176, and Wheeler, John R. C., *et al., Understanding the basic case-mix adjustment for the composite rate,* American Journal of Kidney Diseases, 47, No. 4, April 2006, pp. 666–671. 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 body surface area (BSA) and low body mass index (BMI), calculated based on a patient's height and weight.

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.

Although several co-morbidities were found to have statistically significant relationships to composite rate costs, CMS did not adopt them to develop the basic case-mix system mandated by the MMA for a number of reasons. For instance, the relationship of some co-morbidities to the composite rate costs was not stable over time. In addition, establishment of the diagnostic criteria used in connection with specific co-morbidities required further study.

A few findings were surprising. For example, several patient characteristics, notably type 1 or type 2 diabetes, which generally are important with regard to the etiology of ESRD, did not show statistically significant relationships to composite rate costs for renal dialysis services. While the result that facilities with the greatest number of oldest patients incurred greater composite rate costs was expected, the finding that facilities with a higher proportion of patients in the youngest age group (a group that excludes pediatric patients or those less than age 18) incurred greater composite rate costs as well, was unexpected.

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 were as follows:

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 0.1m^2 change in BSA from national average of 1.84)	1.037
Low Body Mass Index (BMI):	
(<18.5kg/m^2)	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/m^2) and has a BSA of 2.0 m^2 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.

4. MIPPA

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 an expanded or 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 proposed § 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 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 bundled 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 dialysis centers, 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, be 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. We expect to publish the CY 2010 1.0 percent increase to the composite rate in the CY 2010 Physician Fee Schedule final rule.

In the following sections of this notice of proposed rulemaking, we describe the ESRD PPS we are proposing to implement effective January 1, 2011, in compliance with the statutory requirements of MIPPA.

II. Overview of the Proposed ESRD PPS

This proposed rule would 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. We propose to implement this new system as described in proposed § 413.172 and § 413.215. The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and methodologies for the reimbursement of separately billable outpatient ESRD services. Specifically, we propose 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. Under the proposed rule, the base rate would be subsequently adjusted using patient-specific case-mix adjustment factors developed from separate equations for composite rate and separately billable services. The case-mix adjusters would include variables for age, body surface area (BSA), low body mass index (BMI), gender, eleven co-morbidity categories, and the onset of renal dialysis. These proposed adjustment factors were developed using standard techniques of multiple regression 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 Areas (CBSAs definitions). The proposed rule also provides 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 bundled prospective payment amount. The proposed ESRD PPS also provides for special adjustments for pediatric patients and for facilities treating a low volume of ESRD patients, 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.

III. 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.

The methodology, which we subsequently describe, for the development of the proposed ESRD PPS, generally identifies the renal dialysis services that we propose to include in the proposed payment bundle in accordance with our interpretation of the statute. We also discuss in more detail below the definition for renal dialysis services under section 1881(b)(14)(B) of the Act.

A. 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 previously, 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. It applies to Medicare beneficiaries receiving dialysis in ESRD facilities and to patients who have elected Method I home dialysis. (Under Method I, the ESRD facility with which the home patient is associated assumes responsibility for furnishing all home dialysis equipment, supplies, and home support services included in the provision of composite rate services. (See section 2740 of CMS Pub. 15–1.)) The ESRD facility receives reimbursement under the current case-mix adjusted composite payment system. For all other ESRD outpatient services not included in the composite payment rate under the current system, such items and services are billed separately in accordance with Medicare fee schedules and other payment methodologies under Part B and Part D. We propose to include in the proposed ESRD PPS those 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(for greater detail, see discussion on self-dialysis training sessions in section E.2). Therefore, these costs for such composite rate services would be included in our computation of the proposed ESRD PPS base rate as explained in section VII. of this proposed rule. This not only would include payments for the costs of services directly related to dialysis, including payments for the costs of self-dialysis training sessions, but also payments authorized in accordance with the composite payment rate exception provisions set forth in 42 CFR 413.180 through 413.186. The costs for composite rate services are also included in our development of the composite rate regression model used to create the two equation patient specific case-mix adjusters that would be applied to the base rate. Composite rate services are defined in proposed § 413.171.

B. 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. Epoetin alfa (EPO, for example, Epogen®) and darbepoetin (ARANESP®) are injectable ESAs, which are currently separately billable outside of the case-mix adjusted composite payment system. Payments for EPO® and ARANESP® would be included in the calculation of the proposed ESRD PPS base rate. These agents would also be included in the separately billable regression model used to create the two equation patient specific case-mix adjusters for the proposed ESRD PPS. We are currently unaware of any other injectable ESAs or oral forms of such ESAs used for the treatment of ESRD. However, should such agents become available subsequent to the implementation of the ESRD PPS on January 1, 2011, these agents would be considered renal dialysis services and subject to payment under the ESRD PPS. That is, consistent with the statute, we propose that no additional payment would be provided for such agents outside of the bundle of renal dialysis services included in the ESRD PPS. The inclusion of ESA's and their oral forms as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed Medicare regulation 413.171.

C. Other Drugs and Biologicals and Their Oral Equivalents

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. Given the reference to ''this title,'' we interpret clause (iii) as requiring the inclusion in the ESRD PPS payment bundle all drugs and biologicals that were separately billable prior to the implementation of MIPPA under title XVIII of the Act. Therefore, we believe the ESRD PPS payment bundle would include all drugs and biologicals formerly separately payable under Medicare Part B and Part D. We recognize that an alternative reading of the last part of clause (iii) with respect to the phrase ''and any oral equivalent form of such drug or biological'' could be interpreted to limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectables (or other non-oral routes of administration). However, we believe that this reading of the statute is unduly constrained. Therefore, our view is that the intent of clause (iii) is to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration.

We believe that the exclusion of oral drugs and biologicals for which there is no injectable equivalent (or other non-oral form of administration) from the ESRD PPS would defeat one of the very purposes of the new system—the inclusion of all renal dialysis services furnished to ESRD patients in a comprehensive payment bundle to which a reasonable payment amount can be attached empirically. In addition, the exclusion of oral drugs and biologicals for which there is no injectable (or other non-oral) version does not make sense from a payment policy perspective. Such a policy would result in the gradual growth of excluded services from the ESRD PPS payment bundle, and the progressive erosion of the payment system, as new oral-only drugs and biologicals for the treatment of ESRD emerge. Moreover, we believe the inclusion of such drugs and biologicals is supportable under clause (iv). That is, we believe the language under clause (iv) addressing ''other items and services not covered in clause (i),'' provides sufficient authority to include all drugs and biologicals, including oral-only drugs and biologicals, used to treat ESRD in the ESRD PPS payment bundle. Therefore, we are proposing 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. Accordingly, we propose 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. We identified specific National Drug Codes (NDCs) for drugs and biologicals previously payable under part D that we propose to include in the payment bundle. However, we propose that the ESRD PPS will 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, section 1881(b)(14)(B) of the Act specifically excludes vaccines from the payment bundle and, therefore, vaccines will not be included in the proposed ESRD PPS. We are seeking comments on our proposals above.

We have found that eleven drugs and biologicals accounted for 99.7 percent of the payments under Part B for all injectable drugs and biologicals that were furnished to outpatient ESRD patients in CY 2007. These drugs and biologicals are epoetin alfa (EPO®), darbepoetin alfa (ARANESP®), calcitriol, doxercalciferol, paracalcitol, iron sucrose, sodium ferric gluconate, levocarnitine, alteplase recombinant, vancomycin, and daptomycin. These drugs and biologicals, as well as the others comprising 0.3 percent of the total payments for drugs and biologicals under Part B in CY 2007, would be included in the proposed ESRD PPS payment bundle. Of the top eleven injectable drugs and biologicals, several have oral versions. For example, levocarnitine, and the vitamin D analogues calcitriol, doxercalciferol, and paricalcitol are also available in oral form. The oral versions of these drugs are currently covered under Medicare Part D. Other drugs used to treat ESRD are available only in oral form and are currently payable under Part D. These include cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. Consistent with our interpretation of section 1881(b)(14)(B)(iii) of the Act, we propose that payments for all drugs and biologicals furnished to ESRD patients and separately billable prior to January 1, 2011, would be included under the proposed ESRD PPS payment bundle as renal dialysis services. Under this proposal, separate billing for these services would be prohibited. The proposed ESRD PPS methodology, both with respect to the computation of the case-mix adjusters and the calculation of the proposed ESRD base rate to which the adjusters would be applied, includes payments for these services. The inclusion of other drugs and biologicals and their oral equivalents as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed § 413.171.

D. 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 propose 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. Because many of the same diagnostic laboratory tests can be performed for both ESRD and non-ESRD patients, we believe that this approach for including laboratory services appropriately captures tests for inclusion in the payment bundle. We propose 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)''. We believe that this language can be reasonably interpreted to include other separately billable items and services used in the treatment of ESRD, such as supplies. Examples of such items and services would include, but 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 believe that the language also can be interpreted to include the cost of other self-dialysis training services in the ESRD PPS (for further detail on self-dialysis training, see section E.2. below). We propose that such items and services be included in the ESRD PPS bundle. 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.

E. 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. As a result of section 153(b) of MIPPA, as explained above, 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 and for such services and items furnished pursuant to section 1881(b)(4) of the Act. As we explained above, we also believe that self-dialysis training services would be considered renal dialysis services as defined in section 1881(b)(14)(B) of the Act. As a result, we are proposing that the costs of home dialysis services furnished to both Method I and Method II home dialysis patients under the current basic case-mix adjusted payment system, as well as self-dialysis training services, must be combined into a single payment under the proposed ESRD PPS.

1. Payment for Home Dialysis

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 below.

a. Method I—The Composite Rate

If a Medicare home dialysis patient chooses Method I, the ESRD facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies as well as providing home support services and receives the composite payment rate for such services. Support services needed to furnish home dialysis services include, but are not limited to: (1) Periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis; (2) visits by trained technical personnel made in accordance with a plan prepared by a professional team; (3) unscheduled visits on an as needed basis; and (4) providing, installing, repairing, testing, and maintaining home dialysis equipment including appropriate water testing and treatment. For these services, the ESRD facility receives, in accordance with § 414.330(a), the same Medicare dialysis payment rate as it would receive for an in-facility patient under the basic case-mix adjusted composite payment system. Under Method I, the ESRD facility bills the Medicare Administrative Contractor/Fiscal

Intermediary (MAC/FI) and the beneficiary is responsible for paying the Medicare Part B deductible and the 20 percent coinsurance on the Medicare rate to the facility.

b. Method II—Dealing Directly With Suppliers

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 will deal 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 (not a dialysis facility) 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. 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 (57 FR 54186, published November 17, 1992) for all other modalities of home dialysis.

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 MAC/FI for services provided under the agreement. Under Method II, an ESRD facility may be paid up to $121.15 (57 FR 54186, published November 17, 1992) 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. An ESRD facility may not be paid for home dialysis equipment or supplies under Method II.

Based on 2004–2006 data, only 3.1 percent of renal facilities report support service costs furnished to Medicare Method II home dialysis patients. The data also show that the number of Method II patients is small and has significantly declined over the study period (that is, 2004–2006) as shown below.

Patients	Year
5289	2004
4465	2005
2635	2006

We are proposing that payment for all home dialysis services excluding physicians' services (See section III.F. below regarding the exclusion of physicians' services) would be included in the bundled payment to the ESRD facility, under the proposed ESRD PPS.

In addition, as we indicated, 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. Therefore, since we are proposing that the costs of home dialysis services furnished under Method I and Method II (see section V Data Sources), regardless of home treatment modality, would be included in the proposed ESRD PPS, we also are proposing that the Method II home dialysis approach in its present form would no longer exist under the proposed ESRD PPS. With regard to payment limits for home dialysis services, in accordance with 6203(b) of Public Law 101–239, we published a final rule on November 17, 1992 implementing (57 FR 54179), Medicare program payment changes for home dialysis. In section 413.330(c), we set payment limits on what Medicare would pay for home dialysis supplies, equipment, and home support services as explained above. Accordingly, effective January 1, 2011, we propose to revise § 414.330 to reflect that payment as established in section 1881(b)(14) of the Act will be the basis for home dialysis supplies, equipment, and home support services and therefore, Medicare would pay for home dialysis equipment, supplies and support services only under the prospective payment rate established in proposed 413.210 and payment limits previously established for such would no longer apply. We also note, that this proposal would not eliminate Method I in its present form. Therefore, effective 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. We believe that this would reduce the administrative burden of maintaining two payment methods for home dialysis patients, since we believe that section 1881(b)(14)(A)(i) requires that all Medicare home dialysis patients would be paid under the ESRD PPS. We invite public comments on this proposal.

2. Self-Dialysis Training

Currently, Medicare covers 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). Medicare pays the ESRD facility its case-mix adjusted composite rate plus $12 per training treatment for CAPD and $20 per training treatment for CCPD. For hemodialysis training, Medicare pays the ESRD facility its case-mix adjusted composite rate plus $20 per training treatment (Medicare Claims Processing Manual, Chapter 8, Outpatient ESRD Hospitals, Independent Facility, and Physician/Supplier Claims, Section 50.8, Training and Retraining). We point out that effective January 1, 2011, under the proposed ESRD PPS, 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. In addition, ESRD facility training expenses are included in the base period payment rate to which the combined rate and payment multiplier in the proposed two-equation model is applied.

As we indicated, section 1881(b)(14)(B) of the Act, as added by section 153(b) of MIPPA, specifies the renal dialysis services that must be included in the ESRD PPS. Since self-dialysis training is used to train patients for the treatment modality of home dialysis with little or no help, we believe that these services would be considered ''renal dialysis services.'' As we indicated above, services related to self-training would meet the definition under clauses (i) and (iv) of section 1881(b)(14)(B) of the Act. As such, we propose to include the cost of self-dialysis training in the proposed ESRD PPS. We evaluated the current training cost reported by ESRD facilities (see section V Data Sources) to train ESRD patients for home dialysis. Training costs have been included in the composite rate payment adjusters in the proposed ESRD PPS. In section VIII.A. of this proposed rule, we point out that total composite rate costs included in the per treatment calculation include costs incurred for training expenses, as well as all home dialysis costs. We used the ESRD facilities cost reports to identify provider costs for training rather than payments. Therefore, in this proposed rule we propose to include

these costs in the composite rate portion of the two-equation ESRD PPS model described in section VI of this proposed rule. We believe that including training and home dialysis costs in the ESRD PPS would provide increased flexibility to dialysis centers for greater use of less costly PD and alternative treatment regimens such as nocturnal dialysis, home hemodialysis using compact portable dialysis machines, and shorter but more frequent dialysis sessions. For these reasons, we are proposing to include training and home dialysis costs in the proposed ESRD PPS, as set forth in proposed § 413.217. Training costs were included in the calculation of the composite rate costs used to develop the regression-based adjustment factors for the composite rate portion of the two-equation model described in section VIII. In addition, the base rate to which the patient-specific case-mix adjustment factors are applied includes payments to ESRD facilities for training expenses. Because we are proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit adjustment to the bundled payment amount for HD and PD training expenditures would not be necessary. We are seeking comments on our proposal to include home dialysis training services in the proposed ESRD PPS.

F. 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)].''

We believe this provision generally governs payment to ESRD facilities. With regard to physicians' services related to renal dialysis, such services are addressed in section 1881(b)(3) of the Act. At this time, we do not intend to significantly modify payment for physicians' services. Any changes with regard to the payment for physicians' services related to renal dialysis would be addressed in future rulemaking. Therefore, the scope of this proposed rule generally will be limited to payment for home dialysis and renal dialysis services furnished by ESRD facilities.

IV. 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. Approximately 92 percent of ESRD beneficiaries requiring outpatient dialysis undergo hemodialysis (HD), usually furnished in a facility. A small but increasing number of patients perform HD at home. The most typical schedule is 3 treatments per week, with each treatment averaging 3 to 4 hours. The remaining 8 percent of patients use peritoneal dialysis (PD). PD is usually done at home, with or without machine assistance. Unlike HD, which involves the circulation of the patient's blood and filtration of toxins using an artificial kidney machine, PD removes blood toxins through the draining of the dialysate from the lining of the abdomen or peritoneum several times a day. A form of PD, sometimes referred to as continuous cycling PD, is done with machine assistance while the patient sleeps, either at home or in specially designated areas at the ESRD facility.

Since the inception of the composite payment system in 1983, ESRD facilities have been reimbursed the applicable payment per treatment, with a maximum of 3 treatments for each full week a patient undergoes outpatient dialysis, unless additional treatments are justified by medical necessity. The 3-times weekly payment approach has applied regardless of whether the mode of dialysis is HD or PD. For example, an ESRD facility's payment for a Method I home patient on PD for 21 days would be equal to $21/7 \times 3$ or 9 times the composite rate per treatment.

Both the Secretary's May 2003 and February 2008 reports on the development of a bundled ESRD PPS discussed the limitations of the per treatment method of payment under the composite payment system. For example, some have charged that the composite payment system's 3 times weekly payment structure, regardless of dialysis modality, has discouraged innovative treatment approaches that could lead to better clinical outcomes and an enhanced quality of life for patients. We believe that the argument is two-fold. First, 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). Second, others argue 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).

These critics have maintained that combining composite rate and separately billable services during a specified interval of time would provide ESRD facilities the financing flexibility to use whatever forms of dialysis were in the best interests of the patient. Because ESRD facilities generally submit to Medicare a bill for all outpatient dialysis services furnished to a patient during the month, an ESRD PPS based on monthly payments was suggested as an alternative in the Secretary's February 2008 Report to Congress. As we indicated above, section 1881(b)(14)(C) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretion to establish an ESRD PPS based on an interval of time, or other appropriate unit of payment. In this notice we are proposing to establish an ESRD PPS which relies on a per treatment unit of payment. We propose to continue the present per treatment basis of payment in which ESRD facilities would be paid for up to three treatments per week, unless medical necessity justified more than three weekly treatments. ESRD facilities treating patients on PD or home HD would also receive payments for up to three treatments for each week of dialysis, unless medical necessity justified the furnishing of additional treatments. Our reasons for continuing the present per treatment method of payment under the proposed ESRD PPS are set forth below.

A. Administrative Complexity Due to Phase-In

Section 1881(b)(14)(E)(i) of the Act provides for a 4-year phase-in (transition), in equal increments for the implementation of the ESRD PPS. That is, the payments beginning January 1, 2011, must consist of a blend of the payment amounts under the new system and the prior payment rates in the following proportions:

Effective	New PPS (percent)	Prior payment amounts (percent)
1/1/2011	25	75
1/1/2012	50	50
1/1/2013	75	25
1/1/2014	100	0

Although ESRD facilities could elect to be excluded from the phase-in, in accordance with section 1881(b)(14)(E)(ii) of the Act, application of the phase-in under a monthly ESRD PPS would mean that a portion of each ESRD facility's total payments, would be based on a monthly payment methodology, while a portion would be based on the current per treatment system. We believe that combining a monthly ESRD PPS with the current per treatment methodology during the transition period would unduly complicate billing and increase the likelihood of payment errors and processing delays.

B. Administrative Complexity Due to Interruptions in Service

A monthly payment approach under the ESRD PPS likely would not pose a problem for patients who receive their dialysis treatments at a single ESRD facility throughout the month with no interruptions in service. However, we note that this situation applies to about 81 percent of patient months. Approximately 19 percent of outpatient dialysis patients incur an interruption of service or receive their treatments at more than one facility during a month. The combination of intervening events in the available data for CYs 2004–2006 is shown in Table 1.

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Table 1

Distribution of Medicare dialysis patient months by patient event, 2004-06

Patient events during month	2004 n=2,779,893	2005 n=2,878,259	2006 n=2,954,931
No events*	81.67	81.72	82.07
Start of dialysis	0.35	0.35	0.34
Hospitalization	15.17	15.15	14.89
Transplant	0.01	0.01	0.01
Transplant failure	0.02	0.02	0.02
Recovered renal function	0.05	0.05	0.05
Death or withdrawal from dialysis	0.51	0.50	0.49
Start of dialysis + hospitalization	0.94	0.93	0.88
Transplant + hospitalization	0.26	0.26	0.26
Transplant failure + hospitalization	0.05	0.05	0.05
Death/withdrawal + hospitalization	0.92	0.91	0.89
Other combination of events	0.05	0.06	0.05
No facility transfer or other event	78.54	78.45	79.05
Facility transfer only***	3.14	3.28	3.02
Facility transfer and other event	0.83	0.83	0.75
Other event only	17.50	17.45	17.18

*Patient events were identified using the following sources: the ESRD Medical Evidence Form (CMS Form 2728), the ESRD Death Notification Form (CMS Form 2746), and other data from the ESRD Network Standard Information Management System (SIMS); Medicare outpatient dialysis facility claims; Medicare inpatient claims; data from the Organ Procurement Transplant Network (OPTN); and the Social Security System Death Master File.

**This category is based on the definition used for the 2008 UM-KECC report, and includes months with a facility transfer only.

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To properly account for events which interrupt a patient's outpatient dialysis, the days associated with these intervening events would have to be tracked and counted so that a pro rata reduction to the otherwise applicable monthly payment amount could be determined. This becomes especially cumbersome if a patient receives treatments at more than one facility and an interruption in service occurs (for example, due to hospitalization). Although Table 1 reveals that this circumstance occurs in less than 1 percent of patient months, the administrative complexity involved in monitoring events, which cause an interruption in the patient's normal schedule of receiving dialysis treatments, particularly where multiple

facilities are involved, would be considerable.

Table 1 shows that for CY 2006, 79.05 percent of patient months did not involve an intervening event and did not include transfer to another facility. These patient months, when included with CY 2006 events that also account for an interruption of dialysis due to hospitalization, start of dialysis later in the month, or death/withdrawal from dialysis, account for 94.09 percent of CY 2006 patient months. One option that we considered for the approximately 15 percent of patient months in which a patient did not undergo a full month of dialysis due to hospitalization, onset of dialysis later in the month, or death/withdrawal from dialysis, was applying a prorated monthly payment rate to cover these situations, and reverting to a per treatment payment methodology for all other situations. However, we believe that this approach would be too administratively complex. For example, under this approach a facility could find that some of its patients would be paid a full monthly ESRD PPS rate, those with an interruption in service would be paid a prorated monthly rate, and others would be paid based on a per treatment method.

C. No Incentive To Discourage Skipped Treatments

A monthly ESRD PPS would afford facilities the maximum degree of clinical flexibility in treating patients. Facilities could provide whatever mode and frequency of dialysis, were in the best interests of the patient. However, under a monthly ESRD PPS, we believe that facilities may make less of an effort to discourage patients from skipping treatments. Because facilities do not receive reimbursement for skipped sessions under the current per treatment payment system, we are very concerned that a monthly ESRD PPS would provide no incentives for discouraging skipped treatments. Therefore, implementation of a monthly ESRD PPS would require either a stringent monitoring system to ensure the skipping of treatments does not become a byproduct of the new PPS's incentives, or require that a minimum number of treatments must be furnished to each patient in a month to ensure quality of care does not deteriorate. Both options would undercut two of the principles, which are part of the foundation of the new ESRD PPS, administrative simplicity and clinical flexibility.

Given the difficulties of implementing a monthly ESRD PPS during a transition period in which a per treatment methodology applies, we are proposing to continue the present per treatment payment methodology in connection with the proposed ESRD PPS, as set forth in proposed § 413.215. We may reconsider this decision after the transition period has ended. Some of the factors that we may evaluate at that time are whether the ESRD PPS has resulted in improved clinical outcomes, the degree to which facilities have increased the utilization of other modes of dialysis such as home PD, and whether interested stakeholders at that time would favor a monthly or other per unit of time payment methodology. We especially encourage comments from the industry and from organizations representing dialysis patients on our proposal to continue the per treatment methodology under the proposed ESRD PPS. In the following sections, we describe the data sources and analytical techniques used to develop the proposed per treatment ESRD PPS.

V. Data Sources

As discussed above, 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. Based on our interpretation of the statute, we are proposing to construct the payment bundle using the following Medicare cost and payment information:

- Composite rate services as measured using composite rate costs as 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 that 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.

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. Accordingly, the methodology described in this notice of proposed rulemaking applicable to separately billable services relies on separately billable payment information from Medicare claims.

The descriptive statistics, case-mix model, and other analyses presented in this proposed rule are based primarily 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 2004 through 2006. 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 each outpatient dialysis provider and facility (that is, hospital-based and independent facility). For the case-mix model for the proposed ESRD PPS, we relied on Medicare claims and cost reports for CY 2004 through CY 2006, because those years represented the latest most complete data available for the preparation of this proposed rule.

With regard to the budget neutrality requirement under section 1881(b)(14)(A)(ii) of the Act, which requires that the estimated total amount of payments for 2011 for renal dialysis services be equal to 98 percent of the estimated total amount of payments for renal dialysis services, that would have been made for services furnished in 2011 if the ESRD PPS had not been implemented, we are required to use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization. To comply with this provision of the statute, we plan to evaluate available claims for Medicare ESRD beneficiaries for CYs 2007, 2008, and 2009 to determine which year resulted in the lowest average payment amount per treatment. Because the lowest payment amount per treatment would reflect the lowest utilization of outpatient ESRD services among patients absent evidence that per unit prices for those services declined, we believe that selection of the CY with the lowest payment per treatment for calculation of the ESRD base rate would comply with section 1881(b)(14)(A)(ii) of the Act.

Currently, the latest payment information from Medicare claims that is available in sufficient time for the preparation of this proposed rule is for CY 2007. Cost report information subsequent to CY 2006, and Medicare claims data subsequent to CY 2007, could not be evaluated given the necessary lead time required to prepare this proposed rule. We plan to examine

available Medicare cost report information for CYs subsequent to 2006 in developing the case-mix adjusters to ensure use of the latest available data, and available payment data from Medicare claims for CY 2008 and CY 2009 to comply with the lowest per patient utilization requirement of section 1881(b)(14)(a)(ii) of the Act, in preparing the final rule. Any later payment data used in developing the ESRD PPS published in the final rule, would be updated in accordance with the methodology explained elsewhere in this proposed rule. (See Section VII., Development of Budget-Neutral ESRD Bundled Base Rate.)

We used several data sources for evaluating the patient and facility characteristics that were also 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. Patient co-morbidities were measured using the Form 2728, supplemented with diagnoses reported on Medicare hospital inpatient, skilled nursing facility, hospital outpatient, hospice, home health agency, and physician claims. The claims diagnoses were used to identify co-morbidities that were not abstracted using the Form 2728, and to capture changes in patient condition subsequent to the onset of kidney failure. Because diagnoses reported on laboratory claims may represent a suspected condition subject to testing rather than an established diagnosis, laboratory claims were not used to identify co-morbidities in the case-mix models.

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 or OSCAR (hospital affiliation for satellite units), and other available information (for example, identifying facilities with composite payment rate exceptions).

A. Patient Claims Data

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

The case-mix models were based on claims from CYs 2004, 2005, and 2006. 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 lead time necessary for the preparation of this proposed rule. We plan to use available CY data subsequent to 2006 data in developing the payment methodology in connection with the final rule. The number of Medicare claims, patients, dialysis sessions, and ESRD facilities represented in the source claims data are shown in Table 2. We have also provided the same information for CY 2003 for comparison purposes.

TABLE 2—MEDICARE DIALYSIS PATIENTS, TREATMENTS, ESRD FACILITIES, AND CLAIMS BY YEAR, 2003–2007

	2003	2004	2005	2006	2007
Medicare Dialysis Patients[1]	298,617	308,561	318,531	324,836	328,841
Hemodialysis Equivalent Dialysis Treatments[2,3]	32,692,581	34,088,570	35,097,820	35,948,738	36,667,669
ESRD Facilities	4,365	4,523	4,668	4,810	4,955
Patient Month Claims	2,830,215	2,934,505	3,037,965	3,095,996	3,155,553

[1] Includes home dialysis patients for whom payments were made under Method II.
[2] Hemodialysis-equivalent treatments were capped at 20 per month. The number of dialysis treatments for Method II patients was estimated using the average number of hemodialysis-equivalent treatments per month reported for Method I peritoneal dialysis patients during that year (which ranged from 12.50 to 12.66 during 2003–07).
[3] Includes PD in which one week of PD is considered equivalent to 3 HD treatments.

B. 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 2004 through 2006 that contained necessary cost and treatment data for purposes of the composite rate cost analyses are shown in Table 3.

TABLE 3—AVAILABLE COST REPORTS BY ESRD FACILITY TYPE, 2003–2006 [1]

ESRD facility type	2003	2004	2005	2006
Facilities (Independent)	3,689	3,852	4,025	4,140
Providers (Hospital Based)	455	451	448	433
Total	4,144	4,303	4,471	4,573

[1] Based on the June 2008 quarterly update of HCRIS. Includes cost reports with composite rate cost and treatment fields greater than 0.

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.

C. Patient Claim and Cost Report Summary Data, 2004–2006

The case-mix models were based on data sets that linked claims and cost

report records for each year from CY 2004 through CY 2006. 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 4 shows the resulting analysis files that included both claims and cost report data for measuring separately billable and composite rate resource utilization.

TABLE 4—MEDICARE DIALYSIS PATIENTS, TREATMENTS, ESRD FACILITIES, AND CLAIMS FOR PATIENTS AND FACILITIES WITH MEASURED COSTS PER TREATMENT, BY YEAR, 2004–2006 [1]

	2004	2005	2006
Medicare Dialysis Patients	301,625	311,787	317,734
Hemodialysis Equivalent Dialysis Treatments	33,056,812	34,062,969	34,963,270
ESRD Facilities	4,228	4,376	4,489
Patient Month Claims	2,732,001	2,826,580	2,897,424

[1] Includes patient months and ESRD facilities with Medicare hemodialysis-equivalent treatments >0 from the outpatient dialysis facility claims and measured composite rate costs from the cost reports.

D. Data for the Case-Mix Analyses, 2004–2006

The case-mix analyses required data for several patient and facility characteristics. After the exclusion of statistical outliers or otherwise unusable records, the data shown in Table 4 were reduced to yield the data set used in the primary analyses for both composite rate and separately billable services. Table 5 summarizes these records.

TABLE 5—MEDICARE DIALYSIS PATIENTS, TREATMENTS, ESRD FACILITIES, AND CLAIMS FINAL ANALYSIS SAMPLE BY YEAR, 2004–2006 [1]

	2004	2005	2006	Pooled, 2004–2006
Medicare Dialysis Patients	290,102	298,314	303,967	453,789
Hemodialysis Equivalent Dialysis Treatments	31,450,123	32,303,018	33,148,355	96,901,496
ESRD Facilities	3,794	3,948	4,072	4,250
Patient Month Claims	2,604,033	2,685,413	2,751,735	8,041,181

[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 2004 through CY 2006, which included a total of 8,041,181 Medicare ESRD patient months. The case-mix analyses included 95.4 percent of patients with Medicare outpatient dialysis claims during CYs 2004–2006. Over the 3-year period, the case-mix analyses included data for 453,789 Medicare ESRD patients treated in 4,250 ESRD facilities.

E. Prescription Drug Event Data, CY 2007

We obtained the total CY 2007 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 submitted on behalf of Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 and Part D coverage. We used claims for the following classes of drugs to calculate the estimated Part D payments for drugs used to treat ESRD (formerly covered under Part D) for inclusion in the ESRD PPS payment bundle:

Drug class	Ingredient name
Vitamin D analogue	Calcitriol.
	Paracalcitol.
	Doxercalciferol.
Calcimimetic	Cinacalcet hydrochloride.
Oral phosphate binder.	Lanthanum carbonate.
	Calcium acetate.
	Sevelamer hydrochloride.
	Sevelamer carbonate.

The National Drug Codes (NDCs) used to identify the above drugs in the Part D claims are shown below in Table 6.

TABLE 6—LIST OF NATIONAL DRUG CODES USED TO IDENTIFY FORMER PART D DRUGS FOR THE ESRD PPS

Ingredient name	NDC	Strength	Trade name
Drug Class: Vitamin D Analogues			
Calcitriol	260530051	0.25 MCG	Calcitriol Capsules.
	540007	0.25 MCG	Calcitriol Capsules.
	930657	0.25 MCG	Calcitriol Capsules.
	930658	0.5 MCG	Calcitriol Capsules.
	1791578	0.25 MG	Calcitriol Capsules.
	1791603	0.5 MCG	Calcitriol Capsules.
	4800657	0.25 MCG	Calcitriol Capsules.
	4800658	0.5 MCG	Calcitriol Capsules.
	110140011	0.25 MCG	Calcitriol Capsules.
	142880007	0.25 MCG	Calcitriol Capsules.
	178560007	0.25 MCG	Calcitriol Capsules.

TABLE 6—LIST OF NATIONAL DRUG CODES USED TO IDENTIFY FORMER PART D DRUGS FOR THE ESRD PPS—Continued

Ingredient name	NDC	Strength	Trade name
	548684584	0.25 MCG	Calcitriol Capsules.
	551548251	0.25 MCG	Calcitriol Capsules.
	647250048	0.25 MG	Calcitriol Capsules.
	647250049	0.5 MG	Calcitriol Capsules.
	543120	1 MCG/ML ...	Calcitriol Oral Solution.
	682589030	0.5 MCG	Calcitriol Capsules.
	548683461	0.25 MCG	Rocaltrol Capsules.
	604910562	0.5 MCG	Rocaltrol Capsules.
	49115	1 MCG/ML ...	Rocaltrol Oral Solution.
Paricalcitol	744314	2 MCG	Zemplar Capsules.
	744315	4 MCG.	
	744317	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		
	584680121	2.5 MCG.	
Drug Class: Calcimimetic			
Cinacalcet Hydrochloride	682589225	30 MG	Cinacalcet HCL Tablet.
	632850074	66 MG	Sensipak Tablets.
	1791845	30 MG	Sensipar Tablets.
	548685616	30 MG	Sensipar Tablets.
	555130073	33 MG	Sensipar Tablets.
	555130074	66 MG	Sensipar Tablets.
	555130075	99 MG	Sensipar Tablets.
	632850073	30 MG	Sensipar Tablets.
	632850075	K99 MG	Sensipar Tablets.
Drug Class: Oral Phosphate Binder			
Lanthanum Carbonate	540920252	500 MG	Fosrenol Chewable Tablets.
	540920253	750 MG.	
	540920254	1000 MG.	
	635520250	750 MG.	
	635520251	1000 MG.	
	635520252	500 MG.	
Calcium Acetate	540026	667 MG	Calcium Acetate Capsules.
	142880954	667 MG	Calcium Acetate Capsules.
	597306402	667 MG	PhosLo Gelcaps.
	1791371	667 MG	PhosLo Tablets.
	1791934	.....	PhosLo Tablets.
	522680200	667 MG	PhosLo Tablets.
	548683460	667 MG	PhosLo Tablets.
	548685691	.....	PhosLo Tablets.
	647250260	667 MG	PhosLo Tablets.
Sevelamer Hydrochloride	178560020	400 MG	Crenagel Tablets.
	260530308	800 MG	Renagel Tablet.
	260530394	400 MG	Renagel Tablet.
	6155613	800 MG	Renagel Tablets.
	178560021	800 MG	Renagel Tablets.
	242360660	400 MG	Renagel Tablets.
	511293461	800 MG	Renagel Tablets.
	548685615	800 MG	Renagel Tablets.
	551549726	400 MG	Renagel Tablets.
	551549727	800 MG	Renagel Tablets.
	580160778	800 MG	Renagel Tablets.
	584680020	400 MG	Renagel Tablets.
	584680021	800 MG	Renagel Tablets.
	613920721	400 MG	Renagel Tablets.
	647250284	400 MG	Renagel Tablets.
	647250285	800 MG	Renagel Tablets.
	654970020	400 MG	Renagel Tablets.

TABLE 6—LIST OF NATIONAL DRUG CODES USED TO IDENTIFY FORMER PART D DRUGS FOR THE ESRD PPS—Continued

Ingredient name	NDC	Strength	Trade name
	654970021	800 MG	Renagel Tablets.
	675440656	800 MG	Renagel Tablets.
	682990002	400 MG	Renagel Tablets.
	682990021	800 MG	Renagel Tablets.
	584680130	800 MG	Renvela Tablets.
	711144207	403 MG	Sevelamer Hydrochloride Capsules.
	68258–9013	800 MG	Sevelamer Hydrochloride Tablets.
	68258–9070	400 MG	Sevelamer Hydrochloride Tablets.
Sevelamer Carbonate	68299–0130	800 MG	Renvela Tablets.

Table 7 shows the number of Medicare ESRD beneficiaries for which valid type 72X claims were filed in CY 2007, number of ESRD beneficiaries with Part D drug coverage from PDP plans, and number of beneficiaries with Part D claims for the above oral drugs. CY 2006 data are shown for comparison purposes only, as they were not used to calculate the ESRD base rate.

TABLE 7—MEDICARE DIALYSIS PATIENTS WITH PAYMENTS FOR PART D DRUGS, 2006 AND 2007

	2006		2007	
	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims *	324,836	.....	328,841	.....
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	207,035	63.74	219,451	66.73
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS **	159,570	49.12	175,132	53.26

** Includes "type 72X" outpatient institutional claims.
** Includes Vitamin D Analogs (Calcitriol, Paracalcitol, and Doxercalciferol), Calcimimetics (Cinacalcet Hydrochloride), and Oral Phosphate Binders (Lanthanum Carbonate, Calcium Acetate, Sevelamer Hydrochloride, and Sevelamer Carbonate).

VI. Analytical Approach

In this proposed rule, we are presenting a case-mix model that UM–KECC has developed using standard techniques of multivariate regression. In multivariate or multiple regression, a set of independent or predictor variables are tested to determine the extent they can predict or ''explain'' the variation in a related dependent or predicted variable. The unit of analysis in such models is important because the level at which resource use can be measured differs for composite rate and separately billable services. We can measure separately billable services for individual patients using the payment information obtained from Medicare claims. However, the available measure of resource use for composite rate services consists of costs from the Medicare cost reports. These costs do not distinguish patient-specific differences within ESRD facilities, because they combine treatment costs for all ESRD patients.

In the Secretary's February 2008 report to Congress, we described two approaches for developing the case-mix models using multivariate regression. Under the first approach, referred to as the one-equation model, composite rate costs and separately billable payments for all patients treated in each ESRD facility are added together. When the result is divided by the number of corresponding ESRD treatments, the predicted or dependent variable of bundled services reflects a facility-level model of combined composite rate and separately billable services. This approach has the relative simplicity of having the case-mix adjustments based on a single statistical model estimated at the facility level.

The other approach, which we refer to as the two-equation model, relies on two separate regression equations, one to predict variation in composite rate costs at the facility level, and the other to predict variation in separately billable payments at the patient level. This approach has the advantage of measuring patient-level variation in the utilization of separately billable services available from the Medicare claims. It also permits combining separate composite rate and separately billable regression equations into a single payment equation.

The case-mix model, which we have adopted in developing the proposed ESRD PPS, is based on the two-equation model. The basis for our selection of the two-equation model was set forth in the Secretary's February 2008 report to Congress:

> In an extensive series of analyses, UM–KECC determined that application of the one-equation bundled PPS model (that is, a facility-level model) yielded very different regression coefficients for a number of potential case-mix adjusters compared to the two-equation bundled PPS model. These differences were attributed to the correlation between the tested case-mix variables and unobserved facility characteristics. UM–KECC concluded that a patient-level model would have the advantage of reducing potential bias related to unobserved facility characteristics, would result in more precise coefficient estimates, and yield greater stability in these estimates over time. A patient-level model for the separately billable services can be combined with a facility-level model for composite rate services to yield a single payment equation.

This is the approach adopted to develop the case-mix adjusters for the ESRD PPS described in this proposed rule.

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 C).

II. Development of ESRD PPS Base Rate

The patient-specific case-mix adjustments developed from the two-equation regression model for composite rate and separately billable services, which we have described in section VIII. of this proposed rule, would be applied to a base payment rate per treatment (''base rate''). The base rate would also be adjusted to reflect ESRD facility differences in area wage levels using a proposed wage index as described in section VIII.C. In this section, we describe the calculation of the proposed ESRD base rate, as set forth in proposed § 413.220, and the computation of the reduction factors used to adjust the 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. The base rate presented in this proposed rule, and defined in proposed § 413.171, was calculated entirely from CY 2007 Medicare claims data. The proposed 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 for CY 2007 in connection with the preparation of this proposed rule because such data were the latest available. We expect to have claims data for CY 2008 and partial claims information for CY 2009 in connection with our preparation of the final rule. Comparing per treatment payment amounts developed from available claims data for CYs 2007, 2008, and 2009 would permit a determination as to which year resulted in the ''lowest per patient utilization'' of dialysis services as required in accordance with section 1881(b)(14)(A)(ii) of the Act. The components of the proposed base rate based on CY 2007 claims data and the methodology used to project the base rate to CY 2011 (the first year of the ESRD PPS), are described below.

A. 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. Table 8 shows the payments for the various components which comprise the renal dialysis services which we propose to include in our development of the base rate using available CY 2007 claims data, in accordance with our interpretation of the statute. We first describe each of the components of the ESRD PPS payment bundle included in the CY 2007 unadjusted rate per treatment. Thereafter, we describe the adjustments used to calculate the ESRD PPS base rate from the CY 2007 unadjusted rate per treatment.

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Table 8
Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007

Description	Actual MAP for 2007, as reported on claims[1]
Total Medicare Allowable Payments by service category	
Outpatient dialysis and other composite rate services^	$5,705,412,338
Dialysis support services^	$1,447,484
Part B drugs and biologicals^	
Epogen*	$1,846,771,009
Darbepoetin	$167,776,951
Vitamin D	$402,447,416
Calcitriol	$3,116,590
Doxercalciferol	$76,770,839
Paricalcitol	$322,559,988
Iron	$234,031,283
Iron Sucrose	$165,992,904
NA Ferric Gluconate	$68,038,379
Levocarnitine	$5,025,914
Alteplase	$26,682,197
Vancomycin	$3,578,996
Daptomycin	$1,234,405
Other injectables	$7,467,546
Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients**	$319,165,724
DME supplies and equipment	
DME supplies	$15,039,695
DME equipment	$3,358,535
Supplies and other services billed by dialysis facilities^	$44,864,130
Part D drugs	$455,683,740
Total Medicare Allowable Payments for Composite Rate (CR) and Separately Billable (SB) Services	$9,239,987,362
Total Medicare Hemodialysis-equivalent sessions***	36,523,791
Average Medicare Allowable Payment per Session for CR and SB services	$252.99

Based on payment amounts reported on Medicare claims for 2007. Excludes facilities without a valid county code for determining the CBSA wage index and patients with an unknown birthdate.

^Billed by dialysis facilities.

*Monthly payments for EPO were capped to reflect no more than 30,000 units per session.

**Includes lab tests billed by dialysis facilities on outpatient institutional claims and lab tests ordered by physicians receiving monthly capitation payment (MCP) amounts and billed on carrier claims. Labs ordered by physicians receiving MCP amounts were determined using a list of MCP physicians from 2006. The estimates for total lab payments will be updated when the list of MCP physicians for 2007 is available.

***Hemodialysis-equivalent sessions were capped at 20 per patient per month and include both sessions reported on dialysis facility claims and an estimate for Method II patients. The estimated sessions for Method II patients were based on the average number of sessions per month reported for Method I peritoneal dialysis patients (12.5 in 2007).

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1. Composite Rate Services

The first component of the ESRD PPS payment bundle shown in Table 8 is ''Outpatient dialysis and other 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). This total includes all composite rate payments to ESRD facilities, including exception payments made in accordance with § 413.182 through § 413.186. Claims from ESRD facilities that did not have a valid county code, such that the relevant CBSA-based wage index (see section VIII.C.) could not be determined, were excluded. In addition, claims for patients with a missing birth date, which is necessary in order to calculate the basic case-mix adjustment under the composite payment system, were also excluded.

2. Dialysis Support Services

We computed a total amount for the next component of the ESRD PPS payment bundle shown in Table 8, ''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 the type 72X claims.

3. Part B Drugs and Biologicals

The next component of the ESRD PPS bundle shown in Table 8 is ''Part B drugs and biologicals''. We found that total payments for the top 11 Part B drugs and biologicals reported on the type 72X claims, accounted for 99.7 percent of total spending for Part B drugs. Monthly payments for Epogen were capped to reflect no more than 30,000 units per treatment, as amounts in excess of this value were considered clinically implausible.

4. Laboratory tests

Another component of the ESRD PPS bundle shown in Table 8 is ''Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients''. Payments for laboratory tests represent the total amount paid to dialysis facilities for outpatient laboratory tests billed on the type 72X 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 2006, which was the latest available list at the time of this proposed rule. The estimates for total laboratory payments will be updated using the list of CY 2007 MCP physicians in connection with the publication of the final rule.

5. DME Supplies and Equipment

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

6. 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 the type 72X claims.

7. Former Part D Drugs

This amount represents total payments on behalf of the ESRD beneficiaries with Part D coverage in CY 2007 for Part D drugs and biologicals which we consider furnished for the treatment of ESRD. These drugs and biologicals, which are identified by class below, were obtained from CY 2007 Part D claims submitted on behalf of the Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 with Part D coverage, using the NDC codes for the following drugs and biologicals:

Vitamin D Analogues
Calcitriol
Paracalcitol
Doxercalciferol

Calcimimetic
Cinacalcet hydrochloride

Oral phosphate binder
Lanthanum carbonate
Calcium acetate
Sevelamer hydrochloride
Sevelamer carbonate

The NDC codes used to identify the above drugs and biologicals are shown in the Appendix in Table C.

The number of Medicare ESRD beneficiaries for which valid type 72X claims were filed in CY 2007, number of ESRD beneficiaries with Part D drug coverage, and number of beneficiaries with Part D claims for the specified drugs and biologicals noted above, are shown in Table 9. CY 2006 data are also shown in Table 9 for comparison purposes.

TABLE 9—MEDICARE DIALYSIS PATIENTS WITH PAYMENTS FOR PART D DRUGS, 2006 AND 2007

	2006		2007	
	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims *	324,836	.....	328,841	.....
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	207,035	63.74	219,451	66.73
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS **	159,570	49.12	175,132	53.26

* Includes ''type 72X'' outpatient institutional claims.
** Includes Vitamin D Analogs (Calcitriol, Paracalcitol, and Doxercalciferol), Calcimimetics (Cinacalcet Hydrochloride), and Oral Phosphate Binders (Lanthanum Carbonate, Calcium Acetate, Sevelamer Hydrochloride, and Sevelamer Carbonate).

The payment total for former Part D drugs includes payments by Medicare prescription drug plans, and all payments made by or on behalf of ESRD beneficiaries for the specified drugs. As noted in Table 9, the payment total for former Part D drugs only includes data for the 66.73 percent of ESRD beneficiaries who were enrolled in Part D. As a result, we do not have patient-specific information on the cost of drugs (part D equivalent drugs) for the remaining third of ESRD beneficiaries who do not have Part D coverage. To the extent these beneficiaries have drug coverage through their employer or other insurance, we do not have access to specific usage or payment information for these medications. Nonetheless, when the ESRD PPS is implemented January 1, 2011, former

Part D drugs would become renal dialysis services in accordance with section 1881(b)(14)(ii)(B) of the Act. As such, ESRD facilities would be responsible for providing ESRD-related oral drugs formerly covered under Part D to their patients.

We are considering use of a proxy to capture the costs associated with ESRD-related drugs for those patients without Part D coverage. One possible approach would be for us to include payments under the Retiree Drug Subsidy (RDS) program which is described below. We believe that as the RDS payments could be made for ESRD-related drugs under title XVIII of the Act, use of RDS data would be consistent with section 1881(b)(14)(A)(ii) which requires that in implementing the ESRD PPS, the Secretary must ensure that the estimated total amount of payments under this title for 2011 for renal dialysis services equals 98 percent of the estimated total amount of payments that would have been made under this title if the ESRD PPS were not implemented.

The RDS program was enacted in December 2003 by section 101 of the MMA. The program, which was effective January 1, 2006, was designed to support existing retiree benefit arrangements by providing subsidy payments to plan sponsors (that is, employers and unions). Subsidy payments to qualifying drug plan sponsors (for example, employers, unions) equal 28 percent of each qualifying retiree's allowable costs for prescription drugs otherwise covered by Medicare Part D, that are attributable to such drug costs between an applicable cost threshold and cost limit. For plan years ending in 2007, the applicable cost threshold is $265 and the cost limit is $5350.

Based on CMS' Office of the Actuary's most recent CY 2007, we provided subsidy payments totaling $3.8 billion on behalf of 7.0 million beneficiaries. Plans submit aggregate qualifying cost data and a list of eligible beneficiaries. We could determine the number of ESRD qualifying covered retirees under the RDS as a percentage of all qualifying covered retirees under RDS. We could further estimate the ESRD-related percentage of the $3.8 billion in subsidy payments and add this amount to the estimated aggregate payments in 2007. We note that since we do not receive patient-specific information on drug usage under the RDS program, it would not be possible to capture the effect of these drugs on the patient and facility-level adjustment factors. We refer readers to 42 CFR § 423.880 through § 423.894 for more information on the RDS provisions. We invite public comment on this approach and other possible approaches to enable us to capture drug payment information for all Medicare ESRD patients.

8. Total MAP

The total MAP amount represents the total payments made in CY 2007 for the composite rate and separately billable categories described above (that is, the sum of the payments for the items and services described in 1. through 7.) We propose to use the total MAP amount as the ESRD PPS base rate amount.

9. Total Medicare Hemodialysis-Equivalent Sessions

In order to calculate the proposed ESRD PPS base rate per treatment, it was necessary to divide the total MAP amount described above by the number of Medicare HD-equivalent sessions. The number of Medicare HD-equivalent sessions represents the total Medicare treatments for outpatient dialysis as reported on the type 72X claims submitted by dialysis facilities. PD 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) x 3 or 9 HD-equivalent sessions. In determining the total number of Medicare treatments, the number of HD-equivalent sessions were capped at 20 per patient per month. We propose to use the total number of CY 2007 Medicare HD-equivalent dialysis sessions, 36,523,791, to calculate the ESRD PPS base rate.

10. Average MAP per Treatment

We divided the total MAP in item 8, $9,239,987,362, by the total Medicare hemodialysis-equivalent sessions in item 9, 36,523,791, to yield an unadjusted rate per treatment for renal dialysis services in CY 2007. This unadjusted rate per treatment is $252.99. We propose to update this per treatment amount to reflect CY 2011 prices, and to standardize it to eliminate the effects of the case-mix and wage index adjustments in order to ensure duplicate payments do not occur under the ESRD PPS through the subsequent introduction of these variables in the payment formula. We also propose to further reduce the projected CY 2011 payment rate for estimated outlier payments, and the budget neutrality offset as set forth in sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. This is the proposed amount per treatment that would be multiplied under the ESRD PPS to reflect patient-specific differences in case-mix, and other adjustments as set forth in section 1881(b)(14)(D) of the Act. We refer to this projected CY 2011 payment rate, after application of the standardization, outlier, and budget neutrality offsets, as the ESRD PPS base rate. The proposed definition of the base rate is set forth in proposed § 413.171. Our proposed methodology for calculating the base rate to reflect the standardization, outlier, and budget neutrality reductions is explained in the sections that follow.

B. 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 greater detail below. 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. Therefore, we must first estimate what ESRD facilities would have been paid under the current system in CY 2011, by updating the 2007 payments to reflect 2011 prices. We then divide the total estimated CY 2011 payments by the number of CY 2007 treatments to determine the CY 2011 average payment per treatment. We do not make adjustments for future changes in treatments as this would require us to make assumptions about patient specific characteristics. If we were to project CY 2011 treatments we would increase the current basic case-mix adjusted composite payments by the same amount. This would in effect have no impact on the calculation of the per treatment amount. This CY 2011 unadjusted per treatment payment amount becomes the basis for meeting the budget neutrality requirement. Below we describe the update factors used to estimate CY 2011 payments for each component.

1. 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. In accordance with section 153(a) of MIPPA and 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 resulting in a 2011 composite rate of $137.18. A full description of the ESRD bundled (ESRDB) market basket is presented in section XII. of this proposed rule. We are proposing to use this base composite rate for CY 2011, which includes ESRD bundled market basket minus 1 percentage point, to update the CY 2010 composite rate for purposes of establishing the ESRD PPS base rate, given that we interpret section 1881(b)(14)(F)(ii) to require us to update the composite rate portion of the blend by the market basket percentage minus 1.0 percentage point in all years of the transition (which includes CY 2011). Therefore, using the market basket in this way would be a consistent approach. As described in section XII. of this preamble, we are proposing a market basket increase of 2.5 percent for CY 2011. Therefore, we are proposing a 1.5 percent update to the composite rate for CY 2011, resulting in a CY 2011 composite rate of $137.18 ($135.15 * 1.015). We note that the drug add-on percentage is reduced from 15.2 to 14.8 as a result of the increases to the composite rate in CYs 2010 and 2011. Since the drug add-on is calculated as percentage of the base composite rate, the drug add-on percentage decreases with increases in the composite rate. The CY 2009 Physician Fee Schedule final rule provides details on 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 (73 FR 69755). We intend to update the drug add-on, if necessary, for the ESRD PPS final 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 did this to use the most recent wage indexes available in estimating 2011 payments. The other components of the bundle, which are discussed below do not have payments which are computed with wage indexes. We used a 0.60 floor because we anticipate that floor will be in effect in CY 2011. We have been reducing the wage index floor by .05 every year and we expect to continue this policy. (More information on CBSAs and the wage index floor is presented in section VIII.C.1 of this proposed rule).

In addition, 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. See the CY 2005 PFS final rule for a discussion regarding the application of statutory increases to exception amounts (69 FR 66332).

2. Self-Dialysis Support Services for Method II Patients

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, the CY 2007 amounts represent the CY 2011 amounts.

3. 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. We reviewed ASP prices for four quarters of 2006, 2007, 2008 and two quarters of 2009 for the top eleven separately billable drugs. Given the variability shown in the prices over the last several years and the lack of a clear pattern, we propose to use the 2009 prices as proxy for 2011 values. At the time of the final rule, we will reevaluate this decision based on additional quarters of ASP drug pricing data. Thus, we used the growth from the average of the quarters for 2007 to the average of the two available quarters of 2009. For other ESRD-related Part B drugs, we used a weighted average of the top eleven Part B drugs to update those drug prices to 2011. Since the top eleven drugs represent 99.7 percent of total separately billable Part B drug payments, we believe that the overall weighted average was representative for the remaining 0.3 percent. See Table 10 for the growth factor that was applied to the 2007 drug payment levels.

TABLE 10

Drugs and biologicals	Price updates (percent)
EPO	1.7
Paricalcitol	−2.8
Sodium_ferric_glut	−0.5
Iron_sucrose	4.8
Levocarnitine	−19.0
Doxercalciferol	17.8
Calcitriol	−14.1
Vancomycin	−11.1
Alteplase	2.3
Aranesp	−8.2
Daptomycin	13.9
Other injectables	1.1

4. Laboratory Tests

We updated 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. This is the statutory update required for lab services. This amount totaled a growth of 5.1 percent from 2007 to 2011.

5. DME Supplies and Equipment

Since payments for supplies and equipment for Method II patients are subject to a monthly capitation payment that has not increased, the CY 2007 amount represents the 2011 amounts.

6. 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, there was no price update.

7. Former Part D Drugs

Former Part D drugs were updated by the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections. See *http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp#TopOfPage* for further reference on the National Health Expenditure Projections. Since we do not currently have enough data to establish a trend for Part D prices and since we use this price growth in the overall Part D projections, we believe it is an adequate proxy. This amount totaled a growth of 12.2 percent from 2007 to 2011.

Once we determined updated CY 2011 payments for each component of the items and services discussed above, we added 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

yield the unadjusted per treatment base rate for renal dialysis services in CY 2011 of $261.58.

We used $261.58 as the starting point for further adjustments in determining the proposed ESRD PPS per treatment base rate. The 2011 unadjusted average payment per treatment of $261.58 was then used in the payment model to estimate total payments under the proposed ESRD PPS in CY 2011. These CY 2011 ESRD PPS estimated payments were based on treatment data from the CY 2007 claims file.

C. 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. We calculated the 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 note that to simulate payments, we used the latest available final CY 2009 ESRD wage indexes, with no floor. While we anticipate a 0.60 floor for the ESRD wage index for the current basic case-mix composite payment system, we are proposing to eliminate the wage index floor for the ESRD wage index to be used for the proposed ESRD PPS in CY 2011 (see section VIII.C.1 for a detailed discussion of the ESRD wage index).

Next, we standardized the ESRD PPS payments in order to account for the overall positive 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. In order to standardize the ESRD PPS payments, we compared the proposed ESRD PPS amounts calculated from the treatment counts in the 2007 claims file to the current system payments from the 2007 Medicare claims file updated to 2011 (as explained in greater detail in section VII.B. above). A standardization factor was calculated by dividing total estimated payments in 2011 under the current payment system by estimated payments under the proposed ESRD PPS in 2011. The standardization factor was calculated to be 0.7827, or a reduction of 21.73 percent. As a result, the CY 2011 unadjusted per treatment base rate of $261.58 was reduced by 21.73 percent to $204.74.

We are proposing that the base rate per treatment be further modified by the adjustments described below.

D. 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 erythropoiesis-stimulating agents necessary for anemia management. We believe the payment adjustment under section 1881(b)(14)(D)(ii) of the Act for outlier cases should be applied in a budget neutral manner, as doing so will 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.

To ensure that the proposed outlier policy under the ESRD PPS is budget neutral, we propose to reduce the base rate by the proposed outlier percentage, or 1 percent. Specifically, we propose to reduce the base rate from $204.74 to $202.69. We did this to account for the 1 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 percent of payments to be outliers. The appropriate outlier payment amount for each treatment was determined as described in greater detail in section X.A.2 of this proposed rule. The outlier amount was computed for all treatments, and the total outlier payment, across all treatment amounts was added to the prospective payment amount for all treatments.

In summary, we are proposing an outlier percentage of 1 percent; therefore, the proposed base rate per treatment must include a reduction of 1 percent. Thus the proposed standardized base rate of $204.74 was reduced by 1 percent to yield a proposed base rate of $202.69.

b. 98 Percent Budget Neutrality Adjustment

Section 1881(b)(14)(A)(ii) of the Act requires that the proposed 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 reduced the 2011 standardized base rate per treatment, which was already adjusted for 1 percent outlier payments, by an additional two percent, from $202.69, to yield a proposed base rate of $198.64.

To summarize, the proposed base rate per treatment with an outlier adjustment and budget neutrality was calculated to be $198.64. This amount includes a 21.73-percent reduction from $261.58 to account for standardization to the projected CY 2011 current system payment per treatment, a 1-percent reduction to account for proposed outlier payments, and a 2-percent reduction for the required 98-percent budget neutrality. The outlier policy we are proposing is set forth at proposed § 413.237.

E. Calculation of 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,'' for purposes of the proposed ESRD PPS, we will use 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 implementation of the transition is discussed in section XIII.A of this proposed rule. The transition period policy is set forth in proposed § 413.239.

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. The transition budget neutrality adjustment would be comprised of two parts. First, we would make a payment adjustment under the basic case-mix adjusted composite payment system portion of the blended rate during the transition, in addition to computing 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. We describe each part in detail in the paragraphs that follow.

First, to ensure that estimated total payments during the transition equal the estimated total amount of payments that would otherwise occur without such a transition, in addition to accounting for payments for composite rate services and items and services that are separately billable under Part B, it is necessary to reflect payments for ESRD-related Part D drugs that are currently separately payable under Title XVIII. Specifically, as we discussed in section III. of this 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 Parts B and D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

As described in section III. of this proposed rule, we are proposing to include renal dialysis service drugs formerly covered under Part D under the proposed ESRD PPS. As a result, we are further proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement.

As further discussed in section VII. of this proposed rule, the cost of the drugs and biologicals currently separately payable under Part D that we propose 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. That is, once the ESRD PPS is implemented on January 1, 2011, ESRD-related Part D drugs would become Part B renal dialysis service drugs and would no longer be separately covered under Part D. This is due to section 1881(b)(14)(A)(1) of the Act, which specifies that after January 1, 2011, a single payment is made under title XVIII for renal dialysis services furnished by ESRD facilities in lieu of any other payment for such services, as well as the new statutory definition under section 1881(b)(14)(B) of the Act. In addition, we note that ESRD-related Part D drugs are not part of the basic case-mix adjusted composite payment system or otherwise covered under Part B (in contrast to other separately billable ESRD-related items and services). As a result, ESRD facilities that elect to go through the transition would have no mechanism by which to receive payment for former Part D drugs with regard to the basic case-mix adjusted composite payment system portion of the payment blend (though such services would be captured with regard to the portion of the blended payment for the ESRD PPS). Because ESRD-related Part D drug payments would not be included in the portion of the blend based on the basic case-mix adjusted composite payment system, payments to ESRD facilities that elect to go through the transition may be understated during the transition.

Additionally, as required by section 1881(b)(14)(A)(ii) of the Act and described in section VII.D.b of this preamble, the estimated total amount of payments under the proposed ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services under title XVIII that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented. As we noted, Part D drugs are not part of the basic case-mix adjusted composite payment system or otherwise covered under part B as separately billable ESRD-related items or services. However, because the payments for the ESRD-related Part D drugs proposed for inclusion in the ESRD PPS were made under title XVIII, we are required to include such items in the 98 percent budget neutrality adjustment.

Thus, to be consistent with the 98 percent budget neutrality requirement and to make estimated payments during the transition equal payments without the transition, we propose to provide a $14.00 per treatment adjustment to the portion of the blend with regard to the basic case-mix adjusted composite payment system. This amount is based on the 2011 per treatment ESRD-related Part D drug payments included in the proposed ESRD PPS base rate. We first computed the 2007 per Part D payment per treatment described in section VII.A. We then updated this amount to 2011 by applying the 12.2 percent update factor described in section VII.B.

We further propose that the $14 per treatment adjustment that would be made to the portion of the blend with regard to the basic case-mix adjusted composite payment system would be made without regard to basic case-mix adjustments or wage index adjustments. This is because ESRD-related Part D drugs were not included in the development of the adjustments for the basic case-mix adjusted composite payment system.

We considered an alternative approach for meeting the statutory transition budget neutrality adjustment. Under this approach, we would exclude estimated payments for ESRD-related Part D drugs from the estimated 2011 payments related to the basic case-mix adjusted composite payment system. That is to say, we would not pay ESRD facilities for the ESRD-related Part D drug payment with regard to the basic case-mix adjusted composite payment system portion of the blended payment during the transition, and therefore, we estimate that ESRD facilities may receive smaller blended payment amounts during the transition. Excluding ESRD-related Part D drugs from the basic case-mix adjusted composite payment portion of the blended payment would likely lower blended payments under the transition and, as a result, we estimate that many more facilities would elect to be paid 100 percent of the ESRD PPS rather than electing to go through the transition. These facilities would have to give up their option to go through the transition in order to receive 100 percent ESRD PPS payments for ESRD-related Part D drugs. The transition provides a more gradual change to ESRD PPS for those facilities that would receive lower payments under the proposed ESRD PPS. We believe it is more equitable to provide a $14 per treatment adjustment the portion of the blend related to the basic case-mix adjusted composite payment system. In addition, we believe that the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition. This approach would change the incentives because excluding ESRD-related Part D drugs from portion of the blended payment related to the basic case-mix adjusted composite payment system might lower blended payments under the transition, thereby increasing the incentive to elect to be paid under 100 percent ESRD PPS. This approach also would skew the impact analysis because it compares payment amount related to the basic case-mix adjusted composite

payment system without Part D payments, while payments under the proposed ESRD PPS include payments for Part D drugs. For the impact analysis to accurately represent payments that are included in the proposed ESRD PPS and be consistent with the 98 percent budget neutrality requirement, we believe we need to include payments for ESRD-related Part D drugs in our estimate of what ESRD facilities would be paid in 2011 for both the basic case-mix adjusted composite payment system and the proposed ESRD PPS, had an ESRD PPS not been implemented. For these reasons we rejected this alternative.

Accordingly, in order to make ESRD PPS budget neutral during the transition with respect to ESRD-related Part D drugs, we propose to make a $14 per treatment adjustment to the portion of the blend related to the basic case-mix adjusted composite rate payment system.

The second part of the transition budget neutrality adjustment addresses the overall effect of the ESRD facilities' decision whether to be paid under the transition versus being paid under the ESRD PPS. In the absence of such an adjustment, total payments would be higher under the transition payment system (blended payment amount) than under a 100 percent fully implemented PPS payment system, as we presume that each provider would likely choose the option that is most beneficial to them. In other words, we believe ESRD facilities that estimate that their aggregate payments will be higher under the transition than under the ESRD PPS likely will elect to be paid under the transition. This in turn would increase the total payments paid by CMS, with total payments then likely to exceed the 98 percent budget neutrality target amount, as discussed in section VII.D.b of this proposed rule. We interpret this provision as requiring, during the first 3 years of the transition, a budget neutrality adjustment applied to all payments to ESRD facilities (both those paid under the transition and those electing to be paid under the ESRD PPS) to offset the additional payments to those ESRD facilities that elect to be paid a blended payment under the transition rather than to be paid based on 100 percent of the payment amount under the proposed ESRD PPS. Thus, we are proposing to create a transition budget neutrality adjustment factor to be applied to all payments to ESRD facilities during the transition. This transition budget neutrality adjustment factor is intended to make the estimated total payments under the transition equal our estimate of total payments under the ESRD PPS were there no transition.

One alternative we considered was applying the budget neutrality adjustment factor to the 2011 ESRD PPS base rate only. However, we believe this approach would unfairly penalize those facilities that opt to be paid based on 100 percent of the payment amount under the ESRD PPS, as it would lower all of their payments. Those facilities that are paid on a blended payment methodology would only have 25 percent of their payment lowered in CY 2011, as only 25 percent of the blended payment is based on the payment amount under the proposed ESRD PPS. Thus, in effect, this approach would result in those facilities electing to be paid based on 100 percent of the payment rate under the ESRD PPS subsidizing those electing to be paid under the transition. In addition, we believe that the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition. This alternative would change the incentives by lowering payments under the ESRD PPS by a larger percentage than the blended payments under the transition, thereby increasing the incentive to elect to be paid under the transition. For these reasons we rejected this alternative.

Another alternative we considered was applying the adjustment only to the blended payments for facilities that elect to be paid under the transition. However, we believe that this approach would unfairly penalize those ESRD facilities that choose to be paid under the transition, as it would lower their payments but would not lower the payments to those facilities that elect to be paid based on 100 percent of the payment rate under the ESRD PPS. Similar to the alternative in the previous paragraph, this alternative would also affect ESRD facilities' incentives with respect to whether or not to opt out of the transition, and thus we also rejected this alternative.

We therefore propose to apply the transition budget neutrality adjustment factor to all ESRD payments, including the component of the blended rates based on the current basic case-mix adjusted composite payment system. We propose this approach, because we believe that it would not unfairly penalize one group, it would evenly distribute the effect of the transition budget neutrality adjustment, and it would not change ESRD facilities' incentives with respect to whether to opt out of the transition.

In calculating the transition budget neutrality adjustment factor, we propose to first determine the estimated increase in payments under the transition and then determine an offset factor. In order to do this, we must first make assumptions on which facilities would choose to opt out of the transition and be paid based on 100 percent of the payment rate under the ESRD PPS in 2011. In order to estimate which ESRD facilities will and will not elect to opt out of the transition, we are proposing to estimate aggregate payments for each ESRD facility under both the current basic case-mix adjusted composite payment system, including payments for separately billable services, and the proposed ESRD PPS (based on 100 percent of the payment amount under the ESRD PPS). We are assuming that facilities that would receive higher aggregate payments under the proposed ESRD PPS would elect to be paid based on 100 percent of the payment rates under the ESRD PPS. Conversely, ESRD facilities that would receive higher aggregate payments under the current basic case-mix adjusted composite payment system would elect to be paid the blended rate under the transition.

Based on this approach, we estimate that 36 percent of ESRD facilities will choose to be excluded from the transition and that 64 percent of ESRD facilities will choose to be paid the blended rate under 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 proposing to reduce 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 3.0 percent. For 2011, application of this factor would result in a 3.0 percent reduction in all payments to ESRD facilities. We propose to apply this adjustment to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS. We propose to calculate similar factors for CYs 2012 and 2013 that would allow a blended payment system to be budget neutral to a fully implemented 100 percent ESRD PPS.

We invite comments on the calculation and application of the

proposed two part transition budget neutrality adjustment factor.

VIII. Cost Regression Used To Develop Proposed Payment Adjustment Factors

A. Proposed Regression Analysis

1. Dependent Variables

The proposed two-equation regression approach used to develop the proposed ESRD PPS includes a facility–based regression model for composite rate service, and a patient-level regression model for separately billable services. The measures of resource use that were specified as the dependent variables in each of the two equations are explained below.

a. Average Cost per Treatment for Composite Rate Services

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 2004, 2005, and 2006 (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). Continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) patient weeks were multiplied by 3 to obtain the number of hemodialysis 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 CY 2009 ESRD wage index and the estimated labor-related share of costs from the composite rate market basket. The description of that labor-related share was contained in the Secretary's 2008 Report to Congress. That is, 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. 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 methodology used to identify outlier composite rate costs per treatment, see pp 45–48 of UM–KECC's February 2008 report.)

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

Resource use for separately billable dialysis related services was measured at the patient level using the payment data on the Medicare claims for CYs 2004–2006. This time period corresponded to the most recent 3 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; oral forms of ESAs and other oral drugs used to treat ESRD payable under Medicare part D; 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.

We obtained Medicare claims data for separately billable services for CYs 2004–2006 for patient months in which outpatient dialysis was provided and Medicare was the primary payer. For oral drugs (formerly) covered under Medicare part D, we used CY 2007 claims data for ESRD beneficiaries with Medicare part D coverage. Measures of resource use were based on MAPs, which were calculated using the payment data on the claims. Currently, the only payment data available for Part D claims are for CYs 2006 and 2007. However, these data were not available in sufficient time to be included in the development of the proposed separately billable case-mix adjusters, given the lead time necessary for the preparation of the proposed rule. We expect that additional Part D claims data will be available for the preparation of the final rule. Therefore, we intend to include appropriate available payment data from Part D claims for CYs 2006 through 2008 in our development of the regression based case-mix adjusters for the overall payment model, and will address their inclusion in the final rule. Payments for Part D drugs were included in the proposed ESRD base rate, which relied on claims for CY 2007. See section VII.A.7.

Medicare payments were inflated by a factor of 1.25 for services that have a 20 percent patient coinsurance (for example, most injectable drugs) to yield the MAP. For laboratory tests that have no patient coinsurance obligation, the Medicare payment is identical to the MAP. As required under section 1881(b)(14)(B) of the Act, as added by section 153(b)(1) of MIPPA, vaccines are excluded from the ESRD PPS and therefore, were excluded from the computation of separately billable drugs. 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 related services.

For the case-mix analyses, MAP values based on CY 2004 through 2006 claims were adjusted to approximate drug payments for the current year. In CY 2007 the top 11 separately billed Part B drugs accounted for approximately 99.8 percent of drug expenditures for Medicare ESRD beneficiaries. We repriced the MAPs for these drugs in 2004, 2005, and 2006 by using a ratio. That ratio was obtained by dividing the Medicare payment rate in the first quarter of 2008 by the Medicare payment rate in 2004, 2005, and 2006. This repricing was done for the following injectable drugs: epoetin alfa, darbepoetin alfa (ARANESP®), iron dextran, iron sucrose, sodium ferric gluconate, calcitriol, doxercalciferol, paracalcitol, levocarnitine, alteplase recombinant, and vancomycin. (Although iron dextran was among the top 11 drugs in CYs 2004–2006, it was superseded by daptomycin in CY 2007.) The resulting MAP closely reflects the current prices based on Medicare reimbursement rates. The ratios used to

adjust the MAPs for the 11 specified injectable drugs are shown in Table 11.

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Table 11
Payment ratios used to reprice Medicare Allowable Payments (MAP) for 11 separately billable injectable drugs

	Ratios by year/quarter					
Injectable drug	2004	2005	2006, Quarter 1	2006, Quarter 2	2006, Quarter 3	2006, Quarter 4
Epoetin alfa	0.8963	0.9183	0.9366	0.9603	0.9456	0.9489
Darbepoetin alfa	0.6101	**	0.9675	0.9535	0.9557	0.9669
Iron dextran*	0.6488	1.0622	1.0333	1.0242	1.0545	1.0489
Iron sucrose	0.5530	0.9865	1.0224	1.0111	0.9973	1.0055
Sodium ferric gluconate complex	0.5934	0.9794	0.9902	0.9589	1.0208	1.0073
Calcitriol	0.2406	0.3458	0.4709	0.7186	0.6548	0.6324
Doxercalciferol	0.4367	0.9238	0.8946	0.7584	0.7604	0.8355
Paricalcitol	0.7135	0.9508	0.9984	1.0018	0.9982	0.9976
Levocarnitine	0.1677	0.4208	0.5633	0.7135	0.5782	0.5484
Alteplase, recombinant	0.9366	1.0829	1.0944	1.0969	1.0853	1.0717
Vancomycin HCl	0.4909	1.1581	1.1064	1.0655	1.0674	1.0314

*Starting in 2006, the repricing ratio for this drug was determined using the average payment rate for the two forms of iron dextran that could be billed.

**Due to quarterly price changes for darbepoetin alfa during 2005, a different repricing ratio was used for each quarter: 0.8160, 0.8970, 0.9454, and 0.9602 for Quarters 1, 2, 3, and 4 of 2005, respectively.

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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 at 20 treatments in excess of this number were considered implausible. The average MAP per treatment for EPO was limited to no more than 30,000 units, since higher doses were considered clinically suspect or inappropriate. 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, we applied a natural log transformation to the values of the separately billable MAPs per treatment, with statistical outlier values excluded from further analysis employing the same criteria used to identify aberrant composite rate costs.

2. Independent Variables

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. Case-mix payment variables were included as factors that may be used to adjust payments in either the composite rate or 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.

a. Control Variables

Seven control variables were included in the regression analysis. They were: (1) Renal dialysis facility type (hospital-

based versus independent facility); (2) facility size (<3,000 for less than three years, 3,000 to 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. Calendar years 2004, 2005, and 2006 were included as a control variable in analyses that pooled three years of data.

b. Proposed 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. 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). 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's 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 one month (for example, 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). In the sections that follow, we describe how we considered and evaluated independent variables for use as potential case-mix adjusters in the proposed ESRD PPS to determine their relationship to composite rate costs and separately billable payments.

B. Proposed Patient-Level Adjustments

The following are the patient level adjustments we considered for the proposed ESRD PPS. The patient level adjustments that we are proposing are set forth at proposed § 413.235.

1. 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. Consequently, we analyzed age as part of the regression analysis and found that age is a strong predictor of variation in payments for ESRD patients. In addition, age is an objective measure and data on age are readily available.

As discussed previously in section I.B.3., the basic case-mix adjusted composite payment system currently in effect includes payment adjustments for age. As shown in Table 12 below, there are five age groupings and payment adjustment factors that describe the distribution of the patient population:

Table 12
Age Adjustment in the Current Basic Case-Mix Adjusted Composite Payment System

Variable	Multiplier
Pediatrics <18	1.62
Ages 18-44	1.223
Ages 45-59.	1.055
Ages 60-69	1.000
Ages 70-79	1.094
Ages 80+	1.112

As we found when we developed the current basic case-mix adjusted composite payment system, the regression analysis for the proposed ESRD PPS indicates that MAPs rise as a patient's age increases. We analyzed information on patient age from the REMIS system and compared the costs for each age group to a reference group. Although the reference group for age under the current basic case-mix adjusted composite payment system was ages 60–69, the reference group used for the proposed ESRD PPS was determined to be ages 45–59. We selected the 45–59 age range as the reference group because it was identified as the lowest cost group and results in positive adjustments for all age categories except for the 45–59 age group, and avoids age adjustments that are less than one. In addition, we determined the age groupings based upon stability of the data and the similarity of the adjustments for the ages within the group.

The proposed regression analysis for the proposed ESRD PPS revealed the following: (1) Patients in the 18–44 age grouping were 19.4 percent more costly than the reference group; (2) Patients age 45–59 were the reference group; (3) Patients age 60–69 were 1.2 percent more costly than the reference group; (4) Patients age 70–79 were 5.7 percent more costly than the reference group; and (4) Patients over 80 years of age were 7.6 percent more costly than patients in the reference group.

This U-shaped relationship of age with average composite rate per treatment costs in the proposed ESRD PPS is similar to the pattern we observed in developing the current basic case-mix adjusted composite payment system. That is, elevated costs were observed for the youngest and oldest adult age groups (ages 18–44 and 80+, respectively) compared to the reference age group.

Based on age, the model indicates that one of the largest increments in cost is for pediatric patients. We note, however, that using the current regression-based approach, the precision of the pediatric multiplier is limited by the small fraction of pediatric patients in most ESRD facilities and would distort the results. Due to the relatively small number of pediatric patients, we are proposing to use a separate regression analysis for pediatric patients, as discussed in section IX of this proposed rule.

Under the ESRD PPS, we are proposing payment adjustment factors for five age groups as shown in Table 13 below.

TABLE 13—PATIENT AGE

Variable	Multiplier
Ages 18–44	1.194
Ages 45–59	1.000
Ages 60–69	1.012
Ages 70–79	1.057
Ages 80+	1.076

2. 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, we analyzed patient sex as part of the regression analysis and found that patient sex is a strong predictor of variation in payments for ESRD patients. In addition, patient sex is an objective measure and data on patient sex are readily available. In the regression analysis for the proposed ESRD PPS, we found that female ESRD patients are more costly to treat than male ESRD patients. We discuss below, prior research related to patient adjusters for males/females in prior rulemaking for the current basic case-mix adjusted composite payment system, before addressing our proposal for such a case-mix adjuster.

In the CY 2005 Physician Fee Schedule (PFS) proposed rule (69 FR 47487 through 47730), published August 5, 2004, we included an adjustment for gender as part of our proposal for the current basic case-mix adjusted composite payment system. We analyzed the effect of a combination of gender and age on composite rate costs compared to the lowest cost combination (that is, female ages 65–79). No data on separately billable services was analyzed because those services are excluded from the basic case-mix adjusted composite payment system. We found that male patients were consistently more costly than females. However, we did not include an adjustment for gender because of the availability of certain data.

As we explained in the CY 2005 PFS final rule with comment period (69 FR 66235 through 66915), published on November 15, 2004, gender was proposed as a surrogate measure for body size. We believed that using height and weight to measure body size would be better predictors of facility variation in composite rate costs, however, that information was not available on claims at the time the CY 2005 PFS proposed rule was published, whereas gender was reported on the outpatient bill.

During development of the final basic case-mix adjusted composite payment system, we became aware that the National Uniform Billing Committee would be approving the use of two new value codes for reporting weight and height after publication of the final rule. We determined that mandatory reporting of such data would enable the development of case-mix measures that reflected the superior predictors related to body size, that is BMI and BSA. As a result, we adopted in the final rule BSA and low BMI, and eliminated gender as a patient classification variable for purposes of case-mix adjustment.

In developing the proposed ESRD PPS, we again analyzed the extent to which the regression model explains composite rate and separately billable payments based on a patient's sex and, as a result of that analysis, are proposing an adjustment based on a patient's sex. (We believe using the term sex is a more accurate term than gender. Sex is defined as a classification according to an individual's reproductive function while gender is defined in terms of masculine/feminine characteristics). In analyzing more current data on patient sex from the REMIS system, we found that MAPs (including both composite rate and separately billable services) were higher for female patients even when body size measures are included. In the regression 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 between male and female patients. Therefore, we are proposing an adjustment of 13.2 percent for female patients. We are soliciting public comments around unintended consequences of providing a payment adjustment for female patients that may lead to admission practices favoring female patients. Decisions for the final rule regarding this adjustment would be made based on analysis of more current data and public comments received on this issue.

3. 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. For this proposed rule, we analyzed both BSA and low BMI (<18.5kg/m^2) individually as part of 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 low BMI are objective measures and the necessary data, that is, height and weight, to compute the BSA and low BMI are readily available from patient claims.

a. Body Surface Area

As discussed previously in section I.B.3, the current basic case-mix adjusted composite payment system includes a payment adjustment for BSA. The regression analysis conducted for the current basic case-mix adjusted composite payment system indicated that composite rate costs rise as a patient's BSA increases. The payment adjustment factor for BSA in the current basic case-mix adjusted composite payment system is 1.037. This adjustment factor implies a 3.7 percent elevated cost for every 0.1m^2 increase in BSA. The increased costs suggest that there are longer treatment times and additional resources for larger patients.

As discussed in the CY 2005 PFS final rule with comment period, we chose to include BSA as a payment variable because effective January 1, 2005, we were able to collect height and weight data from patient claims (for purposes of calculating the BSA) and determined that including the BSA variable improved the model's ability to predict the costs of the composite rate service compared to using BMI or weight alone. We adopted the DuBois and DuBois formula for BSA because based on our research, this formula was the most widely known and accepted. This formula is: BSA = $W^{0.425} * H^{0.725} * 0.007184$ (DuBois D. and DuBois, EF. ''A Formula to Estimate the Approximate Surface Area if Height and Weight be Known'': Arch. Int. Med. 1916 17:863–71.), where w and h represent weight in kilograms and height in centimeters, respectively.

In addition, we explored a number of options for setting the reference values for the BSA. We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on that analysis, we set the reference point at a BSA of 1.84 (the national patient average). Setting the reference point at the average BSA reflects the relationship of a specific patient's BSA to the average BSA of all patients. Therefore, some adjusters would be greater than 1.0 and some would be less than 1.0. In this way, we were able to minimize the magnitude of the budget neutrality offset to the composite payment rate. (For more information on this discussion, we refer readers to 69 FR 66239.)

The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.84 divided by 0.1. The BSA adjustment factor of 1.037 is then exponentiated based on the calculated BSA factor as $1.037^{(BSA - 1.84)/0.1}$

As we found when we developed the current basic case-mix adjusted composite payment system, the regression analysis conducted for this proposed rule indicates that MAPs rise as a patient's BSA increases. However, we have found that the case-mix adjustment based on a patient's BSA under the proposed ESRD PPS reflects slightly different values from those used in connection with the current basic case-mix methodology under the composite payment system. The BSA case-mix adjustment factor in connection with the current basic case-mix adjustment was 3.7 percent for every 0.1 m^2 change in BSA from the national average of 1.84. The BSA case-mix adjustment factor under the proposed ESRD PPS is 3.4 percent for every 0.1 m^2 change in BSA from a national average of 1.87 based on updated and more complete data.

In the regression analysis we conducted for this proposed rule, we found that BSA continues to be a strong predictor of cost variation among ESRD patients. Accordingly, we are proposing 1.034 as a payment adjustment factor for BSA in the proposed ESRD PPS.

b. BMI

As discussed previously in section I.B.3, the current basic case-mix adjusted composite payment system includes a payment adjustment for low BMI (<18.5 kg/m^2). The regression analysis conducted for the current basic case-mix adjusted composite payment system indicated that those patients who are underweight consume more resources than other patients. The payment adjuster factor for low BMI in the current basic case-mix adjusted composite payment system is 1.112. This adjustment serves as a surrogate for the severity of co-morbid conditions associated with malnourishment in the dialysis population.

As discussed in the CY 2005 PFS final rule with comment period, we elected to include low BMI as a payment variable because effective January 1, 2005, we were going to be able to collect height and weight data from patient claims and including the low BMI variable improved the model's ability to predict the costs of the composite rate services compared to using BMI or weight alone. We chose the measure of low BMI as

less than 18.5 kg/m^2 because it was consistent with the CDC and the NIH's definition for malnourishment. Furthermore, our exploration of alternative BMI thresholds did not improve the model's ability to predict the costs of composite rate services. (For more information on this discussion, we refer readers to 69 FR 66329.)

Based on the regression analysis conducted for this proposed rule, we found that low BMI continues to be a strong predictor of cost variation among ESRD patients. For the proposed ESRD PPS, we are proposing 1.020 as a payment adjustment factor for low BMI. Further discussion of co-morbidities and low BMI as case-mix adjusters can be found below in section VIII.B. of this proposed rule.

4. 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 length of time patients have been receiving dialysis. The regression analysis performed for this proposed rule showed that patients who are in their first four months of dialysis have higher costs. This means that individuals who have been newly diagnosed with ESRD have higher costs for the first 4 months of dialysis. We looked at the amount of separately billable payments relative to the number of months the patient has been on dialysis. After reviewing the separately billable payment amounts for patients ranging from one month to twelve months since onset of dialysis, we found that there was a drop in the amount of separately billable payments after four months on dialysis. These higher costs for new patients may be due to stabilization of the patient's condition; administrative and labor costs associated with the patients being new to dialysis either in-center or home setting; or initial costs incurred to train patients and their caregivers to perform home dialysis.

Based on our analysis and for purposes of the ESRD PPS, we propose to define onset of dialysis beginning with the starting date as reported on the ESRD Medical Evidence Report Form through the first 4 months a patient is receiving dialysis.

Accordingly, we are proposing an adjustment of 1.473 for patients in their first 4 months of dialysis. This adjustment factor is based on the results of regression analysis conducted for this proposed rule as described above. We are proposing that this adjustment be applied to both in-facility and home dialysis patients. We acknowledge that there may be patients whose first 4 months of initial dialysis occur when they are not eligible for the Medicare ESRD benefit. In these circumstances, no adjustment would be made. We also acknowledge that eligibility for the ESRD benefit may occur during the first 4 months. In that situation, only the period of time in the first 4 months of dialysis that occurs while the patient is under the ESRD benefit would apply. In other words, the onset of dialysis adjustment is made only in the initial first 4 months of dialysis and for the period of time that the individual is eligible for the ESRD benefit.

5. Co-morbidities

As discussed above, section 1881(b)(14)(D)(i), as added by section 153(b) of MIPPA, requires that the bundled ESRD PPS include a payment adjustment based on case-mix that may take into account patient co-morbidities. Consequently, we analyzed co-morbidities as part of the regression analysis and found that certain co-morbidities are predictors of variation in payments for ESRD patients. The intent of the proposed co-morbidity adjustment is to recognize the increased costs associated with co-morbidities by providing additional payments for certain conditions that occur concurrently with the need for dialysis. In other words, co-morbidities are specific patient conditions that are secondary to the patient's principal diagnosis that necessitates dialysis, yet have a direct affect on dialysis. In addition, co-morbidities are an objective measure and data are readily available.

In the CY 2005 PFS proposed rule (69 FR 47529 through 47533), we proposed case-mix adjustments for a limited number of patient characteristics including a large number of specific co-morbidities. Using linear regression analyses, we assessed the relationship of patient characteristics and co-morbidity measures to per session cost and Medicare payments to ESRD facilities. We noted that we were able to develop case-mix adjustment factors for a limited number of patient characteristics, which were modest predictors of variation in average costs for composite rate services. However, as ESRD facilities did not list individual composite rate items and services on dialysis claims, the available data did not identify use of resources by individual patients. We acknowledged that ESRD facilities could under report or not report co-morbidities as there was no requirement to do so as the current basic case-mix adjusted composite payment system does not provide for co-morbidity payment adjusters. In an attempt to obtain information on co-morbidities, in the CY 2005 PFS final rule with comment, ESRD facilities were encouraged to report co-morbidities. Therefore, we used a combination of data sources (discussed below), to determine co-morbidities for ESRD patients on maintenance dialysis.

A stepwise regression analysis was conducted for the current basic case-mix adjusted composite payment system to identify case-mix factors that explained statistically significant variation in ESRD facility costs. Stepwise regression is used when there are a large number of potential explanatory variables with variables added or removed from the regression model to identify a subset of predictors and the highest R^2. The forward (step-up) method begins with no variables in the model with variables individually included if they are statistically significant (no additional variables have a p-value level <0.05). Backward (step-down) method begins with a model of all variables and eliminates the least significant variables until no nonsignificant variables remain (until all remaining variables have a p-value <0.10). The step-up method was performed to identify payment variables while the step-down method was performed to determine how much co-morbidity categories affected the R^2. As a result of our analysis, four patient characteristic variables (sex, age, AIDS and peripheral vascular disease) were found to be modest predictors of cost variation among ESRD facilities.

In the CY 2005 PFS proposed rule, we explained that a number of co-morbidities were analyzed, including several that did not have statistically significant relationships to facility costs, as well as co-morbidity conditions that were excluded due to lack of data. For example, we explained that a patient's history of cancer was associated with higher costs; however, we found the measure too broad to be clinically meaningful. We indicated that we would continue to evaluate cancer as a potential variable for refinement purposes.

We also discussed in that proposed rule that we explored whether diabetes as a co-morbidity is predictive of high resource use and found that the predictive power of diabetes was dependent on whether peripheral vascular disease (PVD) was part of the model. We explained that PVD was always statistically significant, when accounted for, while most diabetic measures were not strongly associated with facility costs. Therefore, we

proposed a case-mix adjustment for PVD diagnoses. We note that 73 percent of patients with diabetes also included PVD. (For more information on this discussion, we refer readers to 69 FR 47531).

In the CY 2005 PFS final rule with comment period, which implemented the current basic case-mix adjusted composite payment system, we acknowledged that although the regression modeling suggested the inclusion of co-morbidities in the basic case-mix adjusted composite payment system, we were concerned that the available data to determine patient level co-morbidities might not accurately reflect relevant diagnoses. For example, we explained that AIDS would not likely be recorded on claims for outpatient dialysis patients and that requiring its inclusion could create powerful incentives for ESRD facilities to circumvent confidentiality requirements (69 FR 66326). We also explained that we found that the predictive power of diabetes was dependent on whether PVD, which was statistically significant, was part of the model (69 FR 47531). However, most measures of diabetes were not strongly associated with ESRD facility costs. While we proposed a case-mix adjustment for PVD in the CY 2005 PFS proposed rule (69 FR 47531), we received comments indicating that there was apparent disagreement among clinicians as to whether certain diagnoses are reflective of PVD in ESRD patients. Therefore, we eliminated the case-mix adjustment for PVD in the CY 2005 PFS final rule with comment period.

There also were other factors that contributed to our decision not to include patient-level co-morbidities in the basic case-mix adjusted composite payment system. For example, with regard to substance abuse, we acknowledged in the CY 2005 PFS proposed rule, while the presence of alcohol and drug dependence was found to be predictive of higher facility level costs, we did not propose an adjustment as we believed substance abuse was underreported. Accordingly, we concluded that we would not include co-morbidities as a case-mix adjustment. However, we did establish the case-mix adjustments based on age, BMI, and BSA. Our analysis indicated that patients with extremely low or high BMI were costly to treat and included these as we believed this factor could be an important measure of resource consumption related to the composite rate services and could serve as a surrogate for the severity of co-morbidities. We also noted that the average patient BSA was found to be statistically significant and a consistent predictor of average treatment costs, indicating higher costs for larger adult patients. As discussed above, in the CY 2005 PFS final rule with comment period, we indicated that while co-morbidities were not part of the current basic case-mix adjusted composite payment system, we encouraged all facilities to report co-morbid conditions on the claims in order to enable future refinements to the basic case-mix adjustments that would reflect the type of co-morbidities that beneficiaries receiving ESRD services have which would provide a better database from which we can develop future case-mix measures for the ESRD PPS.

As discussed in section VIII.A, we retained UM–KECC to assist us in developing a case-mix adjustment for the proposed ESRD PPS. One of the tasks was the identification of specific diagnoses within co-morbidity categories. For this proposed rule, to capture changes in patient conditions, patient co-morbidities were measured using a combination of the co-morbidities reported on the Medical Evidence Form (CMS–2728) to obtain co-morbidities at the onset of dialysis adjustment, and diagnoses reported on the Medicare claims to identify co-morbidities not obtained from the Medical Evidence Form (CMS–2728).

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 Medical Evidence Form (CMS 2728). We also used co-diagnoses reported in multiple types of Medicare claims (inpatient dialysis and other outpatient, skilled nursing facility, physician/supplier, hospice, and home health). We are soliciting recommendations on the type of claims that reflect the co-morbidities for beneficiaries receiving renal dialysis services that could be used in future analyses.

We acknowledge the likelihood that some diagnoses reported on laboratory claims may represent a condition being excluded by the test, and therefore, diagnoses reported on laboratory claims were not used. A potential limitation of excluding laboratory claims from the identification process is that we may have underestimated the frequency of certain conditions. Patient characteristics considered for inclusion in the model are based on the magnitude and statistical significance of relationship to composite rate costs and separately billable payments.

To ensure that each potential case-mix adjuster has a relationship to cost which is statistically significant and to ensure that the magnitude of the relationship is economically meaningful, patient co-morbidities having statistically significant, low magnitude association with cost, as well as co-morbidities with ambiguous definitions were excluded. Several patient co-morbidities having statistically significant, low magnitude association with cost in the preliminary models and additional co-morbidities with ambiguous definitions, high prevalence, or both, were excluded.

A refined list of case-mix co-morbidities comprised of 1,022 ICD–9–CM diagnoses codes were evaluated for persistence of effect and cost. The resulting co-morbidity categories 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.

We used the stepwise regression model in analyzing co-morbidity data for case-mix adjustments in the proposed ESRD PPS. The relationship between patient characteristics and cost for composite rate services was estimated using a facility level regression model, as patient level data are not available. In other words, the average patient characteristics are related to the reported facility costs.

A patient level model was used to identify potential payment adjusters for separately billable services. The regression model, weighted by the number of dialysis sessions examined the same refined list of patient characteristics used in the model of composite rate costs. Eleven co-morbidity variables had statistically significant relationships to cost. However, the magnitude of the co-morbidity effects varied substantially. The largest payment multipliers were associated with gastrointestinal (GI) bleeding (31.6 percent), HIV/AIDS (31.6 percent), bacterial and other pneumonias/opportunistic infections (30.7 percent), hereditary hemolytic/sickle cell anemias (22.6 percent) and pericarditis (19.5 percent). As infections, GI bleeding and pericarditis are acute conditions with a diagnosis not exceeding 3 months, these diagnoses would result in a temporary payment adjustment. The chronic conditions

result in a permanent increase on payment which we believe may tend to have a more persistent effect on cost. For example, cancer diagnosis would be eligible for a payment adjustment if the cancer diagnosis has a direct effect on the cost of ESRD treatment. In other words, the fact that an individual has or had cancer would not in itself imply that a co-morbidity payment adjustment is warranted as the adjustment is intended to adjust for higher patient costs. The same applies for any diagnosis in any of the co-morbidity categories.

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. The weights reflect each component's proportion of the total estimated costs, so that the resulting case-mix adjustment reflects the overall relationship between patient characteristics and estimated costs for the proposed ESRD PPS.

We note that cancer is included in the proposed co-morbidity adjustment diagnoses. As discussed above, we indicated in the CY 2005 PFS proposed rule that although a history of cancer was associated with higher costs, it was found that the measure was too broad to be meaningful. Subsequent to the research we performed in support of the basic case-mix adjusted composite payment system, we investigated the relationship between specific categories of cancer and costs. In an effort to create more clinically homogenous groups, we began with clinical categories that were developed for risk adjustment under the Medicare Advantage program. The source for these cancer diagnoses was the Medicare claims, based on any occurrence since 1999. Starting with all cancers except for non-melanoma skin cancers, we split them into groups of cancers that were used by the Medicare Advantage Program namely, lung; upper digestive tract and other severe cancers; lymphatic system, head, and other major cancers; metastatic cancers; breast, prostate, colorectal, and other cancers and tumors; lymphoma; multiple myeloma; and leukemia. We performed analyses to estimate the relationship between these diagnostic categories and separately billable MAPs. These analyses demonstrated statistically significant associations between each of the cancer categories and SB MAP. In fact, the coefficient estimates were similar across categories. To advance the goal of parsimony in the model, we recombined the categories.

We also note that AIDS is included as a co-morbidity case-mix adjustment although it had been eliminated as an adjustment from the current basic case-mix adjusted composite payment system as reporting of AIDS was limited due to confidentiality requirements (69 FR 66326.) However, we found that inclusion of HIV/AIDS in the proposed ESRD PPS increases the explanatory power of the model and provides higher payments for patients who are substantially more costly to treat. We recognize that these benefits must be balanced against the goal to maintain patient confidentiality in this sensitive clinical area. The model that we are currently proposing is the result of applying a combination of empirical results and our policy decision regarding the appropriateness of adjusting for specific patient characteristics. We recognize that this may result in difficulties for ESRD facilities required by State law to maintain patient confidentiality and therefore are unable to comply with reporting HIV/AIDS diagnoses on claims. We also acknowledge facilities may not be aware of patients' HIV/AIDS status. We are specifically soliciting comments on our proposal to include HIV/AIDS diagnoses in the proposed model.

Based upon our analysis, we are proposing adjustments for the following eleven co-morbidity categories under the proposed ESRD PPS as indicated in table 14 below, and seek comment on each adjustment.

TABLE 14—CO-MORBIDITY CASE-MIX ADJUSTMENT

Case-mix adjustment co-morbidity	Modeled case-mix adjustment [1]
Alcohol/Drug Dependence	1.150
Cardiac Arrest	1.032
Pericarditis (0–3 months ago)	1.195
HIV/AIDS	1.316
Hepatitis B	1.089
Infection (0–3 months ago Septicemia	1.234
Bacterial Pneumonia and Other Pneumonias/Opportunistic Infections	1.307
Gastrointestinal Tract Bleeding (0–3 months ago)	1.316
Hereditary Hemolytic or sickle cell anemias	1.226
Cancer Since 1999 (exclude nonmelanoma skin cancer)	1.128
Myelodysplastic Syndrome	1.084
Monoclonial Gammopathy	1.021

[1] Payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers. The weights used reflect each component's proportion of the total estimated costs so that the resulting case-mix adjustment reflects the overall relationships between patient characteristics and estimated costs for an expanded bundle of services.

Diagnoses that relate to earlier periods of care and have no bearing on the current RRT are excluded from the proposed co-morbidity case-mix adjustment. Therefore, we are proposing that in order to be eligible for the proposed co-morbidity payment adjustment, the co-morbid condition must exist (or have existed within the past 3 months for the diagnoses, as noted above) and affect treatment. For each claim, we are proposing that an ESRD facility may receive only one co-morbidity case-mix adjustment per co-morbidity category, but it may receive an adjustment for more than one co-morbidity category.

We are proposing that in order to receive a co-morbidity payment adjustment, the appropriate ICD–9–CM code that corresponds to the specific condition/disease that results in increased costs to ESRD facilities is to be placed on the claims and that coding guidelines are to be used in determining the appropriate codes. This includes using V codes for those conditions that reflect that a patient had a disease/condition in the past and that the disease/condition has no effect on the cost of providing RRT. That is to say, we propose that these V codes (that is, history of a disease) for past disease/condition are not subject to any co-morbidity payment adjustment. We note we will issue through sub-regulatory guidance, any changes in codes eligible for a co-morbidity payment adjustment in the event of any changes in coding (for example, ICD–10–CM) in the future.

We performed analyses on FY 2007 dialysis claims to determine the extent that specific diagnoses within the eleven co-morbidity categories are on ESRD claims. We found that less than 50,000 claims out of three million (representing 1.7 percent of 3 million claims) had a diagnostic code corresponding to the co-morbidity categories eligible for a co-morbidity payment adjustment. Of these, 40,609 diagnoses related to septicemia and shock; 2,853 related to cancer; 1,933

related to Hepatitis B, and 973 to HIV/AIDS.

We also analyzed the ICD–9–CM diagnostic codes as identified by UM–KECC. A complete list of the codes identified by UM–KECC is found in Table A of the Addenda.

Table B, which can be found in the Addenda represents the codes associated with diseases/conditions that would be recognized for the purposes of an ESRD co-morbidity payment adjustment.

Please note that we have eliminated specific ICD–9–CM codes associated with specific diseases/conditions that we propose would not be recognized for purposes of a co-morbidity payment adjustment. These ineligible codes are discussed further below.

ICD–9–CM Codes With Their Associated Conditions/Diseases Not Recognized for the Purposes of a Co-morbidity Payment Adjustment

Based on our analyses, we are proposing that conditions/diseases associated with the following ICD–9 codes will not be recognized for the purposes of a co-morbidity case-mix adjustment. We explain the reason for not recognizing these codes in the sections discussed below. We are soliciting comments regarding the conditions/diseases associated with the excluded codes. We are also soliciting suggestions of ICD–9–CM codes for conditions/diseases associated with which we should consider for future refinements.

1. *ICD–9–CM Co-morbidities Not Affecting Costs in Outpatient ESRD Facility and Not Recognized for Co-morbidity Payment Adjustment(s)*

We believe that patients with the following co-morbidity condition(s) in Table 15 below, would not result in higher costs in an ESRD facility. We believe that patients with these acute conditions/diseases, many which are highly communicable, would not receive dialysis in an outpatient setting and therefore, a history of these conditions/diseases would not have an impact on ESRD provider/facility costs. Therefore, we are proposing that these conditions would not be recognized for purposes of the proposed co-morbidity adjustment. We are soliciting comments on these ICD–9–CM codes and their associated diseases/conditions.

TABLE 15—ICD–9–CM CO-MORBIDITIES NOT AFFECTING COSTS IN OUTPATIENT ESRD FACILITY AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)

Drug and/or Alcohol Induced Mental Disorders	
291.0	Delirium tremors.
291.1	Alcohol psychosis, alcoholic amnestic syndrome.
291.2	Alcoholic psychosis, other alcohol dementia.
291.3	Alcoholic psychosis, alcoholic withdrawal hallucinosis.
291.4	Alcoholic psychosis, idiosyncratic alcohol intoxication.
291.5	Alcoholic psychoses, alcohol jealousy.
Hepatitis B	
070.20	Viral hepatitis B with hepatic coma acute or unspecified w/o hepatitis delta.
070.21	Viral hepatitis B w/hepatic coma acute or unspecified w/hepatitis delta.
070.22	Viral hepatitis B w/hepatic coma chronic w/o hepatitis delta.
070.23	Viral hepatitis B w/hepatic coma chronic w/hepatitis delta.
Septicemia and Shock	
020.2	Septicemic plague.
020.3	Primary pneumonic plague.
036.2	Meningococcemia.
038.3	Septicemia due to anaerobes.
040.82	Toxic shock syndrome.
054.5	Herpetic septicemia.
771.81	Newborn septicemia.
Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias	
003.22	Salmonella pneumonia.
006.4	Amebic lung abscess.
007.4	Cryptosporidosis.
020.4	Secondary pneumonic plague.
021.2	Pulmonary tularemia.
022.1	Pulmonary anthrax.
031.2	Disseminated mycobacteria.
039.1	Pulmonary actinomycosis.
078.5	Cytomagalovirus disease.
112.4	Candidiasis lung.
112.5	Candidiasis disseminated.
114.0	Primary coccidioidomycosis pulmonary.
114.4	Chronic pulmonary coccidioidomycosis.
115.05	Histoplasma capsulatum pneumonia.
115.15	Histoplasma duboisii pneumonia.
115.95	Histoplasmosis unspecified pneumonia.
117.3	Aspergillosis.
117.5	Cryptococcosis.
117.7	Zygomycosis (phycomycosis/mucomycosis).
121.2	Paragonimiais.
122.1	Echinoccus granulosis lung.

TABLE 15—ICD–9–CM CO-MORBIDITIES NOT AFFECTING COSTS IN OUTPATIENT ESRD FACILITY AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

130.0	Toxoplasmosis meningoencephalitis.
130.4	Toxoplasmosis pneumonitis (strep pneumoniae pneumonia).
130.8	Multisystemic disseminated toxoplasmosis.
136.3	Pneumocytosis.

2. *ICD–9–CM NEC/NOS/Unspecified Codes Not Recognized for Purposes of a Co-Morbidity Payment Adjustment(s) Payment*

The following ICD–9–CM codes/diagnoses in Table 16 are designated as not otherwise specified (NOS); not elsewhere specified (NEC) or are unspecified. As these codes are general and do not provide meaningful identification of a disease, we are proposing that these ICD–9–CM codes/diagnoses will not be recognized for purposes of a co-morbidity case-mix adjustment.

TABLE 16—ICD–9–CM NEC/NOS/UNSPECIFIED CODES NOT RECOGNIZED FOR PURPOSES OF A CO-MORBIDITY PAYMENT ADJUSTMENT(S) PAYMENT

Cancer (Excludes Non-Melanoma Skin Cancer)	
141.9	malignant neoplasm tongue NOS.
142.8	malignant neoplasm major salivary NEC.
142.9	malignant neoplasm salivary NOS.
143.8	malignant neoplasm gum NEC.
143.9	malignant neoplasm gum NOS.
144.9	malignant neoplasm mouth floor NOS.
145.5	malignant neoplasm palate NOS.
145.9	malignant neoplasm mouth NOS.
146.9	malignant neoplasm oropharynx NOS.
147.8	malignant neoplasm nasopharynx NEC.
147.9	malignant neoplasm nasopharynx NOS.
148.9	malignant neoplasm hypopharynx NOS.
149.0	malignant neoplasm pharynx NOS.
150.8	malignant neoplasm esophagus NEC.
150.9	malignant neoplasm esophagus NOS.
151.8	malignant neoplasm stomach NEC.
151.9	malignant neoplasm stomach NOS.
152.9	malignant neoplasm small bowel NOS.
153.8	malignant neoplasm colon NEC.
153.9	malignant neoplasm colon NOS.
154.3	malignant neoplasm anus NOS.
154.8	malignant neoplasm rectum/anus NEC.
155.2	malignant neoplasm liver NOS.
156.9	malignant neoplasm biliary NOS.
157.9	malignant neoplasm pancreas NOS.
158.9	malignant neoplasm peritoneum NOS.
159.0	malignant neoplasm intestine NOS.
159.1	malignant neoplasm spleen NEC.
159.8	malignant neoplasm gastrointestinal/intra-abdominal NEC.
159.9	malignant neoplasm gastrointestinal tract ill-defined.
160.9	malignant neoplasm access sinus NOS.
161.9	malignant neoplasm larynx NOS.
162.8	malignant neoplasm bronchus/lung NEC.
162.9	malignant neoplasm bronchus/lung NOS.
163.8	malignant neoplasm pleura NEC.
163.9	malignant neoplasm pleura NOS.
164.8	malignant neoplasm mediastinum NEC.
164.9	malignant neoplasm mediastinum NOS.
165.0	malignant neoplasm upper respiratory NOS.
165.9	malignant neoplasm respiratory system NOS.
170.9	malignant neoplasm bone NOS.
171.7	malignant neoplasm trunk NOS.
171.8	malignant neoplasm soft tissue NEC.
171.9	malignant neoplasm soft tissue NOS.
172.8	malignant melanoma skin NEC.
172.9	malignant melanoma skin NOS.
172.3	malignant melanoma face NEC/NOS.
174.8	malignant neoplasm breast NEC.
174.9	malignant neoplasm breast NOS.
175.9	malignant neoplasm male breast NEC.
176.9	Kaposi's sarcoma NOS.
179.9	malignant neoplasm uterus NOS.
180.9	malignant neoplasm cervix uteri NOS.

TABLE 16—ICD–9–CM NEC/NOS/UNSPECIFIED CODES NOT RECOGNIZED FOR PURPOSES OF A CO-MORBIDITY PAYMENT ADJUSTMENT(S) PAYMENT—Continued

183.8	malignant neoplasm adnexa NEC.
183.9	malignant neoplasm adnexa NOS.
184.4	malignant neoplasm vulva NOS.
184.8	malignant neoplasm female genitals NEC.
184.9	malignant neoplasm female genitals NOS.
187.4	malignant neoplasm penis NOS.
187.9	malignant neoplasm male genital NOS.
187.8	malignant neoplasm male genital NEC.
188.8	malignant neoplasm bladder NEC.
188.9	malignant neoplasm bladder NOS.
189.8	malignant neoplasm urinary NEC.
189.9	malignant neoplasm urinary NOS.
190.9	malignant neoplasm eye NOS.
191.6	mal neoplasm cerebellum NOS.
191.8	malignant neoplasm brain NEC.
191.9	malignant neoplasm brain NOS.
192.8	malignant neoplasm nervous system NEC.
192.9	malignant neoplasm nervous system NOS.
194.8	malignant neoplasm endocrine NEC.
194.9	malignant neoplasm endocrine NOS.
195.8	malignant neoplasm site NEC.
196.9	malignant neoplasm lymph node NOS.
197.3	secondary malignant neoplasm respiratory NEC.
197.8	secondary malignant neoplasm gastrointestinal NEC.
198.82	secondary malignant neoplasm genital.
198.89	secondary malignant neoplasm NEC.
199.1	malignant neoplasm NOS.
200.80	other variant unspecified extranodal.
208.20	subacute leukemia unspecified cell without remission.
208.21	subacute leukemia unspecified cell with remission.
208.80	other leukemia unspecified cell type without remission.
208.81	other leukemia unspecified cell type with remission.
208.90	leukemia NOS without remission.
208.91	leukemia NOS with remission.
209.00	malignant carcinoid tumor small intestine unspecified portion.
209.10	malignant carcinoid tumor large intestine unspecified portion.
209.20	malignant carcinoid tumor of unknown primary site.
209.25	malignant carcinoid tumor of foregut, NOS.
209.26	malignant carcinoid tumor of midgut, NOS.
209.27	malignant carcinoid tumor of hindgut, NOS.
209.29	malignant carcinoid tumor of other sites.
209.30	malignant poorly differentiated neuroendocrine cancer, any site.
237.70	neurofibromatosis NOS.
237.9	uncharacteristic behavior neurologic nervous system NEC.
239.6	brain neoplasm NOS.
259.2	other endocrine disorders, carcinoid syndrome.
Drug and/or alcohol induced mental disorders	
291.81	alcohol psychosis other specified alcohol psychosis/alcohol withdrawal.
291.89	alcohol psychosis, other specified alcohol psychosis, other.
291.9	alcoholic psychoses/unspecified alcohol psycho.
292.0	drug withdrawal.
292.11	paranoid/hallucinatory drugs induced, drug-induced organic delusion syndrome.
292.12	drug psychiatric disorder with hallucinations.
292.2	pathologic drug intoxication.
292.81	other specified drug-induced mental disorders, drug-induced delirium.
292.82	other specified drug-induced mental disorders, drug-induced dementia.
292.84	other specified drug-induced mental disorders, drug-induced organic affective syndrome.
292.89	other specified drug-induced mental disorders, other.
292.9	unspecified drug-induced mental disorders.
303.00	acute alcohol intoxication-unspecified.
303.01	alcohol dependent syndrome, acute alcohol intoxication, continuous.
303.90	alcohol dependence syndrome, other & unspecified alcohol dependence unspecified.
304.00	drug dependence, opioid, unspecified.
304.10	drug dependence barbiturate/similarly acting sedative/hypnotic dependence unspecified.
304.20	drug dependence, cocaine unspecified.
304.30	drug dependence, cannabis unspecified.
304.40	drug dependence amphetamine/other psychostimulator unspecified.
304.50	drug dependence hallucinogen unspecified.
304.60	other specified drug dependence unspecified.
304.70	drug dependence opioid type w/other drug unspecified.
304.80	drug depend comb w/o opioid type unspecified.

TABLE 16—ICD–9–CM NEC/NOS/UNSPECIFIED CODES NOT RECOGNIZED FOR PURPOSES OF A CO-MORBIDITY PAYMENT ADJUSTMENT(S) PAYMENT—Continued

304.90	drug dependence unspecified depend unspecified.
305.00	nondependence drug abuse alcohol unspecified.
571.3	alcoholic liver damage unspecified.
V11.3	personal mental disorder history alcoholism.
Pericarditis	
420.0	acute pericarditis in diseases classified elsewhere.
420.99	other/unspecified pericarditis other.
HIV/AIDS	
079.53	HIV–2 infection other disease.
Septicemia and shock	
038.10	septicemia, staphylococcal unspecified.
038.19	septicemia, staphylococcal other.
038.9	septicemia other unspecified.
785.59	other shock: endotoxic, gram negative hypovolemia.
Bacterial Pneumonias/Opportunistic Infections/Pneumococcal Pneumonias	
482.30	streptococcus pneumonia unspecified.
482.39	streptococcus other strep pneumonia.
482.40	pneumonia due to staphlococcus unspecified.
482.49	pneumonia due to other staphlococcus pneumonia.
482.83	pneumonia due to other gram negative bacteria.
482.89	pneumonia due to other specified bacteria.
484.7	other systemic mycoses pneumonia.
Gastrointestinal tract bleeding	
531.40	chronic/unspecified gastric ulcer w/hemorrhage w/o obstruction.
531.41	chronic/unspecified gastric ulcer w/hemorrhage w/obstruction.
531.60	chronic/unspecified gastric ulcer w/hemorrhage/perforation w/o obstruction.
531.61	chronic/unspecified gastric ulcer w/hemorrhage/perforation w/obstruction.
532.40	chronic/unspecified duodenal ulcer w/hemorrhage w/o obstruction.
532.41	chronic/unspecified duodenal ulcer w/hemorrhage w/obstruction.
532.60	chronic/unspecified duodenal ulcer w/hemorrhage/perforation w/o obstruction.
532.61	chronic/unspecified duodenal ulcer w/hemorrhage/perforation w/obstruction.
533.40	chronic/unspecified peptic ulcer w/hemorrhage w/o obstruction.
533.41	chronic/unspecified peptic ulcer w/hemorrhage w/obstruction.
533.60	chronic/unspecified peptic ulcer w/hemorrhage/perforation w/o obstruction.
533.61	chronic/unspecified peptic ulcer w/hemorrhage/perforation w/obstruction.
534.40	chronic/unspecified gastrojejunal ulcer w/hemorrhage w/o obstruction.
534.41	chronic/unspecified gastrojejunal ulcer w/hemorrhage w/obstruction.
534.60	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation w/o obstruction.
534.61	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation w/obstruction.
Hereditary hemolytic anemias/sickle cell anemias	
282.69	sickle-cell disease other sickle-cell disease w/crisis.
282.9	hereditary hemolytic anemia unspecified.

3. *ICD–9–CM Benign Tumor Codes Not Recognized for Co-Morbidity Payment Adjustment(s)*

As noted previously, the intent of the case-mix adjustment is to provide additional payment for conditions which are predictors of variation of average costs. Although the regression analysis identified cancer as a co-morbidity category because it resulted in higher costs, we believe that this would exclude benign tumors. Therefore, we are proposing that the following benign tumor codes/diagnoses in Table 17 will not be recognized for the proposed cancer co-morbidity payment adjustment.

TABLE 17—ICD–9–CM BENIGN TUMOR CODES NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)

209.40	Benign carcinoid tumor small intestine, unspecified portion.
209.41	Benign carcinoid tumor of the duodenum.
209.42	Benign carcinoid tumor of the jejunum.
209.43	Benign carcinoid tumor of the ileum.
209.50	Benign carcinoid tumor large intestine, unspecified portion.
209.51	Benign carcinoid tumor of the appendix.
209.52	Benign carcinoid tumor of the cecum.

TABLE 17—ICD–9–CM BENIGN TUMOR CODES NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

209.53	Benign carcinoid tumor ascend colon.
209.54	Benign carcinoid tumor of the transverse colon.
209.55	Benign carcinoid tumor descend colon.
209.56	Benign carcinoid tumor of the sigmoid colon.
209.57	Benign carcinoid tumor of the rectum.
209.60	Benign carcinoid tumor unknown primary site.
209.61	Benign carcinoid tumor bronchus/lung.
209.62	Benign carcinoid tumor thymus.
209.63	Benign carcinoid tumor of the stomach.
209.64	Benign carcinoid tumor of the kidney.
22.5	Benign neoplasm brain/other nervous system parts.
225.0	Benign neoplasm brain.
225.1	Benign neoplasm cranial nerves.
225.2	Benign neoplasm cerebral meninges.
225.3	Benign neoplasm spinal cord.
225.4	Benign neoplasm spinal meninges.
225.8	Benign neoplasm nervous system NEC.
225.9	Benign neoplasm nervous system NOS.
226	Benign neoplasm thyroid.
227.3	Benign neoplasm pituitary.
227.4	Benign neoplasm pineal gland.

4. *ICD–9 Codes as Category Headings and Not Recognized for Co-Morbidity Payment Adjustment(s)*

We are proposing that the following ICD–9–CM codes/diagnoses in Table 18 will not be recognized for purposes of a co-morbidity case-mix adjustment because these codes are ICD–9–CM category headings not be used to identify diagnoses.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)

Cancer (excludes non-melanoma skin cancer)	
141	malignant neoplasm tongue.
142	malignant neoplasm major salivary/parotid.
143	malignant neoplasm gum.
144	malignant neoplasm floor of mouth.
145	malignant neo other/unspecified mouth parts.
146	malignant neoplasm oropharynx.
147	malignant neoplasm nasopharynx.
148	malignant neoplasm hypopharynx.
149	mal neoplasm other/ill-defined lip/oral cavity/pharynx.
150	malignant neoplasm esophagus.
151	malignant neoplasm stomach.
152	malignant neoplasm intestine/duodenum.
153	malignant neoplasm colon.
154	malignant neo rectum/rectosigmoid junction/anus.
155	malignant neoplasm liver/intrahepatic bile ducts.
156	malignant neoplasm gall bladder/extrahepatic bile ducts.
157	malignant neoplasm pancreas.
158	malignant neoplasm retroperitoneum/peritoneum.
159	malignant neoplasm other/ill-defined digest org/peritoneum.
160	malignant neoplasm nasal cavities/middle ear/access sinuses.
161	malignant neoplasm larynx.
162	malignant neoplasm trachea/bronchus/lung.
163	malignant neoplasm pleura.
164	malignant neoplasm thymus/heart/mediastinum.
Cancer (excludes non-melanoma skin cancer)	
165	malignant neoplasm other/ill-defined respiratory system/intrathoracic.
170	malignant neoplasm bone/articular cartilage.
171	malignant neoplasm connective/other soft tissue.
172	malignant melanoma skin.
174	malignant neoplasm female breast.
175	malignant neoplasm male breast.
176	Kaposi's sarcoma.
180	malignant neoplasm cervix uteri.
182	malignant neoplasm uterine body.
183	malignant neoplasm ovary/other uterine adnexa.
184	malignant neoplasm other/unspecified female genitals.
186	malignant neoplasm testis.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

187	malignant neoplasm penis/other male genitals.
188	malignant neoplasm bladder.
189	malignant neoplasm kidney/other/unspecified urinary organs.
190	malignant neoplasm eye.
191	malignant neoplasm brain.
192	malignant neoplasm other/unspecified nervous system.
194	malignant neoplasm other endocrine/related structures.
195	malignant neoplasm other/ill-defined sites.
196	secondary/unspecified malignant neoplasm lymph nodes.
197	secondary malignant neoplasm respiratory/digestive systems.
198	secondary malignant neoplasm other specified sites.
199	malignant neoplasm without site specification.
200	lymphosarcoma & reticulosarcoma.
200.1	lymphosarcoma/reticulosarcoma/lymphosarcoma.
200.2	lymphosarc/reticulosarcoma, Berkett tumor/lymphoma.
Cancer (excludes non-melanoma skin cancer)	
200.8	lymphosarcoma/reticulsarcoma other variants.
201	Hodgkin's disease.
201.0	Hodgkin's disease Hodgkin's paragranuloma.
201.1	Hodgkin's disease Hodgkin's granuloma.
201.2	Hodgkin's disease Hodgkin's sarcoma.
201.4	Hodgkin's disease lymphocystic-histiocytic.
201.5	Hodgkin's disease nodular sclerosis.
201.6	Hodgkin's disease mixed cellularity.
201.7	Hodgkin's disease lymphocytic depletion.
201.9	Hodgkin's disease unspecified.
202	other malignant neoplasm lymphoid/histiocytic tissue.
202.0	nodular lymphoma.
202.1	other malignant neoplasm lymphoid/histiocytic tissue; mycosis fungoides.
202.2	other malignant neoplasm lymphoid/histiocytic tissue; Sezary's disease.
202.3	other malignant neoplasm lymphoid/histiocytic tissue; malignant histiocytosis.
202.4	other malignant neoplasm lymphoid/histiocytic tissue, leukemic reticuloendotheliosis.
202.5	other malignant neoplasm lymphoid/histiocytic tissue, Letterer-Siwe disease.
202.6	other malignant neoplasm lymphoid/histiocytic tissue, malignant mast cell tumors.
202.8	other lymphomas.
202.9	other malignant neoplasm lymphoid/histiocytic tissue, other/unspecified.
203	multiple myeloma/immunoproliferative neoplasms.
203.0	multiple myeloma.
203.1	plasma cell leukemia.
203.8	other immunoproliferative neoplasms.
204	lymphoid leukemia.
204.0	acute lymphoid leukemia.
204.1	chronic lymphoid leukemia.
Cancer (excludes non-melanoma skin cancer)	
204.2	subacute lymphoid leukemia.
204.8	lymphoid leukemia other.
204.9	lymphoid leukemia unspecified.
205	myeloid leukemia.
205.0	acute myeloid leukemia.
205.1	chronic myeloid leukemia.
205.2	subacute myeloid leukemia.
205.3	myeloid leukemia, myeloid sarcoma.
205.8	myeloid leukemia other.
205.9	myeloid leukemia unspecified.
206	monocytic leukemia.
206.0	acute monocytic leukemia.
206.1	chronic monocytic leukemia.
206.2	subacute monocytic leukemia.
206.8	monocytic leukemia other.
206.9	monocytic leukemia unspecified.
207	other specified leukemia.
207.0	other specified leukemia, acute erythremia/erythroleukemia.
207.1	other specified leukemia, chronic erythremia.
207.2	other specified leukemia megakaryocytic leukemia.
207.8	other specified leukemia other.
208	leukemia unspecified cell type.
208.0	acute leukemia unspecified cell type.
208.1	chronic leukemia unspecified cell type.
208.2	subacute leukemia unspecified cell type.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

208.8 leukemia unspecified cell type other.
208.9 leukemia unspecified cell type unspecified.
22.5 benign neoplasm brain/other nervous system parts.
237.7 neurofibromatosis.
Drug and/or Alcohol Induced Mental Disorders
291 Alcoholic psychosis.
291.8 Alcohol psychoses, other specified alcohol psychosis.
292 Drug psychoses.
292.1 Paranoid/hallucinatory induced by drugs.
292.8 other specified drug-induced mental disorders.
303 alcohol dependence syndrome.
303.0 alcohol dependence syndrome, acute alcohol intoxication.
303.9 alcohol dependence syndrome, other & unspecified alcohol dependence.
304 drug dependence.
304.0 drug dependence, opioid.
304.1 drug dependence barbiturate/similarly acting sedative/hypnotic dependence.
304.2 drug dependence, cocaine.
304.3 drug dependence, cannabis.
304.4 drug dependence, amphetamine/other psychostimulant.
304.5 drug dependence hallucinogen.
304.6 other specified drug dependence.
304.7 drug dependence opioid type with other drug.
304.8 drug dependence combination without opioid.
304.9 drug dependence unspecified dependence.
305.0 nondependence drug abuse alcohol.
Pericarditis
420 acute pericarditis.
420.9 other/unspecified pericarditis.
Hepatitis B
070.2 viral hepatitis B w/hepatic coma.
070.3 viral hepatitis B w/o hepatic coma.
Septicemia and Shock
031 diseases due to other mycobacteria.
038 septicemia.
038.1 septicemia, staphylococcal.
038.4 septicemia due to other gram negative organisms.
Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias
482 other bacterial pneumonias.
482.3 streptococcus pneumonia.
482.4 pneumonia due to staphylococcus.
482.8 pneumonia due to other specified bacteria.
507 pneumonitis due to solids & liquids.
510 empyema.
513 lung/mediastinum abscess.
Gastrointestinal Tract Bleeding
531.0 acute gastric ulcer w/hemorrhage.
531.2 acute gastric ulcer w/hemorrhage/perforation.
531.4 chronic/unspecified gastric ulcer w/hemorrhage.
531.6 chronic/unspecified gastric ulcer w/hemorrhage/perforation.
532.0 acute duodenal ulcer w/hemorrhage.
532.2 acute duodenal ulcer w/hemorrhage/perforation.
532.4 chronic/unspecified duodenal ulcer with hemorrhage.
532.6 chronic/unspecified duodenal ulcer without hemorrhage/perforation.
533.0 acute peptic ulcer w/hemorrhage.
533.2 acute peptic ulcer w/hemorrhage/perforation.
533.4 chronic/unspecified peptic ulcer w/hemorrhage.
533.6 chronic/unspecified peptic ulcer w/hemorrhage/perforation.
534.0 acute gastrojejunal ulcer w/hemorrhage.
534.2 acute gastrojejunal ulcer w/hemorrhage/perforation.
534.4 chronic/unspecified gastrojejunal ulcer w/hemorrhage.
534.6 chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation.

TABLE 18—ICD–9 CODES AS CATEGORY HEADINGS AND NOT RECOGNIZED FOR CO-MORBIDITY PAYMENT ADJUSTMENT(S)—Continued

Hereditary hemollytic anemias/sickle cell anemias
282 hereditary hemolytic anemias.
282.4 Thalassemias.
282.6 sickle-cell disease.
Myelodysplastic Syndrome
238.7 neoplasm other lymphatic/hematopoietic tissues includes myelodysplastic syndrome.

6. 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. Consequently, we analyzed race and ethnicity as part of the regression analysis for the proposed ESRD PPS to inform our proposal for this rule.

Prior to the enactment of MIPPA, we considered race and ethnicity as potential patient level payment adjusters. First, race was one of the 35 patient characteristics that were examined in developing the basic case-mix adjustments to the ESRD composite rate required under section 1881(b)(12) of the Act. Ultimately, however, the final basic case-mix adjusted composite payment system published in the CY 2005 PFS final rule with comment period did not include adjustments for race and ethnicity. (For more information, we refer readers to 69 FR 66330.)

We again considered race and ethnicity as potential patient level payment adjusters as part of our research for the Secretary's 2008 Report to Congress. In the Report, we concluded that although race and ethnicity perhaps had a statistically significant relationship with costs and payments, such indicators were judged not to be suitable for making payment distinctions in a bundled ESRD PPS given that race/ethnicity is not objectively measured.

Specifically, because there is no quantifiable mechanism by which to measure one's race or ethnicity, the classification is commonly based on self-reported information. We believed that more measurable indicators of cost and payment would be the patient's underlying clinical conditions. We further noted in the Report a demonstrated significance that race has on provider costs and drug utilization, indicating that this adjustment may warrant further consideration in the development and implementation of a new ESRD PPS. We note that any relationship between race/ethnicity and costs and payments revealed in the analyses conducted for purposes of this ESRD PPS proposed rule is discussed further in the sections that follow.

The regression analysis conducted for purposes of this 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). In Table 19 below, the table captures the key differences in racial and ethnic categorizations between the REMIS and EDB databases.

TABLE 19—RACE/ETHNICITY OF MEDICARE DIALYSIS PATIENTS [1, 2]

REMIS/CMS Form 2728	Percent	Medicare Enrollment Database (EDB)	Percent
Race:		Race:	
American Indian/Alaskan Native	1.6	North American Native	1.4
Asian/Pacific Islander	3.6	Asian	2.7
Black	38.5	Black	37.7
White	55.2	White	48.7
Other	1.1	Hispanic	5.2
Unknown	<0.1	Other	2.1
		Unknown	2.2
Ethnicity:			
Hispanic	12.2		
Not Hispanic	83.8		
Unknown	4.0		

[1] n = 890,776 patient years.
[2] Hispanic ethnicity is reported separately from race on CMS Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

Most notably, REMIS data includes both beneficiary race and ethnicity designations whereas EDB data includes ethnicity as a racial category. For example, an individual self-identifying as being of Hispanic ethnicity and White race would be reflected as both Hispanic and White in the REMIS database but this same individual would be categorized as either Hispanic or White in EDB. A summary of each analysis is set forth below.

a. REMIS Data Analysis

REMIS, a tracking system for the ESRD patient population for both Medicare and non-Medicare patients, is populated by the ESRD Networks with race and ethnicity data that are collected on the ESRD Medical Evidence Report (Form CMS–2728). The form is completed, signed and certified by the patient's physician at the onset of ESRD treatment.

As noted previously, the proposed ESRD PPS model set forth is based on 2004–2006 data. During this 3-year timeframe, two versions of the Medical Evidence Report Form were used, each with differing categorizations for race and ethnicity.

The earlier version (dated 6/1997), included three ethnicity categories from which to choose—(1) Hispanic: Mexican, (2) Hispanic: Other, and (3) Non-Hispanic. The form did not specify whether to check one or more ethnicity categories. In addition, the form included nine race categories from which to choose—(1) White, (2) Black, (3) American Indian/Alaskan Native, (4) Asian, (5) Pacific Islander, (6) Mid-East/Arabian, (7) Indian sub-Continent, (8) Other, specify, and (9) Unknown. The form instructed individuals to check the *one* race category that applied.

The later version (dated 6/2004), includes two ethnicity categories from which to choose—(1) Not Hispanic or Latino and (2) Hispanic or Latino (including country/area of origin or ancestry). While the form does not include instructions for selecting ethnicity, it is assumed that the individual would choose one of the two categories. In addition, the form includes five race categories from which to choose—(1) White, (2) Black or African American, (3) American Indian/Alaskan Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. This form instructs individuals to check all race categories that apply.

Reporting using the later version (dated 6/2004) became mandatory on June 1, 2005. Therefore, for purposes of our analysis using REMIS race and ethnicity data, beneficiaries for whom the Medical Evidence Report Form 2728 was completed prior to June 2005 comprise the race and ethnicity categories of the earlier version of the form whereas beneficiaries for whom the Medical Evidence Report Form was completed between June through December of 2005 and 2006 comprise the race and ethnicity categories of the later version of the form. We note that for comparison purposes between the two versions of the Medical Evidence Form, it was necessary to designate the following beneficiaries into the category of ''Other'': (1) beneficiaries for whom more than one racial category was marked on the 2004 version of the form and (2) beneficiaries for whom the Mid-East/Arabian or the Indian sub-Continent categories were marked on the 1997 version of the form.

Relying on REMIS as the basis of race and ethnicity data, it was possible to evaluate 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.

In our analysis using REMIS data in examining race, we found that combined composite rate and separately billable payments are lowest in the category ''Asian/Pacific Islander.'' As a result, this category was used as the reference group. Compared to the reference group, ''Native American/Alaskan Natives'' are 12.6 percent costlier; ''Whites'' are 14.2 percent costlier; ''Blacks'' are 20.7 percent costlier; and individuals in the category ''Other'' are 64.6 percent costlier. As noted previously, for purposes of our analysis, it was necessary to default beneficiaries into the ''Other'' category to reconcile differences between the two versions of the Medical Evidence Report Form and in instances where multiple race categories were selected on the form. As a result of defaulting individuals into the ''Other'' category, we believe that this designation may fail to reflect an individual's true racial status.

In our analysis using REMIS data in examining ethnic background, we found that non-Hispanic patients are 6.5 percent more costly than Hispanic patients.

b. EDB Data Analysis

The EDB is the source of enrollment and entitlement information for all people who are or were ever entitled to Medicare. The EDB is populated with race and ethnicity data that come from the Social Security Administration (SSA). The SSA's race and ethnicity data are collected on the SS–5 form. Unlike CMS' Medical Evidence Report Form that captures both race and ethnicity, the SSA's SS–5 form combines these two elements, instructing the individual to voluntarily select one of the following 5 categories: (1) Asian, Asian-American or Pacific Islander; (2) Hispanic; (3) Black (Not Hispanic); (4) North American Indian or Alaskan Native; or (5) White (Not Hispanic). The SS–5 form is completed when an individual does the following: (1) applies for a social security number; (2) requests a replacement of the social security card; or (3) requests changes to personal information on their record, such as a name change (Social Security Administration Web site instructions *http://www.ssa.gov/online/ss-5.pdf*). Prior to 1980, the SS–5 form included 3 categories for race: White, Black or Other.

The EDB is also populated with data collected by the Railroad Retirement Board (RRB). However, the data are not inclusive of race and ethnicity as these elements are not collected or maintained within the RRB's system. In 1964, the RRB began requiring new railroad industry employees to obtain social security numbers from the SSA, despite ineligibility for Social Security benefits. As a result, race or ethnicity data voluntarily specified by these individuals are reflected in EDB. However, the EDB does not include race or ethnicity on behalf of railroad industry beneficiaries lacking social security numbers; that is, those individuals entering the RRB system prior to 1964. As a result, the race and ethnicity of these individuals is defaulted to ''Unknown'' within EDB.

Each January, CMS creates a finder file consisting of those beneficiaries who were added to CMS' EDB during the previous calendar year as well as all living beneficiaries whose race is identified as ''Other'' or ''Unknown.'' This finder file is sent to the SSA to be processed against their Numerical Identification file, referred to as ''NUMIDENT'', which contains the expanded race categories captured on the SS–5 form. When the results are returned to us, the EDB is updated with the latest information. During subsequent iterations of this annual process, we do not include those beneficiaries that were processed in previous years into the subsequent finder file unless the race was either ''Unknown'' or ''Other.''

In addition to the NUMIDENT file provided by the SSA, several other efforts have been undertaken in an attempt to improve the validity of EDB data including (1) a one-time, voluntary survey of beneficiaries, conducted by CMS in 1997, whose race was identified as ''Unknown'' or ''Other,'' and (2) coordination with the Indian Health Service (IHS) since 2000 on a quarterly basis to record beneficiaries race as American Indian or Alaskan native. Despite these efforts, researchers have identified concerns with CMS' continued reliance on SSA race and ethnicity data collected through the SS–5 form, pointing to deficiencies in data among the smaller minority groups of Asians, Hispanics, and American Indians/Alaskan Natives. A study of 2002 data revealed that only 52 percent of Asian, 33 percent of Hispanic, and 33 percent of American Indian/Alaskan Native Medicare beneficiaries can be correctly identified in the Medicare data (McBean, M, ''Medicare Race and Ethnicity Data Report.'' December 2004.). However, EDB codes are generally reliable for White and Black affiliations (Waldo, D, ''Accuracy and Bias of Race/Ethnicity Codes in the

Medicare Enrollment Database.'' HCFA Review Vol. 26 No. 2 (Winter 2004–2005): 61–72).

Linking race and ethnicity data from the EDB to ESRD patients, we evaluated 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.

In our analysis using EDB data in examining race and ethnicity, we found that combined composite rate and separately billable payments are lowest among those individuals categorized as ''Other'' and ''Hispanic.'' In using the category ''Asian'' as the reference group, individuals categorized as ''Other'' and ''Hispanic'' have approximately 6 percent and 4 percent lower costs, respectively than the reference group. Individuals categorized as ''North American Native'' have 7.4 percent higher costs; individuals categorized as ''White'' have 11.9 percent higher costs; and individuals categorized as ''Black'' have 17.8 percent higher costs. Please see Table 20 below.

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Table 20

Modeled case-mix adjustment for an expanded ESRD prospective payment system

Comparison of payment models with vs. without patient race/ethnicity

Variable	Modeled case-mix adjustment[1]		
	Payment model without race/ethnicity	Payment model with race and ethnicity from REMIS/CMS Form 2728	Payment model with race from the Medicare Enrollment Database (EDB)
	$Multiplier_{EB}$	$Multiplier_{EB}$	$Multiplier_{EB}$
Adjustments for dialysis patient characteristics			
Age			
18-44	1.194	1.154	1.158
45-59	1.000	1.000	1.000
60-69	1.012	1.001	1.001
70-79	1.057	1.038	1.011
80+	1.076	1.037	1.008
Female	1.132	1.080	1.058
Race/ethnicity			
American Indian / Alaskan Native (Form 2728) or North American Native (EDB)	--	1.126	1.074
Asian / Pacific Islander (Form 2728) or Asian (EDB)	--	1.000	1.000
Black	--	1.207	1.178
White	--	1.142	1.119
Other	--	1.645	0.939
Hispanic[2]	--	1.000	0.956
Non-Hispanic[2]	--	1.065	--
Body surface area (per 0.1 m^2)	1.034	1.014	1.006
Underweight (BMI <18.5)	1.020	1.012	1.013
Duration of RRT: <4 months	1.473	1.493	1.439
Alcohol/drug dependence (claims since 2000 or 2728)	1.150	1.085	1.074
Cardiac arrest (claims since 2000 or 2728)	1.032	1.035	1.034
Pericarditis from same month to three months ago	1.195	1.195	1.195
HIV/AIDS (claims since 2000 or 2728)	1.316	1.197	1.237
Hepatitis B (claims since 2000)	1.089	1.083	1.081
Specified infection from same month to three months ago			
Septicemia	1.234	1.230	1.231
Bacterial pneumonia and other pneumonias/opportunistic infections	1.307	1.414	1.407
Gastro-intestinal tract bleeding from same month to three months ago	1.316	1.307	1.307
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.226	1.188	1.187
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.128	1.080	1.087
Myelodysplastic syndrome (claims since 2000)	1.084	1.093	1.093
Monoclonal gammopathy (claims since 2000)	1.021	1.017	1.017
Low volume facility adjustment			
Facility size < 3,000 treatments during each year from 2004-06	1.202	1.209	1.202

[1]The combined payment multipliers for patient characteristics were calculated as PmtMultEB = WeightCR×PmtMultCR +

WeightSB×PmtMultSB, where PmtMultCR is the estimated multiplier from a facility level model of composite rate costs and PmtMultSB is the estimated multiplier from a patient level model of separately billable costs. Based on total estimated costs of $169.67 per session for composite rate services, $82.45 per session for separately billable services, and $252.12 per session for an expanded bundle ($169.67+$82.45), the relative weights are WeightCR=0.673 for composite rate services ($169.67/$252.12) and WeightSB=0.327 for separately billable services ($82.45/$252.12).

[2]Hispanic ethnicity is reported separately from race on CMS Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

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c. Concerns With Available Race/Ethnicity Data

There are several specific concerns with the quality of the REMIS and the EDB data. The race and ethnicity data in REMIS have been collected with different versions of the Medical Evidence Report Form, making it difficult to accurately assess the effect of race and ethnicity on composite rate costs and separately billable payments. That is, a significant portion of the payment is reflected in the default category ''Other''. In addition, while not relevant for purposes of modeling the ESRD PPS, we are concerned about relying on the race and ethnicity data collected from the Medical Evidence Report Form for purposes of future refinements to the ESRD PPS. This form is routinely completed and signed by the physician at the ESRD facility. To mitigate the potential for provider manipulation of Medical Evidence Report Form in the interest of racial or ethnic payment adjustment, we would expect that ESRD facilities would accurately document race or ethnicity within the patient's medical record along with any care planning activities that may be based on the individual's race or ethnicity. There are also concerns related to relying on EDB data for modeling race and ethnicity data within the proposed ESRD PPS. Specifically, race and ethnicity classification on behalf of some segments of the population is either unavailable or defaulted into the ''Unknown'' category within EDB, for example, RRB beneficiaries that entered the RRB system prior to 1964. In addition, we have concerns regarding the race and ethnicity data for individuals entering the SSA system via the enumeration at birth (EAB) process that has been in place since 1989. The EAB process allows the parent, at the time of the child's birth, to indicate on the child's birth certificate that they are interested in obtaining a social security number (SSN) for their child. Therefore, the parent is not required to file a separate application for an SSN for the child. The State vital statistics office receives the request with the birth registration data from the hospital and then forwards this information to SSA. Absent the SS–5 form that includes race and ethnicity fields, we are not aware of any current mechanism by which these data elements are captured by the SSA on behalf of individuals entering the SSA system via the EAB process.

We note that relying on EDB data for purposes of ESRD PPS modeling is that they are not updated in real time. To the extent a beneficiary completes a new SS–5 form for any of the reasons discussed above and there are changes in race information, those changes are not currently reflected in CMS' EDB data in real time. Rather, they occur only after the annual NUMIDENT update.

In addition to the REMIS and EDB data concerns, racial and ethnic categories are not well defined as evidenced by the ongoing changes to the instruments used in collecting these data. Lastly, it is not possible to quantify an individual's race absent a genetic test to determine racial status. This presents the greatest challenge when considering individuals who identify with more than one race. Collection tools such as the SSA's SS–5 form and the Census Bureau's survey instrument depend on the individual to self select the one racial category with which they associate. While the current Medical Evidence Report Form allows for selection of more than one racial category, absent a mechanism for establishing a primary race, it is difficult to conduct comparisons without first defaulting those with multiple race selections into the ''Other'' category.

In summary, the analyses of REMIS and EDB race and ethnicity data demonstrate associations between these patient characteristics and facility level composite rate costs and patient level separately billable payments. As such, including these factors may improve the predictive value of the proposed ESRD PPS. However, we have concerns about whether the data are of sufficient quality upon which to base payment adjustments. The race or ethnicity status designations within the current CMS data systems may fall short in assigning individuals to the most correct racial and ethnic categories and reflecting the unique and measurable traits of individuals. As a result, ESRD facilities may be overpaid for certain patients and underpaid for others. However, to the extent that including race and ethnicity in the model explains additional variation in treatment costs not otherwise reflected, such adjustments may be warranted. We specifically invite public comment on the data issues presented in this section, other data sources for race and ethnicity we should consider, and specifically, the need for adjustments for race and ethnicity in the final ESRD PPS. It is important to note that any adjustments for race would result in additional reductions to the base rate through the standardization process described in section VII.C.

d. CMS Initiatives to Evaluate Health Disparities Based on Race and Ethnicity

In accordance with MIPPA, we plan to explore opportunities for improving Medicare program data on race and ethnicity. Specifically, section 185 of MIPPA amends the Act to add new section 1809 entitled ''Addressing Health Care Disparities.'' This section charges the Secretary with several key

tasks and goals including (1) evaluating approaches for Medicare data collection that will allow for collection and evaluation of data on disparities in health care services and performance based on race, ethnicity and gender; (2) submitting several Reports to Congress that describe the evaluation of Medicare data and make recommendations for improving the identification of health care disparities for Medicare beneficiaries; and (3) implementing the identified approaches for the ongoing, accurate, and timely collection and evaluation of data on health care disparities on the basis of race, ethnicity and gender.

In addition to the tasks associated with MIPPA section 185 that will focus on addressing health care disparities, health care disparities across several settings of care are currently being monitored by the Quality Improvement Organization (QIO) Program. In three cases, active intervention projects are underway to reduce health care disparities. As part of this department-wide effort, we will continue to explore additional approaches to improve the accuracy of this data. Some of these approaches will involve cooperation with entities outside of the Department of Health and Human Services (for example, the SSA), as described above. The first Report to Congress summarizing the possible approaches is due January 1, 2010.

In summary, we believe that the analyses that we will conduct for purposes of developing the Reports to Congress will serve as the basis for improving the accuracy of Medicare race and ethnicity data.

7. Modality

Section 1881(b)(14)(D)(iv) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretionary authority to establish an ESRD PPS, which may include payment adjustments as the Secretary determines appropriate. PD, which is the primary mode for home dialysis, is a substantially less costly mode of dialysis compared to in-center HD. Therefore, the Act gives the Secretary the authority to develop an ESRD PPS, which would establish payment rates based on dialysis modality.

Table K.5 from the 2008 Annual Data Report of the U.S. Renal Data System indicates that the average annual cost for all HD patients in 2006 was $71,889, whereas the corresponding figure for PD patients was $53,327 (Table K.7). Data from the Medicare cost reports and Medicare claims for CYs 2004–2006 show a similar difference in resource utilization, with PD patients incurring significantly lower composite rate and separately billable expenses.

COMPARISON OF COMPOSITE RATE COSTS BY MODALITY, CY 2004–06 [1]

Facility type	Hemodialysis		Peritoneal dialysis	
	Facility years (n)	Average composite rate cost per treatment	Facility years (n)	Average composite rate cost per treatment
Freestanding	11,058	$159.60	3,839	$150.39
Hospital based	878	248.92	349	155.99
Total	11,936	168.99	4,188	151.15

[1] Based on the Medicare Independent Renal Dialysis Facility and Hospital Cost Reports. ESRD facilities that opened or closed or reported less than one full dialysis patient year for the modality (156 hemodialysis-equivalent treatments) during the calendar year were excluded. Excludes potential outliers using a standard outer fence methodology that was applied on the log scale. Average CR costs were weighted by the total hemodialysis-equivalent treatments in the facility.

COMPARISON OF SEPARATELY BILLABLE MEDICARE ALLOWABLE PAYMENTS BY MODALITY, CY 2004–06 [1]

Hemodialysis		Peritoneal dialysis	
Patient facility months (n)	Average separately billable MAP per treatment	Patient facility months (n)	Average separately billable MAP per treatment
2,817,067	$87.20	186,296	$35.15

[1] Based on the Medicare claims. MAP for the top 11 injectable drugs were repriced to reflect the payment rates used in the first quarter of 2008. MAP for EPO were capped at 30,000 units per treatment. Average SB MAPs were weighted by the Medicare hemodialysis-equivalent treatments in each patient facility month.

Despite this distinction, we are proposing not to develop an ESRD PPS which uses type of dialysis modality as a payment variable, despite the increased predictive power a modality variable would yield 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 PD patients from the average payment amount that would apply to HD patients. We believe that 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. Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we are proposing an ESRD PPS which does not rely on separate payment rates based on modality. 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 believe home dialysis will be encouraged for patients able to use PD. We invite comment on this approach.

However, we note that the case-mix adjustments we are proposing for pediatric patients, described in section IX. of the proposed rule, distinguish 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 section IX., use modality, in part, to determine the case-mix adjusters for pediatric dialysis patients. Except for pediatric patients, modality is not otherwise used in developing the proposed case-mix adjustments under the ESRD PPS.

C. Proposed Facility-Level Adjustments

1. 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, as the Secretary determines to be appropriate.

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 that we intended to update the 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 section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685; 73 FR 69758). We apply the current ESRD wage index to a 53.711 labor share of the composite rate. As we indicated, this labor 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.

For purposes of the current basic case-mix adjusted composite payment system, section 1881(b)(12)(D) of the Act required the Secretary to adjust payment rates, as the Secretary determined appropriate, and if the Secretary applied a geographic adjustment that differed from the current index applied under the old (composite rate) system, the Secretary would be required to phase in such an index over a multi-year period. Under this authority, CMS elected a 4-year transition from the wage index based on MSAs to an updated wage index based on CBSAs. This 4-year transition began in CY 2006 and ended in CY 2009, when ESRD facilities receive a wage adjusted composite rate that is computed using 100 percent CBSAs in CY 2009 (70 FR 70167).

For the proposed ESRD PPS, we are proposing 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 propose that the ESRD wage index values used in the proposed ESRD PPS be calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act, and utilize pre-floor hospital data that are unadjusted for occupational mix. We also propose to use the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values. 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, as we indicated above, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We propose that this and all subsequent ESRD PPS rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index. The OMB bulletins may be accessed online at: *http://www.whitehouse.gov/omb/bulletins/index.html.* Consistent with those definitions, we are proposing to define urban and rural areas in proposed § 413.231(b) of this proposed rule as follows: The term ''urban area'' would mean 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. The term ''rural area'' would mean any area outside an urban area.

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, and 0.70 in CY 2009 (73 FR 69758). We also stated that a gradual reduction was needed to ensure that 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.

For the ESRD PPS proposed rule, we are proposing not to adopt a wage index floor, as we believe we have provided a gradual reduction to the ESRD wage index floor through the existing basic case-mix adjusted composite payment system and that the impact on ESRD facilities will be minimal. We note 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 will be gradually increased from 25 percent of their payments in 2011 to 100 percent of their payments in 2014. We intend 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. Applying a gradual reduction only to the floor that applies to the existing basic case-mix adjusted composite payment system ESRD wage index will accelerate the decline in the floor so that ESRD facilities are less dependent on the floor and at the end of the transition we would apply their actual wage index values.

In CY 2006, while adopting the CBSA designations, 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, and we provide the details of these policies below (72 FR 66283). The areas with ESRD facilities that have no hospital data are rural Massachusetts, rural Puerto Rico, and Hinesville, GA (CBSA 25980). In the CY 2008 PFS final rule with comment (72 FR 66283), we stated that we would continue to evaluate exiting hospital wage data and possibly wage data from other sources such as the Bureau of Labor Statistics, to determine if other methodologies might be appropriate for imputing wage index values for areas without hospital wage data for CY 2009 and subsequent years. To date, no data from other sources, superior to that currently used in connection with the inpatient hospital PPS wage index, have emerged. Therefore, for purposes of the proposed ESRD PPS, we are proposing to continue with our current policies for rural Massachusetts and Hinesville, Georgia:

- For rural Massachusetts, we propose to adopt the methodology originally adopted for CY 2008 for establishing a wage index value for rural Massachusetts. Because we had used the same wage index value for 2 years with no update, we believed it was appropriate to establish a methodology which employed reasonable proxy data for rural areas (including rural Massachusetts) and also permitted annual updates to the wage index based on that proxy data. We used the average wage index values from all contiguous CBSAs as a reasonable proxy for rural Massachusetts. In determining an imputed rural wage index, we interpret the term ''contiguous'' to mean sharing a border. In the case of Massachusetts, 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-MA. We propose to continue to use this methodology that averages the wage index values for the contiguous CBSAs, Barnstable Town, MA (CBSA 12700) and Providence-New Bedford-Fall River, RI-MA (CBSA 39300) for an imputed wage index value for rural Massachusetts for CY 2011.
- For Hinesville, GA (CBSA 25980), which is an urban area without specific hospital wage data, we propose to continue to use the methodology that was adopted in the CY 2007 PFS final rule (71 FR 231), which was to impute a wage index value for Hinesville, GA, using the average proposed ESRD wage index value for all urban areas within the State of Georgia.

With regard to rural Puerto Rico, we are proposing a different policy under the proposed ESRD PPS. 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 floor. However, as we stated earlier in this section, for the proposed ESRD PPS, we are proposing to eliminate the use of a wage index floor under the proposed ESRD PPS wage index. Therefore, for rural Puerto Rico, we propose to use the value for rural Puerto Rico (0.4047) that has been used by other payment systems that do not use a wage index floor. This wage index value is the latest available wage index value for rural Puerto Rico and is currently used for rural Puerto Rico by other payments systems that do not have a wage index floor. We note that there are currently no ESRD facilities located in rural Puerto Rico.

We are also proposing to use the labor share as measured by the proposed ESRD bundled market basket, which is 38.160 percent (as described in section XII. of this proposed rule). We note that the labor-related share from the proposed ESRD bundled market basket (38.160 percent) is lower than the labor-related share from the existing ESRD composite rate index (53.711 percent) because there are no labor costs associated with the separately billable portion of the proposed ESRD bundled market basket. Our proposed adjustment for wages is set forth in proposed § 413.231. For this proposed rule, we used the most current final wage index that was available at the time analysis was completed. This was the final CY 2009 wage index data. As stated earlier in this section, the ESRD wage index values used in the basic case-mix adjusted composite payment system are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685; 73 FR 69758). We are proposing to use the same wage index for the ESRD PPS.

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 values. Since the CY 2009 ESRD wage index has the same values as the FY 2009 SNF PPS wage index, we recommend that entities wishing to replicate our analysis refer to the FY 2009 final rule where the FY 2009 Skilled Nursing Facility (SNF) PPS wage index was published. The FY 2009 SNF PPS final rule (73 FR 46415) includes tables with these wage index values. Table 8 shows the wage index values for urban areas (73 FR 46441 through 46462) and table 9 shows the wage index values for rural areas (73 FR 46462).

Since the ESRD PPS will be implemented in CY 2011, we believe it is appropriate to use CY 2011 wage index values. However, the wage data will not yet be available when the ESRD PPS final rule is published. Therefore, we propose to include 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. We anticipate that this would be published in the CY 2011 Physician Fee Schedule proposed rule, which we expect to be published in the summer of 2010. We also propose 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. We anticipate that this would be published in the CY 2011 Physician Fee Schedule final rule, which we expect to be published in November of 2010.

2. Low-Volume Adjustment

a. Statutory Authority

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.''

b. 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. We believe 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. UM–KECC has 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 what is a low-volume facility.

To begin our process of developing the methodology for defining a low-volume facility, we set parameters for ESRD facility size. In this explanation and throughout this section, the term 'year' is established by the ESRD facility's final-settled cost report, where the final-settled cost report reports costs for 12-consecutive months. Under the initial categorization, an ESRD facility with less than 5,000 treatments per year was considered small, a ESRD facility with 5,000 to 10,000 treatments per year was considered medium, and an ESRD facility with 10,000 treatments per year or more was considered large. The average ESRD facility size is relatively close to 10,000 treatments and this threshold has been used by others, for example, MedPAC.

With the data compiled and analyzed by UM–KECC, we were interested to see the distribution of ESRD facility size across the different ESRD facility ownership types. For purposes of defining a low-volume facility, we chose to categorize 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 are independent, 10.7 percent are members of a regional chain/other category, 0.7 percent are members of an LDO, and 13.2 percent have unknown chain status. UM–KECC's comparison between ESRD facility size and ownership type, (Table 21: ESRD facility size and ownership type, 2004–2006), indicated that ownership varies with ESRD facility size and smaller ESRD facilities, especially those with less than 3,000 treatments, are relatively more likely to be independent than larger ESRD facilities. For example, 31 percent of ESRD facilities with less than 3,000 treatments are independent while only 18 percent of ESRD facilities with more than 10,000 treatments are independent.

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Table 21

ESRD facility size and ownership type, 2004-06

Preliminary

December 4, 2008

Total dialysis sessions at ESRD facility based on Cost Reports	ESRD facility ownership type										
	Independent		Regional chain		Large dialysis organization (LDO)*		Unknown		All		
	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	% of column
<5,000	588	23.7%	298	12.0%	1,521	61.4%	70	2.8%	2,477	100.0%	20.3%
<2,000	131	37.3%	47	13.4%	147	41.9%	26	7.4%	351	100.0%	2.9%
2 to 3,000	140	27.0%	63	12.1%	301	58.0%	15	2.9%	519	100.0%	4.2%
3 to 4,000	156	20.7%	86	11.4%	493	65.4%	19	2.5%	754	100.0%	6.2%
4 to 5,000	161	18.9%	102	12.0%	580	68.0%	10	1.2%	853	100.0%	7.0%
5 to 10,000	628	15.3%	361	8.8%	3,079	75.2%	29	0.7%	4,097	100.0%	33.5%
Total	2,277	18.6%	1,233	10.1%	8,500	69.6%	203	1.7%	12,213	100.0%	100.0%

* LDO status includes Fresenius, Davita, and Dialysis Clinic Inc. along with the following recent acquisitions:

Renal Care (acquired by Fresenius), Gambro (acquired by Davita), and National Nephrology Associates (acquired

by Renal Care in 2004 before Renal Care was acquired by Fresenius).

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UM–KECC's comparison also indicated that while smaller ESRD facilities are less likely to be members of an LDO than larger ESRD facilities, a relatively large fraction of smaller ESRD facilities are members of an LDO. For an example, 61.4 percent of ESRD facilities with less than 5,000 treatments and 41.9 percent of ESRD facilities with less than 2,000 treatments are 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 varies by ESRD facility ownership type within a ESRD facility size category.

With the data analyzed by UM–KECC, we were also interested to see the distribution of ESRD facility size across ESRD facilities that have an urban or rural status. UM–KECC's comparison of ESRD facility size and urban/rural status, (Table 22: ESRD facility size and rural status, 2004–2006 (n=11,814)), indicated that nearly half of the small ESRD facilities are rural and larger ESRD facilities are less likely to be rural.

TABLE 22—ESRD FACILITY SIZE AND RURAL STATUS, 2004–2006 (N=11,814)*

[Preliminary]

Total dialysis sessions at ESRD facility based on Cost Reports	ESRD facility rural status								
	Rural			Urban			All		
	Facility years (n)	% of row	% of column	Facility years (n)	% of row	% of column	Facility years (n)	% of row	% of column
<1,000	11	19.6	0.4	45	80.4	0.5	56	100	0.5
1 to 2,000	78	47.3	2.9	87	52.7	1.0	165	100	1.4
2 to 3,000	210	49.3	7.7	216	50.7	2.4	426	100	3.6
3 to 4,000	312	44.4	11.5	390	55.6	4.3	702	100	5.9
4 to 5,000	334	41.1	12.3	481	59.0	5.3	815	100	6.9
5 to 10,000	1164	28.8	42.8	2877	71.2	31.6	4041	100	34.2
10,000+	611	10.9	22.5	4998	89.1	55.0	5609	100	47.5
Total	2720	23	100.0	9094	77	100.0	11814	100	100.0

* Excludes facilities that opened or closed during the year. Based on data reported in SIMS.

UM–KECC's comparison also indicated that because most ESRD facilities are 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 chose to use urban/rural status as a variable in a two-equation regression analysis to test whether cost varies by urban/rural status within a ESRD facility size category.

UM–KECC was able to develop a two-equation regression analysis using the variables discussed above (Table 23: Analysis for ESRD facility size, rural/urban status, and ownership type, 2004–2006 Model 2 and Table 24: Analysis for ESRD facility size, rural/urban status, and ownership type, 2004–2006 Model 4).

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Table 23
Analysis for facility size, rural/urban status, and ownership type, 2004-2006^, Model 2
Preliminary
December 17, 2008

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 46.08% Average $169.67/session		****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.73% Average $82.45/session		
Variable	CR Multiplier	p-value	SB Multiplier	p-value	Combined
Facility: < 1,000 treatments, Rural	1.410	0.1396	0.713	<.0001	1.182
Facility: < 1,000 treatments, Urban	1.792	<.0001	0.899	0.0151	1.500
Facility: 1,000 - 1,999 treatments, Rural	1.414	<.0001	0.953	0.012	1.263
Facility: 1,000 - 1,999 treatments, Urban	1.558	<.0001	1.110	<.0001	1.411
Facility: 2,000 - 2,999 treatments, Rural	1.413	<.0001	0.930	<.0001	1.255
Facility: 2,000 - 2,999 treatments, Urban	1.427	<.0001	0.947	<.0001	1.270
Facility: 3,000 - 3,999 treatments, Rural	1.297	<.0001	0.978	0.0027	1.193
Facility: 3,000 - 3,999 treatments, Urban	1.329	<.0001	1.010	0.1501	1.225
Facility: 4,000 - 4,999 treatments, Rural	1.208	<.0001	0.960	<.0001	1.127
Facility: 4,000 - 4,999 treatments, Urban	1.255	<.0001	1.018	0.002	1.177
Facility: 5,000 - 9,999 treatments, Rural	1.121	<.0001	0.984	<.0001	1.076
Facility: 5,000 - 9,999 treatments, Urban	1.122	<.0001	1.017	<.0001	1.087
Facility: 10,000+ treatments, Rural	1.001	0.9319	0.997	0.3507	0.999
Facility: 10,000+ treatments, Urban	1.000	ref	1.000	ref	1.000
Large dialysis organization (chain1-chain6)	1.017	0.0002	1.157	<.0001	1.063
Regional chain	1.024	<.0001	1.059	<.0001	1.036
Unknown chain status	1.049	<.0001	1.002	0.7254	1.034
Independent facility	1.000	ref	1.000	ref	1.000
Hospital-based facility***	1.442	<.0001	1.022	<.0001	1.304

^Excludes facilities that opened or closed during the year and patients treated in those facilities during that year. Based on data reported in SIMS.

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro- intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

***Of hospital-based facilities, 75.5% are independent, 10.7% are members of a regional chain/other organization, 0.7% are members of an LDO, and 13.2% have unknown chain status.

Table 24
Analysis for facility size, rural/urban status, and ownership type, 2004-2006, Model 4
Preliminary
December 17, 2008

	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 46.26% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.71% Average $82.45/session		
Variable	CR Multiplier	p-value	SB Multiplier	p-value	Combined
Fac: <3,000 treatments, rural, LDO	1.480	<.0001	0.917	<.0001	1.296
Fac: <3,000 treatments, rural, not LDO	1.327	<.0001	0.950	0.0002	1.204
Fac: <3,000 treatments, urban, LDO	1.604	<.0001	0.957	0.0012	1.392
Fac: <3,000 treatments, urban, not LDO	1.321	<.0001	1.004	0.7802	1.217
Fac: 3,000-5,000 treatments, rural, LDO	1.288	<.0001	0.983	0.0056	1.188
Fac: 3,000-5,000 treatments, rural, not LDO	1.163	<.0001	0.939	<.0001	1.090
Fac: 3,000-5,000 treatments, urban, LDO	1.318	<.0001	1.010	0.059	1.217
Fac: 3,000-5,000 treatments, urban, not LDO	1.206	<.0001	1.027	0.0011	1.147
Facility: 5,000 - 9,999 treatments	1.122	<.0001	1.007	<.0001	1.084
Facility: 10,000+ treatments	1.000	ref	1.000	ref	1.000
Large dialysis organization (chain1-chain6)	1.010	0.0377	1.157	<.0001	1.058
Regional chain	1.024	<.0001	1.060	<.0001	1.036
Unknown chain status	1.047	<.0001	1.001	0.8261	1.032
Independent facility	1.000	ref	1.000	ref	1.000
Hospital-based facility***	1.438	<.0001	1.021	<.0001	1.302

^Excludes facilities that opened or closed during the year and patients treated in those facilities during that year. Based on data reported in SIMS.

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, HIV/AIDS, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro-intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

***Of hospital-based facilities, 75.5% are independent, 10.7% are members of a regional chain/other organization, 0.7% are members of an LDO, and 13.2% have unknown chain status.

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In Table 23, UM–KECC split the ESRD facility size variable into 7 categories including rural/urban status with increments of 1,000 treatments (<1,000, 1,000–1,999, 2,000–2,999, 3,000–3,999, 4,000–4,999, 5,000–10,000, and 10,000+). They then estimated ESRD facility-level models for composite rate costs and patient-level models for separately billable MAP per treatment. UM–KECC attempted to exclude ESRD facilities whose small number of treatments might be a temporary phenomenon (for example, ESRD facilities that opened, changed ownership, or closed). This was done using the initial certification date reported in OSCAR and the date of ESRD facility closure reported in SIMS. Changes of ownership where the new owner of the existing ESRD facility continues under the existing ESRD facility's provider number were included in the analysis. UM–KECC's analysis indicated that composite rate costs per treatment decline substantially as ESRD facility size increases and separately billable MAPs per treatment do not change substantially by ESRD facility size. UM–KECC's analysis also indicated that by controlling for ESRD facility size, being a member of an LDO does not lower costs and rural ESRD facilities do not report higher costs than urban ESRD facilities.

UM–KECC's two-equation regression analysis gave us the ability to see what other factors can be targeted to ensure that we have the right population of ESRD facilities that are low-volume. From UM–KECC's comparisons discussed above, we were able to determine that small rural ESRD facilities did not have higher composite rate costs in any of the small ESRD facility categories when compared to small urban ESRD facilities. In Table 24 we were able to see interactions between LDO status/small ESRD facility size/rural vs. urban status. We found that small ESRD facilities owned by LDOs were shown to have higher costs than small ESRD facilities that are non-LDOs.

We further evaluated how many dialysis treatments per year would best describe low-volume. As mentioned above, we began with our definition of a small ESRD facility, that is, less than 5,000 treatments. UM–KECC was able to provide us with another two-equation regression analysis that controlled for ESRD facility size and divided the small ESRD facility size variable into 3 categories; less than 2,000 treatments, less than 3,000 treatments, and less than 4,000 treatments. (Table 25: Analysis for low-volume ESRD facility size, 2004–2006).

TABLE 25—ANALYSIS FOR LOW-VOLUME ESRD FACILITY SIZE, 2004–2006—INCLUDE ADDITIONAL CONTROLS FOR ESRD FACILITY SIZE: MODEL 1

[Preliminary January 29, 2009]

Variable	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 45.8%, Average $169.67/session			**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.7%, Average $82.45/session			Combined payment multiplier^
	Modeled CR multiplier	p-value	CR payment multiplier^	Modeled CR multiplier	p-value	CR payment multiplier^	
Facility size < 2,000 treatments during each year from 2004–06	1.497	<.0001	1.439	0.878	0.0929	0.876	1.254
Facility size < 2,000 treatments during current year but not during all 3 years	1.520	<.0001	1.000	1.055	0.0002	1.000	1.000
Facility size 2,000–4,999 treatments	1.290	<.0001	1.000	0.992	0.0101	1.000	1.000
Facility size 5,000–9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.4674		0.981	<.0001		

TABLE 26—MODEL 2

Variable	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 46.0%, Average $169.67/session			**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.7%, Average $82.45/session			Combined payment multiplier^
	Modeled CR multiplier	p-value	CR payment multiplier^	Modeled CR multiplier	p-value	CR payment multiplier^	
Facility size < 3,000 treatments during each year from 2004–06	1.383	<.0001	1.330	0.940	<.0001	0.938	1.202
Facility size < 3,000 treatments during current year, but not during all 3 years	1.478	<.0001	1.000	0.976	0.0036	1.000	1.000
Facility size 3,000–4,999 treatments	1.268	<.0001	1.000	1.000	0.9622	1.000	1.000
Facility size 5,000–9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.4419		0.981	<.0001		

TABLE 27—MODEL 3

Variable	*Facility level log-linear model of average cost per session (n=11,814) R-sq: 45.9%, Average $169.67/session			**Patient level log-linear model of MAP per session (n=890,776) R-sq: 8.7%, Average $82.45/session			Combined payment multiplier^
	Modeled CR multiplier	p-value	CR payment multiplier^	Modeled CR multiplier	p-value	CR payment multiplier^	
Facility size < 4.000 treatments during each year from 2004–06	1.348	<.0001	1.300	0.978	0.0002	0.976	1.194
Facility size < 4,000 treatments during current year, but not during all 3 years	1.373	<.0001	1.000	0.997	0.5825	1.000	1.000
Facility size 4,000–4,999 treatments	1.237	<.0001	1.000	0.999	0.766	1.000	1.000
Facility size 5,000–9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.427		0.981	<.0001		

^ The potential low-volume payment adjustment was calculated relative to all other facilities combined (i.e., using a weighted average of the other ESRD facility size coefficients).

* Other variables included in the CR model are age, female, body surface area, duration of RRT: <4 month, alcohol/drug dependence, HIV/AIDS, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, ESRD facility ownership type, composite rate payment exception, and % of patients in the ESRD facility with URR <65%.

** Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT: <4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, ESRD facility ownership type, composite rate payment exception, and % of patients in the ESRD facility with URR <65%.

We found that the cost multipliers for small ESRD facilities are greater than 1.1 for any of the definitions for small ESRD facility size with respect to number of treatments per year and that they decline for successively higher cutoffs for defining small ESRD facilities. We also found that if a payment multiplier fully reflects the cost multiplier, there will be a strong disincentive for ESRD facilities to increase volume above cutoff. However, to the extent that a payment multiplier is smaller than the cost multiplier, this disincentive is somewhat diminished.

Since UM–KECC's 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 paragraph's 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.

In this evaluation, we excluded ESRD facilities that opened, changed ownership, or closed during any one of the 3 years used for data. Status as a ''closed'' ESRD facility was based on information in the SIMS that the ESRD facility closed. Status as an ''opening'' ESRD facility was based on the initial Medicare certification date reported in OSCAR. Changes of ownership where the new owner of an existing ESRD facility continues under the existing ESRD facility's provider number were included in the analysis. We found there were 25 dialysis ESRD facilities that provided less than 2,000 treatments annually across the 3-year period (2004–2006), 89 ESRD facilities provided less than 3,000 treatments annually across the 3-year period, and 241 ESRD facilities provided less than 4,000 treatments annually across the 3-year period. These data indicate that ESRD facilities that provide less than 2,000 treatments per year across the 3-year period would result in low-volume adjustments being applied to very few ESRD facilities. These data also indicate that ESRD facilities that provide less than 4,000 treatments across the 3-year period would apply to almost 10 times more the number of ESRD facilities that provided less than 2,000 treatments and almost 3 times more the number of ESRD facilities that provided less than 3,000 treatments.

Accordingly, we propose to use a threshold of ESRD facilities that provide less than 3,000 treatments per year across the 3-year period. The threshold at 3,000 treatments strikes a balance between establishing an increment in payment that reflects the substantially higher treatment costs incurred by low-volume facilities (an increment that decreases relatively quickly as the low-volume threshold is raised) but still applies to a sufficiently large number of ESRD facilities to have an impact.

As mentioned above, the statute gives the Secretary the authority to define ''low-volume facilities''. Based on the above results, we propose in § 413.232, that a ''low-volume facility'' is 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. In the event an ESRD facility provides 3,000 or more treatments during their payment year, that is, no longer eligible for the low-volume adjustment; the ESRD facility would stop receiving the adjustment at the time they reach their 3,000th treatment. Where a change of ownership occurs and the new owner receives a new provider number during the 3-year period, the ESRD facility would not be eligible for the adjustment until it demonstrates that it meets the low-volume criteria under its new provider number. We are aware that there are Medicare-certified ESRD facilities that solely furnish support services and training for home peritoneal dialysis and home hemodialysis ESRD beneficiaries. Therefore, we are concerned that it may not be appropriate to extend low-volume eligibility to these types of facilities. We also are concerned that a treatment threshold may create an incentive for ESRD facilities to turn away patients rather than lose their low-volume status. We are requesting comment on the change of ownership element of our proposed definition, the appropriateness of applying the low-volume adjustment to training ESRD facilities, and the possible unintended effects of having a treatment threshold.

We believe that this approach would identify appropriate ESRD facilities for an adjustment and provide access to care for a vulnerable patient population. Under this proposal, new ESRD facilities would not be able to benefit from a low-volume adjustment until the 4th year in operation. For example, an ESRD facility opening in 2008 would need to meet the low-volume criteria for 2009, 2010, and 2011 to be eligible for the low-volume adjustment in 2012.

We are very concerned about potential misuse of the proposed 20.2 percent low-volume adjustment (the proposed figure is discussed below). Specifically, our concern is 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 are proposing additional criteria described below in connection with the proposed definition discussed above.

We propose, for purposes of determining the number of treatments under the proposed definition of a low-volume facility, that 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. Under our proposal, ''common ownership'' means the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more of each ESRD facility. Our intention is to create a disincentive for commonly-owned ESRD facilities to purposively establish new ESRD facilities in close geographic proximity to other ESRD facilities, which could lead to unnecessary inefficiencies. The 25 road mile threshold is a standard that is used for low-volume adjustments in Medicare. For example, this criterion is used in the prospective payment system for inpatient hospital services. We are soliciting comment on our proposed definition of a ''low volume facility'' and our proposed geographic requirement with regard to determining the number of treatments furnished. We are also requesting comment concerning other potential vulnerabilities of the proposed low-volume definition and ways to address them.

Although we propose to limit the application of the low-volume adjustment to ESRD facilities with common ownership in a certain geographic location for purposes of determining the number of treatments under the proposed definition, we propose to grandfather those commonly owned ESRD facilities that have been in existence and certified for Medicare participation on or before December 31, 2010. Specifically, ESRD facilities that are in existence and certified for Medicare participation prior to January 1, 2011, will be exempt from treatment determination requirement and the geographic proximity restriction discussed above. We intend to monitor this grandfathering provision for abuse on a going forward basis and invite comment on the vulnerability it may present and ways to address them.

We also intend to work with our Regional Offices to monitor changes in the ESRD industry's behaviors and emerging trends in the ESRD industry nationwide. In this way, we would be able to monitor survey and certification activities and impose additional safeguards that maybe necessary in the interest of program integrity.

In order to identify which existing ESRD facilities meet the low-volume criteria, we propose that ESRD facilities could attest to the FI/MAC that they qualify as a low-volume facility. In this approach the FI/MAC would verify the ESRD facility's attestation of their low-volume status using the ESRD facility's final-settled cost reports. We invite comments on this approach and welcome other suggestions to identify

existing low-volume facilities. Instruction as to how the FIs/MACs would implement the proposed ESRD PPS will be provided in future guidance.

c. Defining the Percent of Increase

As discussed above, section 1881(14)(D)(iii) of the Act also requires the ESRD PPS to 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.'' Based on the definition described above and on the analysis discussed above in Table 26, Model 2, limiting the low-volume category to ESRD facilities that had not open, closed, or received a new provider number due to a change in ownership and remained small, that is, less than 3,000 treatments during all 3 years from 2004–2006 and including additional controls for ESRD facility size, the resulting low-volume payment adjustment was determined to be 20.2 percent. This chart takes into consideration paying the low-volume facilities based on the model's multiplier relative to the weighted average of the multipliers of the other ESRD facility size classes, therefore the extra payment would be calculated relative to an ESRD facility of typical size, not a ESRD facility in the largest size category.

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 (see Table 28: Measured costs, current payments and proposed payment per dialysis session for an expanded bundle, 2006).

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Table 28
Measured costs, current payments and proposed payments per dialysis session for an expanded bundle, 2006*
Low-volume facility definition: did not open or close and reported <3,000 total sessions for each year from 2004-06
Preliminary
February 12, 2009

	Dialysis facilities	Mean	Median	Percent of facilities with a given change in payment per session					
				Loss in payment of 10% or more	-10% to -5%	-5% to 0%	0% to 5%	5% to 10%	Gain in payment of 10% or more
Total									
Measured costs for an expanded bundle (CR+SB)	4,286	$256.64	$248.54	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	4,399	$153.49	$152.67	--	--	--	--	--	--
Separately billable services	4,399	$79.33	$78.66	--	--	--	--	--	--
Total	4,399	$232.82	$232.82	--	--	--	--	--	--
Proposed MAP for an expanded bundle									
No low-volume adjustment	4,399	$232.82	$230.16	10.7%	18.3%	25.1%	21.0%	12.1%	12.8%
Low-volume facility multiplier: 1.100	4,399	$232.82	$230.20	10.5%	18.1%	25.1%	20.8%	12.2%	13.3%
Low-volume facility multiplier: 1.150	4,399	$232.82	$230.25	10.5%	18.2%	25.0%	20.7%	12.1%	13.6%
Low-volume facility multiplier: 1.202	4,399	$232.82	$230.20	10.6%	18.2%	24.9%	20.5%	12.1%	13.7%
Low-volume facilities (as defined above)									
Measured costs for an expanded bundle (CR+SB)	88	$299.31	$289.55	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	89	$150.25	$148.84	--	--	--	--	--	--
Separately billable services	89	$73.66	$73.46	--	--	--	--	--	--
Total	89	$223.91	$221.93	--	--	--	--	--	--
Low-volume facilities (as defined above)									
Proposed MAP for an expanded bundle									
No low-volume adjustment	89	$224.27	$216.68	15.7%	14.6%	19.1%	19.1%	12.4%	19.1%
Low-volume facility multiplier: 1.100	89	$246.31	$237.73	4.5%	3.4%	9.0%	16.9%	15.7%	50.6%
Low-volume facility multiplier: 1.150	89	$257.32	$248.30	1.1%	3.4%	4.5%	12.4%	13.5%	65.2%
Low-volume facility multiplier: 1.202	89	$268.77	$259.47	1.1%	1.1%	3.4%	4.5%	13.5%	76.4%
Other facilities									
Measured costs for an expanded bundle (CR+SB)	4,198	$256.48	$248.39	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	4,310	$153.51	$152.71	--	--	--	--	--	--
Separately billable services	4,310	$79.35	$78.69	--	--	--	--	--	--
Total	4,310	$232.86	$232.88	--	--	--	--	--	--
Proposed MAP for an expanded bundle									
No low-volume adjustment	4,310	$232.86	$230.24	10.6%	18.4%	25.3%	21.0%	12.1%	12.7%
Low-volume facility multiplier: 1.100	4,310	$232.76	$230.14	10.6%	18.5%	25.4%	20.9%	12.1%	12.5%
Low-volume facility multiplier: 1.150	4,310	$232.71	$230.10	10.7%	18.5%	25.4%	20.8%	12.1%	12.5%
Low-volume facility multiplier: 1.202	4,310	$232.66	$230.05	10.8%	18.6%	25.3%	20.8%	12.1%	12.4%

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Based on the analysis provided by UM–KECC, we are proposing 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 is set forth in proposed § 413.232. We invite comments on the low-volume facility proposed adjustment.

For purposes of determining the appropriate adjustment for the low-volume facilities defined above, we are considering other options in addition to the 20.2 percent adjustment we described. 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. We

believe that adopting the statutory adjustment of 10 percent 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 which would apply to treatments furnished by all ESRD facilities.

Another option for the low-volume adjustment would be the midpoint between the statutory adjustment of 10 percent and the results of our data analysis which is 20.2 percent. We believe 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 invite comments on these alternative options for determining the percent low-volume adjustment.

3. 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 Hawaii and Alaska. 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 cost more because there are additional (higher) transportation costs incurred to receive the same supplies compared to an ESRD facility located in the mainland United States. 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 proposed ESRD PPS.

Our analysis continues to support that the proposed ESRD PPS would adequately reimburse ESRD facilities located in Alaska and Hawaii. Therefore, we are not proposing to adopt COLA adjustments for ESRD facilities in Alaska and Hawaii under the proposed ESRD PPS. We invite public comments on this proposal.

4. 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. Accordingly, we analyzed rural status as part of the regression analysis for the proposed ESRD PPS to inform our proposal for this rule.

As discussed previously in section VIII. C. 1. of the proposed rule, we are proposing to define rural facilities in proposed § 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. To decrease distortion among independent variables, rural facilities were considered control variables rather than payment variables.

We do not believe that the proposed ESRD PPS would result in decreased access to care for beneficiaries residing in rural areas based on the results of the impact analysis. Specifically, as illustrated in the impact table in Table 48, the proposed ESRD PPS reveals an overall decrease in payment of 2.5 percent for rural facilities under the proposed ESRD PPS in 2011 as compared to the current basic case-mix adjusted composite payment system. However, 2 percent of this amount is associated with the statutory requirement that payments under the ESRD PPS equal 98 percent of what ESRD facilities would have received had this ESRD PPS not been implemented (98 percent of payments to ESRD facilities under the current payment system). In summary, this analysis reveals that rural ESRD facilities would be adequately reimbursed under the proposed ESRD PPS.

We also included facility treatment volume as a control variable in the payment model. Based on the analysis conducted by UM–KECC, 66 of the 166 ESRD facilities that met the low volume criteria discussed further in section VIII.C.2 of this proposed rule are located in rural areas. Thus, some of the effects of rural status on cost and payment are captured via the low volume payment adjustments. Therefore, we are not proposing a facility level adjustment that is based on rural location. We invite public comments on this proposal.

5. Site Neutral ESRD PPS Rate

For dialysis services furnished prior to January 1, 2009, the basic case-mix 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, as amended by section 153(a)(2), requires a site neutral composite rate so that the payment rate for services furnished on or after January 1, 2009, by hospital-based facilities is the same as the payment rate paid to independent renal dialysis facilities under the current system. In addition, section 1881(b)(12)(A) of the Act, as amended by section 153(a)(2) of MIPPA, requires that in applying the geographic index to hospital-based facilities, the labor share shall be based on the labor share otherwise applied to the renal dialysis facilities. In the CY 2009 final rule (72 FR 69881 and 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, as amended by section 153(b) of MIPPA, 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 automatically be incorporated under the ESRD PPS and used to establish a single base rate that will apply to ESRD facilities.

D. Determination of ESRD PPS Payment Adjusters

We have described the selection of patient characteristics as potential case-mix adjusters using a modeling approach that has relied on separate regression equations for CR and SB services. 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. While the case-mix adjustments were based on separate estimating equations, the equations can be combined into a single payment formula for the ESRD PPS.

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Table 29				
Payment multipliers for an expanded bundle of services, ages 18 and older, 2004-06				
	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]	
	Composite rate services[1]	Separately billable services[2]		
Variable	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$	
Adjustments for dialysis patient characteristics				
Age				
18-44	1.280	1.018	1.194	
45-59	1.000	1.000	1.000	
60-69	1.014	1.006	1.012	
70-79	1.105	0.960	1.057	
80+	1.150	0.923	1.076	
Female	1.124	1.149	1.132	
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.035	1.033	1.034	
Underweight (BMI <18.5)	1.000^	1.060	1.020	
Time since onset of renal dialysis: <4 months	1.508	1.401	1.473	
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	1.139	1.150	
Cardiac arrest (claims since 2000 or 2728)	1.000^	1.098	1.032	
Pericarditis from same month to three months ago	1.000^	1.595	1.195	
HIV/AIDS (claims since 2000 or 2728)	1.363	1.220	1.316	
Hepatitis B (claims since 2000)	1.115	1.035	1.089	
Specified infection from same month to 3 months ago				
Septicemia	1.000^	1.715	1.234	
Bacterial pneumonia and other	1.256	1.412	1.307	
pneumonias/opportunistic infections				
Gastro-intestinal tract bleeding from same month to 3 months ago	1.000^	1.965	1.316	
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	1.179	1.226	
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	1.097	1.128	
Myelodysplastic syndrome (claims since 2000)	1.000^	1.257	1.084	
Monoclonal gammopathy (claims since 2000)	1.000^	1.063	1.021	

Low volume facility adjustment Facility size < 3,000 treatments during each year from 2004-06	1.383	0.940	1.202	
^A multiplier 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time 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 2004-06 (n=11,814 facility years). This model also 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%) and the percent of pediatric patients as additional covariates (R-sq=46.0%).				
[2]Based on a patient level log-linear regression model of separately billable Medicare Allowable Payments/session for 2004-06 (n=890,776 patient years) that included 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 (R-sq=8.7%).				
[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 costs. Based on total estimated costs of $169.67 per session for composite rate services, $82.45 per session for separately billable services, and $252.12 per session for an expanded bundle ($169.67+$82.45), the relative weights are $Weight_{CR}$=0.673 for composite rate services ($169.67/$252.12) and $Weight_{SB}$=0.327 for separately billable services ($82.45/$252.12).				
[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 1.383 and 0.940, 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 1.202. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.				

Table 29 shows how the payment adjusters from the separate CR and SB regressions were combined. The first two columns in Table 29 represent the CR and SB model results for each of the regression equations, carried to three significant figures. The third column of Table 29 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 2004–2006, as shown in Table 30.

Table 30
Estimated costs for composite rate and separately billable services, CY 2004-06[1]

	2004		2005		2006		Pooled, 2004-2006	
Measure of resource use	n	Average $ per treatment	n	Average $ per treatment	n	Average $ per treatment	n	Average $ per treatment
Facility composite rate costs[2]	3,794	$161.33	3,948	$168.09	4,072	$179.24	11,814	$169.67
Patient separately billable Medicare Allowable Payments (repriced)[3]								
Ages <18	719	$44.76	866	$52.42	790	$49.60	2,375	$49.11
Ages 18 and older	289,587	$82.97	297,718	$84.39	303,471	$80.07	890,776	$82.45

[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. MAP amounts were repriced to reflect 2008Q1 payment rates for the top injectable drugs.

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The weights were calculated using the 3 years of pooled data. Based on this analysis, the average cost for CR services per treatment as computed from the Medicare cost reports was $169.67. The average MAP per treatment for SB services based on Medicare claims for the same period was $82.45. Based on total estimated costs of $252.12 per treatment ($169.67 + $82.45), the relative weights are $weight_{CR}$ = 0.673 for composite rate services ($169.67/$252.12) and $weight_{SB}$ = 0.327 for separately billable services ($82.45/$252.12). The payment multipliers presented in the third column of Table 29 were calculated as $PmtMult_{EB} = 0.673 \times PmtMult_{CR} + 0.327\ PmtMult_{SB}$. 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 29) 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 29 of 1.000. For these co-morbidities, there is no payment adjuster for composite rate services. Therefore, the payment multiplier is equal to $0.673 \times 1.000 + 0.327 \times PmtMult_{SB}$. The payment multipliers in the third column of Table 29 reflect the combined results from the two-equation model previously described in this proposed rule, and represent the case-mix adjustment factors that we propose to apply to the base rate to compute the payment amount per treatment under the proposed ESRD PPS.

IX. Pediatric Patients

Section 1881(b)(14)(D)(iv)(I) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretionary authority to develop pediatric payment adjustments in connection with the ESRD PPS. Below we discuss the current system with regard to ESRD facilities that furnish renal dialysis services to pediatric patients, as well as our proposed methodology for developing a pediatric payment adjustment under the proposed ESRD PPS.

A. Current System

The current basic case-mix adjusted composite payment system uses a set of case-mix adjusters or multipliers based on three variables—age, BSA, and low BMI. Employing the same 2000 to 2002 data and regression methodology used to derive the basic case-mix adjusters, we attempted, when implementing the current payment system, to develop case-mix adjusters for outpatient ESRD patients under age 18. However, we found that for the approximately 600 Medicare pediatric patients for whom claims were available from 2000 through 2002, the results were highly variable and statistically unstable, and therefore, inappropriate for the development of case-mix adjusters in accordance with the same methodology otherwise applicable to adult Medicare ESRD patients (see 69 FR 66326–27 published November 15, 2004). Section 623(b)(1)(D) of the MMA amended section 422(a)(2) of BIPA to provide that beginning October 1, 2002, ESRD facilities in which at least 50 percent of patients are under age 18, are considered ESRD pediatric facilities, and are eligible for a pediatric exception to the composite payment rate. However, due to the relative costliness of pediatric ESRD patients, we believed that it was appropriate to develop a temporary methodology applicable to ESRD facilities, which furnish outpatient dialysis to pediatric patients, regardless of whether the facility met the definition of a pediatric facility. Our intent was to rely on a temporary methodology pending the completion of research, which could yield empirically based case-mix adjusters under a bundled ESRD PPS.

In the CY 2005 PFS final rule with comment period, published on November 15, 2004 (69 FR 66327), implementing the basic case-mix adjustment to the composite payment system we described the methodology used to develop a 62 percent pediatric increase (that is, an adjustment factor of

1.62) automatically applied to the composite payment rate per treatment for any facility furnishing outpatient dialysis services to pediatric patients. That factor was based on the average amount of the atypical services exceptions granted for 20 ESRD facilities, each of which sought and received an exception for the atypical costs incurred for the treatment of outpatient pediatric patients, compared to the average unadjusted composite payment rate (that is, the payment without regard to exception amounts) for these same 20 facilities. We explained that application of the pediatric adjustment factor of 1.62 in lieu of an explicit pediatric case-mix adjustment was temporary, and would be eliminated once an appropriate methodology, preferably one applicable to both pediatric and adult Medicare patients, could be developed.

The Secretary's 2008 Report presented a design for a case-mix adjusted ESRD PPS, which included not only composite rate services but also separately billable dialysis services, weighted in accordance with the two-equation model described in section VIII. of this notice of proposed rulemaking.

In applying the case-mix adjustment factors resulting from the two-equation regression model described in the Secretary's 2008 Report to pediatric patients, we noted the following:

> [P]ediatric dialysis patients are comparatively rare among Medicare dialysis patients, comprising about 0.2 percent of the population. The impact of the BSA adjustment in the above example is a payment reduction of over 37 percent, compared to the age related increase of 9.1 percent. UM–KECC has performed analyses which demonstrate that the predicted separately billable MAP falls substantially short of the actual separately billable MAP for pediatric patients (that is, those less than age 18). This occurs because the BSA multiplier of 1.035 does not accurately reflect the relationship between BSA and separately billable services for pediatric patients because of their small size and relative rarity in the Medicare dialysis population. Given the small number of pediatric patients, there is a lack of statistical robustness in the payment model with respect to those patients. The data limitations do not permit a ready solution to this problem. We are currently examining approaches to determine if modifications to the regression based payment methodology for pediatric patients is feasible.
>
> See Secretary's February 2008 Report to Congress, pp. 47–48.

Based on UM–KECC research subsequent to the issuance of the Secretary's 2008 Report, we believe that a separate regression based case-mix model is feasible for pediatric patients using a limited number of variables. In the following sections, we describe the payment model used to develop the payment adjusters which we are proposing to apply for Medicare pediatric ESRD patients.

B. Selection of a Pediatric Composite Rate Payment Adjustment

One approach to developing a payment adjustment is to use the results of an updated composite rate cost model. Such a model could employ one or several age categories for pediatric patients. Table 31 presents a model of composite rate costs for the purpose of demonstrating a method for arriving at a pediatric composite rate multiplier, with a single pediatric age category. This model was estimated using Medicare cost report, claims, and other data for CYs 2004–2006. The model uses ESRD facility data on composite rate costs and average patient characteristics. Because pediatric patients comprise such a low percentage of the total patient load of most facilities, the measures of many patient characteristics at the facility level (that is, the average patient characteristics at the facility) are dominated by the characteristics of adult patients. Therefore, while average patient characteristics are shown in Table 31 in the model, they are only used as control variables. That is, while statistically significant payment adjusters may be shown in Table 31 for patient characteristic variables, there is no actual associated payment adjustment that would apply to composite rate services for pediatric patients. For example, the pediatric composite rate cost model assumes no payment adjustment for body size (BSA or low BMI), gender, duration of renal replacement therapy, or co-morbidities. The key coefficient is the one for the age less than 18 variable. The estimated regression-based multiplier of 1.199 reflects an increase in the composite rate portion of the base payment rate of 19.9 percent for patients less than 18, relative to patients age 45–59. The model shown in Table 31 with a single pediatric age category is the model we are proposing to use to adjust the composite rate portion of the proposed ESRD for pediatric patients.

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Table 31
Payment multipliers from a facility level model of composite rate costs

Variable*	Composite rate services (n=11,814 facility years; R-sq=46.0%)	
	$Mult_{CR}$	p-value
Adjustments for dialysis patient characteristics		
Age		
<18	1.199	<0.001
18-44	1.280	<0.001
45-59	1.000	ref
60-69	1.014	0.665
70-79	1.105	<0.001
80+	1.150	<0.001
Female	1.124	<0.001
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.035	<0.001
Underweight (BMI <18.5)	1.000^	--
Time since onset of renal dialysis: <4 months	1.508	<0.001
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	<0.001
Cardiac Arrest (claims since 2000 or 2728)	1.000^	--
Pericarditis from same month to three months ago	1.000^	--
HIV/AIDS (claims since 2000 or 2728)	1.363	<0.001
Hepatitis B (claims since 2000)	1.115	<0.001
Specified infection from same month to three months ago		
Septicemia	1.000^	--
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	0.021
Gastro-intestinal tract bleeding from same month to three months ago	1.000^	--
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	<0.001
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	<0.001
Myelodysplastic Syndrome (claims since 2000)	1.000^	--
Monoclonal Gammopathy between (claims since 2000)	1.000^	--
Low volume facility adjustment		
Facility size < 3,000 treatments during each year from 2004-06	1.383	<0.001

*Both the composite rate and separately billable models included the following facility control variables: facility size categories other than the low volume category, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%.

^A multiplier of 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time in the estimated multipliers.

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The type of cost model shown in Table 31 could also employ multiple pediatric age categories. However, because of the small number of patients in each pediatric age category, the payment adjusters, based on the coefficients of the age variables, are unstable. Therefore, with respect to a payment adjustment applicable to composite rate services for pediatric patients, we believe that a single age

category is most appropriate. Although the proposed payment adjuster of 1.199 for the composite rate portion of the ESRD PPS for pediatric patients is substantially less than the current adjustment of 1.62, we point out that this is an empirically developed measure derived from data for all Medicare outpatient ESRD pediatric patients treated by ESRD facilities. The 1.62 value was developed from only those facilities that sought and obtained an exception to their otherwise applicable composite payment rates.

C. Selection of a Pediatric Separately Billable Payment Adjustment

Although the number of pediatric patients is small, we believe that it is feasible to estimate a payment model for separately billable services furnished to pediatric patients. However, the small sample size limits statistical power and results in a more limited set of potential payment adjusters. Unlike the adult separately billable payment model, which includes multipliers for particular patient co-morbidities, age, body size, and other variables, we evaluated pediatric separately billable payment models based on categories defined by patient characteristics including age, the presence of co-morbidities, and dialysis modality. This model structure is feasible because of the relatively small number of characteristics generating adjustments.

We considered several factors in developing the payment model for separately billable services: The number and definition of the age categories; the number and set of co-morbidities; the reflection of modality as a payment variable; and the potential inclusion of other patient characteristics, such as gender, onset of renal dialysis, and history of transplantation. We developed several exploratory models for separately billable services furnished to pediatric patients in order to develop the model proposed in this notice.

All of the analyses were performed using log-linear regression models of the average separately billable MAP per treatment during the year as the dependent variable. The data were pooled over the 3-year period CY 2004–2006, resulting in up to three yearly observations for each pediatric patient. The potential payment multipliers that were estimated by the model often required a statistical ''smearing'' adjustment 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 data that 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 make valid inferences about 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 the measured MAP and predicted MAP for each observation (that is, the residuals) did not vary in the desired random pattern, indicating correlation between the variance of the residuals and some of the patient characteristics in each model (statistically known as ''heteroscedasticity''), separate smearing factors 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.

We examined numerous separately billable payment models to determine the most appropriate age categories (defined by two age groups), and the selection of co-morbidity categories, defined as two groups (no co-morbidities, and the presence of one or more of the co-morbidities listed in the footnotes to Table 32). Individual co-morbidities that were considered for inclusion in the co-morbidity categories were each identified as statistically significant predictors of separately billable MAP per treatment based on a stepwise regression model. Some of the more important factors which we considered before arriving at the pediatric payment model we are proposing in this notice of proposed rulemaking are discussed below. Because our consideration of each of these factors resulted in the pediatric payment adjustments we are proposing in this rule, we invite comment on their use.

(1) Use of two age categories <13, and 13–17

Because of the small number of pediatric patients, we limited the number of age groups to two. Because the data revealed a natural break relating to increased body size and greater utilization of resources corresponding with the onset of adolescence, we defined the pediatric age categories as less than 13, and age 13–17.

(2) Omission of hyperparathyroidism as a co-morbidity

Hyperparathyroidism had a relatively low reported incidence in the claims data. However, hyperparathyroidism clinically is a frequently encountered condition in pediatric dialysis patients. This co-morbidity has a relatively high potential for overreporting compared to other co-morbidities. Because hyperparathyroidism was associated with a relatively small payment increase, omitting this diagnosis from the list of co-morbidities generating a payment adjustment increases the potential payment multipliers for other co-morbidities. However, given the widespread occurrence of hyperparathyroidism in the pediatric dialysis patient population, we believe its omission results in minimal distortion in the adjusters for most payment categories. We invite comment on our proposal to omit hyperparathyroidism as a co-morbidity in our proposed pediatric payment model.

(3) Capping Separately Billable MAP per Treatment at $289.00 per Treatment for All Pediatric Patients

The cap of $289.00 was based on a standard outer fence method for identifying statistically aberrant values. (For a further explanation on the application of this method, see p. 46 of UM–KECC's February 2008 report, ''End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle'' and footnote 35 of the Secretary's February 2008 Report to Congress, both cited previously in this proposed rule. 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.) Capping the separately billable MAP does not lead to substantially different payment multipliers. The standard deviation of the prediction error falls substantially for some of the payment groups, especially those that were quite large. Some of this reduction may be

due to the elimination of erroneous data through the capping mechanism. In any case, the fact that the case-mix payment adjusters did not materially change regardless of the application of the standard outer fence method for eliminating aberrant values suggests that the predicted payments are not biased through the inclusion of valid or invalid values.

(4) Adjustment for Dialysis Modality

Our analysis revealed that the main problem with a separately billable payment model that does not recognize modality is that it results in an underpayment for HD and an overpayment for PD. For models that did not pay differentially by modality, the average prediction errors were all positive for PD and negative for HD. The errors in both directions were large relative to the predicted means. By contrast, the prediction errors in models that distinguish payment by modality were much smaller and did not consistently favor PD over HD. Hence, payment by modality reduces the difference between actual and predicted payments. In doing so, it reduces the incentive to steer patients to a particular modality based purely on the payment implications. It also substantially improves the predictive power of the payment models.

However, payment by modality introduces an inconsistency with how modality is treated currently under the basic case-mix adjusted composite payment system, and with how we are proposing to treat it for adults under the proposed ESRD PPS. There are a small number of payment groups with relatively large differences between actual and predicted payments even when the models adjust for modality. Paying by modality for pediatric patients is also inconsistent with the payment goal of encouraging home dialysis. However, we note that partly because of the popularity of PD among pediatric patients, it may not be necessary to encourage home therapies for this population. In addition, paying by modality doubles the number of payment categories from four to eight, increasing administrative complexity. We are specifically soliciting comments on our proposal to use modality as a payment variable in our pediatric payment model.

(5) Exclusion of Other Patient Characteristic Variables

Among the other patient characteristics that were considered as potential payment adjusters for separately billable pediatric services, gender, and onset of dialysis (that is, the start of dialysis within 4 months of the current treatment), were not identified as statistically significant predictors of MAP using CY 2004–2006 data. Based on models that included adjustments for age, dialysis modality, and number of co-morbidities, history of transplantation was associated with a higher separately billable MAP per treatment. However, the inclusion of an additional adjustment for history of transplantation did not substantially improve the explanatory power of the model, or substantially reduce the prediction errors for most patient subgroups. In addition, its inclusion would double the number of payment categories in the model from 8 to 16, six of which had very small numbers of patients (less than 50 patients).

Given the results of the analyses described, we are proposing a pediatric payment adjustment for separately billable services that uses two age categories (<age 13, age 13–17), two co-morbidity categories (none, and one or more co-morbidities from among the following diagnoses: HIV/AIDS, septicemia, cardiac arrest, and diabetes), and dialysis modality (HD or PD), as the bases for classifying pediatric patients into one of eight groups. The specified co-morbidities were the only statistically significant predictors of SB MAP resulting from the application of the stepwise regression. Using data available for CY 2004–2006, we present the results in Table 32. Similar to the adult ESRD PPS payment model, the proposed pediatric separately billable payment model reflects the repricing of the top 11 Part B separately billable drugs to the payment rates used in the first quarter of 2008. The ratios used to adjust the MAPs for the 11 specified injectable drugs are identical to those used to reprice the drugs for the adult separately billable MAPs shown in Table 11.

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Table 32
Measured and predicted separately billable Medicare Allowable Payments (MAP) for pediatric patients, 2004-2006

Preliminary **Predicted MAP based on age, modality, and comorbidity groups**

	Patient characteristics					Modeled separately billable (SB) multiplier[3]	Separately billable MAP per session			
									Prediction error	
Cell	Age	Modality	Comorbidities[1]	Patients[2]	Patient-facility months		Actual mean	Predicted mean[4]	Mean	SD
1	<13	PD	None	333	3,376	1.000	$12.28	$12.06	-$0.22	$21.39
2	<13	PD	1 or more	68	310	1.485	$10.14	$17.90	$7.76	$17.35
3	<13	Hemo	None	267	1,757	3.861	$51.82	$46.55	-$5.27	$52.81
4	<13	Hemo	1 or more	120	751	5.647	$83.35	$68.08	-$15.27	$67.89
5	13-17	PD	None	296	2,598	1.508	$19.70	$18.18	-$1.52	$37.12
6	13-17	PD	1 or more	66	456	2.244	$33.49	$27.06	-$6.43	$54.88
7	13-17	Hemo	None	656	5,765	5.831	$70.95	$70.30	-$0.65	$62.28
8	13-17	Hemo	1 or more	255	2,002	8.534	$87.61	$102.89	$15.28	$64.08

[1]The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

[2]Note that individual patients can appear in more than one cell during 2004-06.

[3]Based on a pediatric patient level regression model of SB MAP/session for 2004-06 (n=2,375 pediatric patient years) that included age (<13 vs. 13-17), modality (PD vs. HD), and comorbidity (none vs. 1 or more) as covariates (R-sq=32.8%). Subgroup-specific smearing adjustments were applied to the model estimates.

[4]Predicted SB MAP per session are based on a log-linear regression model that included the patient characteristics in this table, subgroup-specific smearing adjustments, and a budget neutrality adjustment.

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For purposes of the payment adjustments, the relevant column is labeled ''Modeled separately billable (SB) multiplier''. These values reflect the relative costliness of separately billable services for each of the eight pediatric patient groups, with the reference category (under 13, PD, no co-morbidities) having a multiplier set to 1.00. We invite comment on our proposed use of these variables to construct the proposed pediatric ESRD payment model.

D. A Combined Composite Rate and Separately Billable Payment Model for Pediatric Patients

Similar to the payment model for adult patients described in section X of this proposed rule, a payment model for pediatric patients can be constructed from cost/payment models of composite rate and separately billable services. A composite rate cost model can be estimated to generate a payment adjuster or multiplier for patients in a pediatric age group or groups. Because this kind of composite rate cost model is based on ESRD facility data, and there are very few pediatric patients, estimating additional pediatric co-morbidity multipliers is not feasible. However, a separately billable cost model can be estimated that would generate payment adjustments for particular patient characteristics. While the results from the composite rate and separately billable cost models can be combined into a single payment model following the same approach used in connection with the two equation adult payment methodology, the payment model for adult patients cannot be applied to pediatric patients without modification.

The results presented in Tables 31 and 32 can be used to develop a payment model for ESRD pediatric patients (age < 18). The method which we propose combines results from a facility-level model for CR services (Table 31) and a pediatric patient-level model for SB services (Table 32). The outcome is a single set of payment multipliers that can be used to determine the case-mix adjusted payment rate for individual pediatric patients.

The process of combining the CR and SB adjustments required decisions about the following issues:

1. How to apply the modeled SB multipliers, which are based on a separate payment model for pediatric patients, to the SB portion of the overall base rate, which applies to both adult and pediatric patients as described in section VII.

2. The relative weighting of CR and SB services for pediatric patients.

For each of the 8 pediatric classification categories in Table 32, the modeled SB multipliers are expressed relative to a reference category of pediatric patients (age < 13, PD, no co-morbidities). To obtain payment multipliers that can be applied to an overall base rate, the modeled SB multipliers need to be expressed relative to the estimated SB portion of the overall base rate for all patients. This can be accomplished by adjusting the modeled SB payment multipliers by the ratio of the actual SB MAP for the pediatric reference category ($12.28 per treatment for patients < age 13, PD, no co-morbidities) to the actual SB MAP among patients of all ages ($82.38 per treatment). These SB MAP values were computed from claims for CYs 2004 through 2006, the latest available in time for the preparation of this proposed rule. This results in an SB adjustment factor of $12.28/$82.38 or 0.1491. This adjustment was applied to each of the modeled SB multipliers in Table 33, and results in SB payment multipliers which range from 0.149 to 1.272 across the 8 pediatric classification groups. These payment multipliers can be applied to the SB portion of the overall base rate described in section VII. under the ESRD PPS.

The pediatric SB MAP for CYs 2004 through 2006 is $49.11. This SB MAP

reveals that most pediatric patients use substantially fewer SB services than adult patients, for which the comparable SB MAP is $82.45. Consequently, SB services account for a relatively smaller portion of total ESRD facility costs for pediatric patients. To develop overall payment adjustments that reflect the different mix of resources required to treat pediatric patients, the CR and SB multipliers were weighted according to the relative utilization of resources among pediatric patients. Based on the average SB MAP of $49.11 per treatment for pediatric patients and an overall average ESRD facility CR cost for CYs 2004 through 2006 of $169.67 per treatment, the resulting SB and CR weights were calculated as follows:

SB_{weight} = $49.11/ ($49.11 + $169.67) = 0.2245

CR_{weight} = $169.67/ ($49.11 + $169.67) = 0.7755

The multipliers from the CR and SB models can be used to calculate combined payment multipliers using the following formula:

$Mult_{PPS} = (Mult_{CR} * CR_{weight}) + (Mult_{SB} * SB_{AdjFactor} * SB_{weight})$

Using the SB adjustment factor of 0.1491, and the CR and SB weights of 0.7755 and 0.2245, respectively, that were calculated above, the formula becomes:

$Mult_{PPS} = (Mult_{CR} * 0.7755) + (Mult_{SB} * 0.1491 * 0.2245)$

By applying this formula to each of the 8 pediatric classification groups, we obtained the payment multipliers shown in the last column of Table 33.

TABLE 33—CALCULATING COMBINED PAYMENT MULTIPLIERS FOR PEDIATRIC PATIENTS BASED ON ADJUSTMENTS FOR AGE, MODALITY, AND CO-MORBIDITY

Cell	Patient characteristics			Modeled separately billable (SB) multiplier	Payment multipliers		
	Age	Modality	Comorbidities [1]		SB payment multiplier ($PmtMult^{SB}$)	CR payment multiplier ($PmtMult^{CR}$)	Expanded bundle payment multiplier ($PmtMult^{EB}$)
1	<13	PD	None	1.000	0.149	1.199	0.963
2	<13	PD	1 or more	1.485	0.221	1.199	0.980
3	<13	Hemo	None	3.861	0.576	1.199	1.059
4	<13	Hemo	1 or more	5.647	0.842	1.199	1.119
5	13–17	PD	None	1.508	0.225	1.199	0.980
6	13–17	PD	1 or more	2.244	0.335	1.199	1.005
7	13–17	Hemo	None	5.831	0.869	1.199	1.125
8	13–17	Hemo	1 or more	8.534	1.272	1.199	1.215

[1] The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

These combined multipliers range from 0.963 to 1.215. These are the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. For comprehensive examples of how the proposed pediatric payment adjusters would be applied, see examples 6 and 7 in section XI. of this proposed rule.

Using CY 2007 claims data, we calculated combined payment multipliers for pediatric patients. The average pediatric patient-specific payment adjustment multiplier was 1.067, without any adjustment for budget neutrality. This compares with an average payment multiplier of 1.287 for adult patients based on CY 2007 claims. These average payment multipliers reflect both the case-mix and low volume adjustments.

The multipliers in Table 33 do not include the proposed adjustment for low-volume ESRD facilities described in section VIII.C.2. of this proposed rule. In CY 2007, approximately 24 percent of pediatric outpatient Medicare dialysis treatments were provided in facilities with less than 3,000 total treatments. This figure compares to 2.3 percent of Medicare dialysis treatments among adult patients. In addition, approximately 12.6 percent of Medicare treatments for pediatric patients were furnished in facilities with less than 3,000 treatments during each year from CY 2004 through 2006, and which neither opened nor closed during CY 2006. The comparable figure for adult patients was 0.6 percent. Therefore, pediatric patients would be much more likely to be eligible for the low-volume facility adjustment of 20.2 percent, which we have proposed, as described in section VIII.C.2. of this proposed rule.

X. Other Proposed Adjustments

A. 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 erythropoiesis stimulating agents necessary for anemia management. The outlier payment policy would be designed to protect an ESRD facility from significant financial losses due to unusually high costs. Any outlier payment due would be added to the per-treatment, patient and facility-level adjusted ESRD PPS payment amount.

Generally, outlier payment mechanisms in Medicare prospective payment systems are based on a provider's cost for care compared to projected payments under the PPS. When a provider's cost exceeds a threshold amount (the projected payment plus a fixed dollar loss amount), Medicare pays a percentage of the difference (the loss sharing percentage) as an outlier payment. We propose that the ESRD outlier policy parallel the outlier policies adopted under other Medicare PPSs.

Specifically, as discussed in more detail below, we would compare an ESRD facility's predicted Medicare Allowable Payment (MAP) amount per treatment for outlier services to the facility's imputed MAP amount per treatment for outlier services to determine whether the ESRD facility would be eligible for additional payment under the proposed outlier policy. We propose to limit the outlier services to those items and services that currently are separately billable under Part B and renal dialysis service drugs proposed for inclusion under the ESRD PPS that currently are separately billable under Part D.

An ESRD facility would be eligible for an outlier payment when its imputed MAP amount per treatment for the outlier services exceeds the outlier

threshold, or the facility's predicted MAP amount per treatment for the outlier services plus the fixed dollar loss amount. We propose that the outlier payment would be equal to 80 percent of the amount by which the facility's imputed costs exceeds the outlier threshold.

The current basic case-mix adjusted composite payment system does not provide for outlier payments. However, in the 2008 Report to Congress entitled ''A Design for a Bundled End Stage Renal Disease Prospective Payment System'', we discussed outlier payments as a way of mitigating risk incurred by ESRD facilities in providing treatment to patients with characteristics associated with higher costs. The 2008 report described a hypothetical outlier policy that would target higher payments to facilities for patients who encountered higher than average monthly Medicare Allowable Payments (MAPs) for items and services that currently are separately billable under Part B. Specifically, the report proposed setting the hypothetical outlier payment amount at 80 percent of the difference between the separately billable MAP and a threshold amount. The report proposed that the threshold amount be based on the average separately billable MAP amount per treatment plus 2 or more standard deviations. ESRD facilities meeting this criterion were assumed to receive an outlier payment equal to a percentage of the difference between the separately billable MAP amount and the threshold amount.

To maintain budget neutrality, the 2008 report proposed that the portion of the base rate attributable to items and services that currently are separately billable under Part B be reduced by 2.5 percent to fund projected outlier payments. This percentage would have qualified approximately 5 percent of total patient months as outliers. A copy of the 2008 report is available at: *http://www.cms.hhs.gov/ESRDGeneralInformation/Downloads/ESRDReportToCongress.pdf*.

1. Eligibility for Outlier Payment

We are proposing 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 exceed the predicted per treatment MAP amount for outlier services plus the fixed dollar loss amount, as indicated in proposed § 413.237(b). We propose to base eligibility for outlier payments on ESRD outlier services, that is, only those items and services that are separately billable under Medicare Part B with regard to 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.

The comprehensive listing of our outlier policy definitions are set forth in § 413.237 of this proposed rule.

a. ESRD Outlier Services

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 erythropoiesis stimulating agents necessary for anemia management.

We believe that any unusual variation in the cost of the renal dialysis services comprising the base rate under the proposed ESRD PPS is likely to be due to variation in the items and services that currently are separately billable under Part B and those renal dialysis service drugs currently covered under Part D. Therefore, including these items and services that are either currently separately billable under Part B or covered under Part D under the proposed ESRD PPS creates new financial risk for ESRD facilities. In addition, significant variations in these services may impair access to appropriate care, as an ESRD facility may have a disincentive to provide adequate treatment to those ESRD patients likely to have significantly higher than average costs. We believe these concerns could be addressed by an outlier policy.

As set forth in proposed § 413.237(a), we are proposing 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 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. From this point forward, we refer to these services as the ''ESRD outlier services.''

As described further in section XIV, of this proposed rule, we are considering the extent to which the 50 percent rule that pertains to the Automated Multi-Channel Chemistry (AMCC) separately billable laboratory tests under the basic case mix adjusted composite payment system should continue to apply in the context of the proposed ESRD PPS.

Section 1881(b)(14) prohibits the unbundling of services, including laboratory services. Thus, under the proposed ESRD PPS, 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.

As described above, we are proposing to define outlier services as items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and 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. Under this proposal, to ensure that the AMCC tests qualify as separately billable under the basic case mix adjusted composite payment system, and thus, qualify as outlier services, it would be necessary for ESRD facilities to continue applying the 50 percent rule under the proposed ESRD PPS. Conversely, excluding AAMC tests to which the 50 percent rule apply from the definition of outlier services would negate the need to apply the 50 percent rule under the proposed ESRD PPS.

We believe that the overall impact of excluding the AMCC tests to which the 50 percent rule applies from the definition of outlier services would be small. As shown in table 8, laboratory tests comprise 3.45 percent of the total MAP amount which is the basis of the ESRD PPS base rate. The subset of laboratory tests associated with the AMCC tests to which the 50 percent rule applies under the basic case mix adjusted composite payment system comprises an even smaller proportion of the overall base rate. As a result, we are considering excluding AAMC tests to which the 50 percent rule apply from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS. We request public comments on whether or not to include the 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. We also invite comment on our proposal to limit the ESRD outlier services to items and services currently separately billable under Part B and those renal dialysis service drugs currently covered under Part D.

We note that if we also were to base eligibility for outlier payments on

variation in the cost of all items and services included in the ESRD PPS bundle, including those services included in the bundle under the current ESRD basic case-mix adjusted composite payment amount (hereinafter the ''composite rate items and services''), this may require an expansion in the data that we currently collect from ESRD facilities, which would increase ESRD facilities' reporting burden. Specifically, if we were to base eligibility for outlier payments on variation in the cost of all items and services included in the ESRD PPS bundle, we would need to compare a more comprehensive predicted MAP amount for a treatment to the ESRD facility's more comprehensive imputed MAP amount for the treatment. However, composite rate items and services, and the ESRD facilities' costs associated with providing these items and services, are not listed individually on the claims. As a result, it would not be possible to compare an imputed MAP amount for the more comprehensive definition of outlier services, that is, all items and services included in the ESRD PPS bundle, to the predicted MAP amount for these items and services.

To correct this deficiency, we could collect patient-level data reflecting the cost of the composite rate items and services. Under this approach, we believe that it would be necessary to revise the ESRD facility claim form. For example, ESRD facilities would need to report by line item all composite rate services and the associated charges of each of those services. However, we are not proposing revisions to the ESRD facility claim.

We believe that under a bundled payment system, in the future we may be able to simulate ESRD facility costs for outlier services using charges on the claims and applying the cost-to-charge ratios calculated using the cost reports. However, this data would only become available after the 2011 cost reports had been settled.

b. Predicted ESRD Outlier Services MAP Amounts

Predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount, described further below, by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers used in the regression analysis to compute the payment adjustments.

As described previously in section VIII. of this proposed rule, the predicted separately billable MAP amounts are based on the patient-level regression model for separately billable services. Thus, it is 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. However, although in this proposed rule we have included the cost of the Part D drugs in the base rate, the Part D drugs have not been incorporated into the separately billable services regression model that generates case-mix payment adjusters. Therefore, we are unable to predict payment for renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D. As a result, the predicted MAP amounts are understated. Nonetheless, within this proposed rule, our references to predicted outlier services MAP amounts assume the inclusion of these additional drugs to demonstrate the way in which the outlier policy would apply when these additional drugs are incorporated into the regression model for purposes of the final rule. For the final rule we intend to incorporate these drugs into the regression analysis to derive a comprehensive predicted MAP amount for all proposed ESRD outlier services, including (1) the items and services that currently are separately billable under Medicare Part B and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS that currently are covered under Medicare Part D.

Specifically, for the final rule, the separately billable case-mix adjusters could either be updated to reflect Part D drugs, assigning appropriate weights to the separately billable and Part D portions of the outlier services case-mix adjusters, or distinct payment multipliers for the Part D drugs could be developed.

Please refer to Table 34 below for the list of case-mix adjustment multipliers for outlier services for adult patients.

TABLE 34—PAYMENT MULTIPLIERS FOR AN EXPANDED BUNDLE OF SERVICES, AGES 18 AND OLDER, 2004–06

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment [3,4]
	Composite rate services [1]	Outlier services [2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for dialysis patient characteristics:			
Age:			
18–44	1.280	1.018	1.194
45–59	1.000	1.000	1.000
60–69	1.014	1.006	1.012
70–79	1.105	0.960	1.057
80+	1.150	0.923	1.076
Female	1.124	1.149	1.132
Body surface area (BSA, per 0.1 m^2; mean BSA = 1.87)	1.035	1.033	1.034
Underweight (BMI <18.5)	∧1.000	1.060	1.020
Time since onset of renal dialysis: < 4 months	1.508	1.401	1.473
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	1.139	1.150
Cardiac arrest (claims since 2000 or 2728)	∧1.000	1.098	1.032
Pericarditis from same month to three months ago	∧1.000	1.595	1.195
HIV/AIDS (claims since 2000 or 2728)	1.363	1.220	1.316
Hepatitis B (claims since 2000)	1.115	1.035	1.089
Specified infection from same month to 3 months ago			
Septicemia	∧1.000	1.715	1.234
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	1.412	1.307
Gastro-intestinal tract bleeding from same month to 3 months ago	∧1.000	1.965	1.316
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	1.179	1.226

TABLE 34—PAYMENT MULTIPLIERS FOR AN EXPANDED BUNDLE OF SERVICES, AGES 18 AND OLDER, 2004–06—Continued

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment [3,4]
	Composite rate services [1]	Outlier services [2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	1.097	1.128
Myelodysplastic syndrome (claims since 2000)	∧1.000	1.257	1.084
Monoclonal gammopathy (claims since 2000)	∧1.000	1.063	1.021
Low volume facility adjustment			
Facility size < 3,000 treatments during each year from 2004–06	1.383	0.940	1.202

∧ A multiplier 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time 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 2004–06 (n = 11,814 facility years). This model also 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%) and the percent of pediatric patients as additional covariates (R-sq = 46.0%).

[2] Although we refer to outlier services, these multipliers are limited to the inclusion of items and services that currently are separately billable under Medicare Part B and do not reflect renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D. Based on a patient level log-linear regression model of separately billable Medicare Allowable Payments/session for 2004–06 (n = 890,776 patient years) that included 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 (R-sq = 8.7%).

[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 costs. Based on total estimated costs of $169.67 per session for composite rate services, $82.45 per session for separately billable services, and $252.12 per session for an expanded bundle ($169.67 + $82.45), the relative weights are $Weight_{CR}$ = 0.673 for composite rate services ($169.67/$252.12) and $Weight_{SB}$ = 0.327 for separately billable services ($82.45/$252.12).

[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 1.383 and 0.940, 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 1.202. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

Please refer to Table 35 below for the list of case-mix adjustment multipliers for outlier services for pediatric patients.

TABLE 35—CALCULATING COMBINED PAYMENT MULTIPLIERS FOR PEDIATRIC PATIENTS BASED ON ADJUSTMENTS FOR AGE, MODALITY, AND COMORBIDITY

Cell	Patient characteristics			Modeled outlier services[2] multiplier	Payment multipliers		
	Age	Modality	Comorbidities[1]		Outlier Services[2] payment multiplier ($PmtMult_{SB}$)	CR payment multiplier ($PmtMult_{CR}$)	Expanded bundle payment multiplier ($PmtMult_{EB}$)
1	<13	PD	None	1.000	0.149	1.199	0.963
2	<13	PD	1 or more	1.485	0.221	1.199	0.980
3	<13	Hemo	None	3.861	0.576	1.199	1.059
4	<13	Hemo	1 or more	5.647	0.842	1.199	1.119
5	13–17	PD	None	1.508	0.225	1.199	0.980
6	13–17	PD	1 or more	2.244	0.335	1.199	1.005
7	13–17	Hemo	None	5.831	0.869	1.199	1.125
8	13–17	Hemo	1 or more	8.534	1.272	1.199	1.215

[1] The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

[2] Although we refer to outlier services, these multipliers are limited to the inclusion of items and services that currently are separately billable under Medicare Part B and do not reflect renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D.

To generate the adjusted average outlier services MAP amount that is multiplied by the product of the patient-specific outlier services case-mix adjusters, we begin with the average outlier services MAP amount per treatment. The average outlier services MAP amount per treatment is based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. As discussed above, payments for Part D drugs are not included. The average MAP amount per treatment for outlier services is then adjusted by the case-mix and wage adjustment standardization factor, a MIPPA reduction of .98, and the outlier policy of .99 resulting in the adjusted average outlier services MAP amount by which the product of the patient-

specific outlier services case-mix adjusters are multiplied.

The proposed adjusted average outlier services MAP amount is $64.54. As illustrated in the hypothetical examples in section X.A.3, the adjusted average outlier services MAP amount would be multiplied by the product of the patient-specific outlier services payment multipliers to yield the predicted outlier services MAP amount.

As described further in section X.A.1.d., the fixed dollar loss amount would be added to this amount.

TABLE 36—ADJUSTED AVERAGE OUTLIER SERVICES MAP AMOUNT

Average outlier services MAP amount per treatment [1]		$84.99
Adjustments		
Standardization for case mix and wage adjustments [2]		0.7827
MIPPA reduction		0.98
Outlier policy		0.99
Adjusted average outlier services MAP amount [3]		$64.54
	Patient age	
	<18	18 and older
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$174.31	$134.96

[1] Excludes patients for whom not all case mix measures were available to calculate projected payments under an expanded bundle.
[2] Applied to the average outlier MAP per treatment.
[3] Because Part D drugs are not yet reflected in the outlier services payment multipliers, this number is understated. 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. These amounts correspond to 1.963 times the standard deviation of the prediction error for ages <18 and 1.952 times the standard deviation of the prediction error for ages 18 and older.

c. Estimating the Imputed ESRD Outlier Services MAP Amounts

As discussed above, we propose to base eligibility for outlier payments on a comparison of an ESRD facility's predicted Medicare Allowable Payment (MAP) amount per treatment for the ESRD outlier services to the facility's imputed MAP amount per treatment for the ESRD outlier services. We discuss above our proposed methodology for determining the predicted outlier services MAP amounts for a patient. In estimating a provider's imputed costs, under some Medicare PPSs, such as the Hospital Inpatient Prospective Payment System, we estimate a provider's costs by applying a provider-specific cost-to-charge ratio to the covered charges for the treatment. The cost-to-charge ratio is based in part on the provider's cost report. Under other Medicare PPSs, we estimate a provider's costs using available data. For example, under the Prospective Payment System for Home Health Agencies we impute the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines (42 CFR § 484.240(d)). For the reasons discussed below, we are proposing to estimate an ESRD facility's imputed costs for the ESRD outlier services based on available data rather than a provider-specific cost-to-charge ratio.

Although ESRD facilities currently identify costs associated with certain ESRD outlier services such as EPO and vaccines, our analysis revealed that 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 for drugs. We therefore are proposing to estimate a provider's costs based on available data, rather than applying a cost-to-charge ratio to facility charges to impute their cost.

As described in greater detail below, the imputed separately billable MAP amounts would be based on pricing mechanisms currently in place for these services. Whereas, in the case of Part D drugs proposed for inclusion in the ESRD PPS, we have not proposed a preferred pricing mechanism for the imputed MAP amounts but rather, solicit comments on several approaches for imputing these drug prices.

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 propose to use Average Sales Prices (ASP) data for the Part B ESRD-related drugs (which is updated quarterly) and annual laboratory fee schedules for the previously separately billable laboratory tests. We propose 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 propose 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 claims processing manual 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 propose 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.

Finally, payment for blood, supplies used to administer blood, and blood processing fees furnished by hospital-based ESRD facilities under the current basic case-mix adjusted composite payment system is based on a reasonable cost basis. Payment for blood, supplies used to administer the blood, and blood processing fees, on behalf of patients in independent ESRD facilities currently is made at the lower of the actual charge on the bill or a reasonable charge that the MAC/FI determines. We are proposing 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. We are not in this proposed rule, specifying the mechanism by which we propose to estimate 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 request public comment on the following potential approaches for estimating the imputed MAP amounts of these drugs and on alternative approaches.

Approach 1:

First, although we believe ASP pricing data for renal dialysis service drugs currently covered under Part D would facilitate the computation of the estimated costs of these drugs, we do not collect ASP pricing information under section 1927 of the Act for these drugs. We request public comment on whether manufacturers would be willing to submit ASP pricing data for renal dialysis service drugs currently covered under Part D on a voluntary basis.

Approach 2:

An alternate approach for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D would be to use data retrieved from the online Medicare Prescription Drug Plan Finder. (This online tool, available at medicare.gov provides the prices that are charged by each Part D plan's network pharmacy.) For example, the Part D drug prices for each drug designated as a Part B renal dialysis service could be estimated based on a national average price charged by all Part D plans and their network pharmacies. We believe that establishing a single national average price for each drug designated as a Part B renal dialysis service would be consistent with the approach for Part B drugs in which we use national ASP pricing.

These national average prices could be updated on an ongoing basis using data on the Medicare Prescription Drug Plan Finder. Similar to the way in which we update Part B ASP pricing, national average Medicare Prescription Drug Plan Finder prices could be updated on a quarterly basis. The prices reflected in the Medicare Prescription Drug Plan Finder are reflective of the prices that are negotiated by larger buying groups. As a result, our primary concern with this pricing approach is that such prices may fail to reflect the drug prices that smaller facilities may pay in acquiring these drugs and could therefore disadvantage these facilities.

Approach 3:

An alternative approach for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D would be to use Wholesale Acquisition Cost (WAC). Because WAC is the manufacturer's list price to wholesalers, we believe that it is more reflective of the price paid by the end user than the Average Wholesale Price. In addition, as set forth in CMS Pub 100–04, Chapter 17, Section 20.1.3, payment allowance limits for drugs and biological that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. As a result, we believe that this pricing mechanism would be consistent with pricing that currently occurs for drugs that are separately billable under Part B.

Approach 4:

Another alternative option for estimating the imputed MAP amounts of the renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle but currently covered under Part D would be to use the national average prescription drug event (PDE) data that is submitted for each Part D claim. To correct for the lag time for receipt of complete PDE data by CMS, we would update the most recent PDE data by the CPI update for drugs.

Approach 5:

A final approach for estimating the imputed MAP amounts for renal dialysis service drugs currently covered under Part D would be to require ESRD facilities to list on their claims forms their costs for the renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D. The facility cost that would be reported on the claim would need to be the amount after accounting for manufacturer rebates, discounts, and other price concessions. Under this approach, payment would be based on an ESRD facility's cost as identified on the claim. As indicated previously, while it may be possible to use cost-to-charge ratios on the cost report to simulate cost in the future, that information would not be available when the ESRD PPS would begin in 2011.

We believe that most, if not all, of the renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D have clinical treatment indications beyond ESRD, such as for the treatment of bone disease in advanced chronic kidney disease patients. These drugs therefore will continue to be covered under Part D for these other indications. Consequently, Part D pricing information would continue to be available for these drugs and could be used in the computation of outlier eligibility and payment under the approaches #2, and #4 discussed above.

We request public comment on the potential approaches set forth above for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Part D. We are also interested in any other potential data sources for estimating the imputed MAP amount of those ESRD-related drugs currently paid under Part D.

ii. Determining Imputed Per Treatment ESRD Outlier Services MAP Amount

ESRD facilities currently submit claims on a monthly basis that identify line item dates of service. For purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient. Specifically, we are proposing 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 methodologies discussed above in section X.A.1.

c. i. The imputed outlier services MAP amounts for each of these services would be aggregated and then 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 exceeds the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount, as described below.

d. Outlier Percentage and Fixed Dollar Loss Amounts

As discussed in section VII.D.a, we are proposing that payments under section 1881(b)(14)(D)(ii) of the Act for outlier cases be applied in a budget

neutral manner. Therefore, to ensure that the proposed outlier policy under the ESRD PPS is budget neutral, we propose to reduce the base rate by the proposed outlier percentage, or the percentage of total ESRD PPS payments that are intended for payment of outlier cases, as defined in proposed § 413.220(b)(4).

Using an outlier loss sharing percentage of 80 percent (which is discussed in the following section), we considered various percentages from 1 percent to 3 percent of aggregate payments and the fixed dollar loss amount that is computed from these two factors. (As discussed below, we are proposing separate fixed dollar loss amounts for the pediatric and adult populations.) The appropriate outlier amount was determined by comparing the predicted outlier services MAP amount (which, for the reasons explained previously was limited to items and services that were separately billable under Medicare Part B), for the treatment plus the fixed dollar loss amount to the imputed per treatment ESRD outlier services MAP amount. For example, using an outlier percentage of 1 percent, if the total outlier payment amount for all providers was determined to be higher or lower than 1 percent of the total payments under the proposed ESRD PPS, then the fixed dollar loss amount was adjusted accordingly. This was done in an iterative fashion until the fixed dollar amount produced total outlier payment amounts for all ESRD facilities equal to 1 percent of total payments. We applied a similar process to identify the fixed dollar loss amount associated with other outlier percentages.

We analyzed outlier percentages from 1 to 3 percent of total ESRD PPS payments and the corresponding fixed dollar loss amounts and percentage of patient months qualifying for outlier payments, which are presented in Table 37.

TABLE 37—IMPACT OF OUTLIER PERCENTAGE ON PATIENT MONTHS QUALIFYING FOR OUTLIER PAYMENT

	1%	1.5%	2%	2.5%	3%
Age 18 and Older: Patient months qualifying for outlier payment	5.3%	7.3%	9.3%	11.5%	13.8%
Age < 18: Patient months qualifying for outlier payment	2.6%	3.8%	5.7%	7.6%	10.7%
Age 18 and Older: fixed dollar loss amount	$134.96	$109.24	$89.88	$74.32	$61.67
Age < 18: Fixed dollar loss amount	$174.31	$124.32	$90.04	$65.62	$47.70

Based on consideration of the various outlier percentages, we are proposing that the outlier percentage would be 1 percent of total ESRD PPS payments. We believe an outlier percentage of 1 percent 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. In addition, this outlier percentage is consistent with other Medicare PPSs, such as the 1 percent policy paid under the Outpatient PPS.

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 usage of separately billable services among adult and pediatric patients, especially drugs. As a result, we are proposing separate fixed dollar loss amounts, defined in proposed § 413.237(a)(4–5) of $134.96 for adult patients and $174.31 for pediatric patients.

2. Outlier Payments

The loss sharing percentage is the percentage of costs exceeding the fixed dollar loss amount that is paid by Medicare. We considered various loss sharing percentages for the proposed ESRD PPS outlier policy. We are proposing an 80 percent loss sharing percentage because this percentage is consistent with certain other Medicare payment systems, including the Inpatient Rehabilitation Facility and Home Health PPSs, and, more importantly, is consistent with the amount Medicare pays, in general, for Part B services.

In addition, while for the reasons stated above we believe it is important to ensure that we pay ESRD facilities an outlier payment that is an adequate amount for treatments involving high costs, at the same time we want to preserve the efficiency incentives inherent under a prospective payment system. We believe an 80 percent loss sharing percentage strikes a reasonable balance between these policy objectives. In particular, we note that to the extent the cost to ESRD facilities of the inputs required to deliver additional services beyond the outlier threshold (the sum of the predicted outlier services MAP amount plus the fixed dollar loss amount) is greater than the 80 percent loss sharing ratio, there would be less incentive to increase utilization of outlier services inappropriately to receive outlier payments.

We propose to implement an annual monitoring process that would identify patterns of increased utilization of outlier services and any associated outlier payments across ESRD facilities. For example, we would be most interested in identifying ESRD facilities that receive significant outlier payments. We believe that this monitoring effort would prevent potential abuse and provide us with an outlet for addressing abuse.

For treatments eligible for outlier payments, we are proposing 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). For treatments eligible for the outlier payment, the outlier payment would be added to each ESRD PPS per treatment payment amount.

3. Hypothetical Outlier Payment Examples

Please refer to the hypothetical outlier examples for both adult and pediatric patients set forth below for an illustration of (1) the way in which predicted and imputed ESRD outlier services MAP amounts are calculated and compared in determining eligibility for outlier payment, and (2) the way in which outlier payments would be calculated.

Hypothetical Example—Adult Patient:

Martha, a 66 year old female who is 167.64 cm. tall, weighs 105 kg. and has three co-morbid conditions; HIV/AIDS, septicemia and hereditary hemolytic or sickle cell anemia. As described in hypothetical example number 4 within section XI. of this proposed rule, 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} = 0.00718 * $167.64^{.725}$ * $105^{.425}$
= 0.007184 * 40.9896 * 7.2278
= 2.1284

As identified in table 29, the separately billable multiplier for BSA would be 1.033. Martha's case-mix adjustment based on her BSA of 2.1284 would be:

= $1.033^{(2.1284-1.87/0.1)}$ = 1.088
= $1.033^{2.584}$
= 1.088

Step 1: Determine the predicted, ESRD outlier services MAP amount.

The product of the patient-level outlier services case-mix adjusters as identified in table 34:= 66 year old: 1.006, female: 1.149, BSA: 1.088, HIV/AIDS: 1.220, septicemia: 1.715, and hereditary hemolytic or sickle cell anemias: 1.179

= 1.006 * 1.149 * 1.088 * 1.220 * 1.715 * 1.179
= 3.10231

The adjusted, average, ESRD outlier services MAP amount

= $64.54

The adjusted, average ESRD outlier services MAP amount * product of the outlier services case-mix adjusters:

=$64.54 * 3.10231
= $200.22

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = $4000
The corresponding total number of treatments = 10
The imputed, average, per treatment, outlier services MAP amount =
= $4000/10
= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $134.96
The predicted, ESRD outlier services MAP amount = $200.22
= $200.22 + $134.96
= $335.18

Step 4: Calculate outlier payment.

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 − $335.18) * .80
= $64.82 * .80
= $51.22

Hypothetical Example—Pediatric Patient:

John, a 13 year old hemodialysis pediatric patient with 1 or more co-morbidities.

Step 1: Determine the predicted, ESRD outlier services MAP amount.

As identified in table 35, the patient-level ESRD outlier services case-mix adjuster:

=13 year old hemodialysis patient with 1 or more co-morbidities
= 1.272
The adjusted, average, ESRD outlier services MAP amount = $64.54

The adjusted, average, ESRD outlier services MAP amount * the product of the outlier services case-mix adjusters:

= $64.54 * 1.272
= $80.09

Step 2: Determine the imputed, average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = $4000
The corresponding total number of treatments = 10
The imputed, average, per treatment, outlier services MAP amount =
= $4000/10
= $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = $174.31
The predicted, ESRD outlier services MAP amount = $80.09
= $80.09 + $174.31
= $254.40

Step 4: Calculate outlier payment.

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 − $254.40) * .80
= $145.60 * .80
= $116.48

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 section XI. of this proposed rule.

4. Application of Outlier Policy During the Transition and in Relation to the ESA Monitoring Policy

As discussed in section XIII. A. of this proposed rule, section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide a four-year transition from the current basic case-mix adjusted composite payment system to the ESRD PPS for renal dialysis services furnished beginning January 1, 2011. Under the transition, ESRD facilities would receive a blended rate based in part on the payment rates under the current basic case-mix adjusted composite rate payment system and in part on the payment rates under the ESRD PPS. Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition from the current case-mix adjusted composite payment system to the ESRD PPS. Those ESRD providers and facilities that elect to be excluded from the transition would receive 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 rate.

As indicated above, the current ESRD basic case-mix adjusted composite payment system does not provide for outlier payments. Rather, the proposed outlier payment policy would be limited to the proposed ESRD PPS. We therefore propose that for those ESRD facilities that do not elect to be excluded from the 4-year transition, outlier payments would be limited to the portion of the blended rate based on the payment rates under the proposed ESRD PPS.

Nothing within this proposed outlier payment policy would replace the claims monitoring implications related to the utilization of separately billable erythropoiesis-stimulating agents (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. As we discuss in section XIV.B of this proposed rule, we are evaluating the extent to which we could continue to apply the ESA Monitoring Policy under the proposed ESRD PPS. We are also considering ways in which outlier payments would be computed under the proposed ESRD PPS. We believe that any dosing reductions associated with the application of the ESA Monitoring Policy would be factored in prior to determining eligibility for outlier payment.

We expect that ESRD facilities would exercise prudent clinical judgment in prescribing ESAs for patients who are resistant to these drugs, so as not to over-prescribe with the intent of capitalizing on outlier payments. However, we request public comments that would outline additional safeguards to protect against overuse of ESAs among the ESA-resistant patient population.

XI. Comprehensive Payment Model Examples

In section VIII., 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 proposed ESRD PPS. Table 29 in that section contained the proposed case-mix adjustments applicable to adult patients. In section IX, we presented our proposed pediatric payment model under the ESRD PPS. Table 33 in that section contained the pediatric classification categories and corresponding case-mix adjusters which we propose to apply to pediatric ESRD patients. In this section, we explain how the area wage index and the case-mix adjustments would be applied to the proposed base rate described in section VII. reflecting combined CR and SB services, resulting in a patient-specific per treatment payment amount under the proposed ESRD PPS, as set forth in proposed § 413.215. We demonstrate how the proposed case-mix adjustments presented in Tables 29 and 33 would be applied for 7 hypothetical ESRD patients to obtain the per treatment payment amounts under the ESRD PPS. The product of the applicable case-mix adjustment factors is the patient multiplier or PM. The ESRD PPS case-mix adjusters are shown in Table 29 for adult patients and Table 33 for pediatric patients. Each example uses the base rate of $198.64, 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. Therefore, our starting point in each example prior to determining the patient-specific PM is a wage index adjusted base rate of $206.22. This amount was computed as follows:

Base rate $198.64

Labor-related share of base rate

($198.64 * .38160 = $75.80) 75.80

Wage index adjusted labor-related share

($75.80 * 1.1000) = $83.38 83.38

Non labor-related share of base rate

($198.64 * (1 − 0.38160) = $122.84 122.84

Wage index adjusted base rate

($83.38 + $122.84) = $206.22 $206.22

(The labor-related and non labor-related shares of the base rate (that is, 38.160 percent and 1–0.38160 or 61.840 percent, respectively, represent the labor-related and non labor-related components of the bundled ESRD PPS market basket, described in section XII. of this proposed rule.)

Example 1—Relatively Healthy ESRD Patient With no 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 2009 and has been on HD since August 2009. He has chronic glomerulonephritis and hypertension, and has an AV fistula. The patient also has secondary hyperparathyroidism.

Table 29 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/m^2, which is greater than the threshold value of 18.5, the cut-off for underweight status:

$BMI = weight_{kg}/height\ (m^2)$
$= 95/1.8796^2$
$= 95/3.5329$
$= 26.89$

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 29 multiplier of 1.034, John's case-mix adjustment based on his BSA of 2.2161 is computed as follows:

$PmtMult_{BSA} = 1.034^{(2.2161-187)/0.1}$
$= 1.034^{3.461}$
$= 1.1227$

John's PM would reflect the applicable case-mix adjustments from Table 29 for both age and BSA and may be expressed as:

$PM = PmtMult_{age} * PmtMult_{BSA}$
$= 1.000 * 1.1227$
$= 1.1227$

The ESRD PPS payment rate per treatment would be:

$206.22 * 1.1227 = $231.52

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. This particular adjustment would continue to apply for treatments furnished between January 1, 2011 and March 15, 2011. The applicable case-mix adjustments would be for a patient new to dialysis, age, and BSA, and may be expressed as:

$PM = PmtMult_{DialOnset} * PmtMult_{age} * PmtMult_{BSA}$
$= 1.473 * 1.000 * 1.1227$
$= 1.6537$

The ESRD PPS payment rate per treatment would be:

$206.22 * 1.6537 = $341.03

Example 3—Same as Example 1, with outlier payments. (For a description of the outlier payment methodology, see section X.)

John normally receives HD 3 times weekly. However, in January 2011 he suffered a compound ankle fracture and was hospitalized for 5 days. During the hospitalization John did not undergo any dialysis treatments. After John was discharged and he resumed receiving outpatient dialysis, it was noted that John's dialysis clinical indicators were depressed, requiring additional laboratory testing and above average doses of several injectable drugs, particularly EPO®, to bring them to normal levels. During January, John, who received HD at his usual facility, received only 9 treatments. The facility submitted a bill for allowable total SB drugs and biologicals, laboratory tests, and supplies for January totaling $3000.00.

John's dialysis facility would receive $231.52 for each of the 9 treatments it furnished. The SB MAP per treatment averaged $3000.00/9 or $333.33 per session. We first determine if John's dialysis facility would be entitled to outlier payments:

Using Table 29 we compute the predicted SB MAP per treatment based on SB case-mix adjustments for BSA and age.

BSA $PmtMult_{SB} = 1.033^{(2.2161–1.87)/0.1}$
$= 1.033^{3.461}$
$= 1.1189$
Age $PmtMult_{SB} = 1.000$
$PM_{SB} = 1.1189 * 1.000 = 1.1189$
SB MAP per treatment (see section X.A.1.b) $64.54

The case-mix adjusted predicted SB MAP is:

$64.54 * 1.1189 = $72.21

The fixed dollar loss amount for the predicted SB MAP, reflecting the case-mix adjustments for BSA and age, becomes:

$72.21 + $134.96 = $207.17

Because John's average SB MAP for services furnished was $333.33, which exceeds the case-mix adjusted fixed dollar loss amount of $207.17, John's ESRD facility is eligible for outlier payments beyond the otherwise applicable $231.52 ESRD PPS amount. The outlier payments are computed as follows:

Amount in excess of fixed dollar loss amount

($333.33—$207.17) = $126.16

Loss sharing ratio 80%

Outlier payments per treatment

($126.16 * .80) = $100.93 $100.93

Outlier payments
($100.93 * 9 treatments) = $908.37

The total ESRD payments to this facility on behalf of John for January would be:

Regular ESRD payments
$231.52 * 9 = $2083.68
Outlier payments 908.37
Total payments $2992.05

Example 4—ESRD Patient With Multiple Co-morbidities

Mary, a 66 year old female, is 167.64 cm. in height and weighs 105 kg. She has diabetes mellitus, a history of chronic Hepatitis B, parathyroidism, and liver cirrhosis. She was diagnosed with ESRD in 2005, esophageal varices in 2006, and had a diagnosis of upper gastrointestinal (GI) bleeding in January 2011. Mary receives HD at an ESRD facility which qualifies for the low volume adjustment. We will not repeat the calculation for BMI in this example. Suffice it to say that this patient does not have a BMI less than 18.5 kg/m^2, the required threshold for underweight status. Table 29 reveals that the PM in this example must be calculated to reflect the case-mix adjustments for gender, BSA, Hepatitis B, and upper GI bleeding, as well as a facility low volume adjustment. The formula for calculation of a patient's BSA is:

$$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$$

Mary's BSA is calculated as:

$$BSA_{Mary} = 0.00718 * 167.64^{.725} * 105^{.425}$$
$$= 0.007184 * 40.9896 * 7.2278$$
$$= 2.1284$$

Based on the Table 29 multiplier of 1.034, Mary's case-mix adjustment based on her BSA of 2.1284 would be:

$$PmtMult_{BSA} = 1.034^{(2.1284-1.87)/0.1}$$
$$= 1.034^{2.584}$$
$$= 1.0902$$

Mary's PM, including application of the low volume payment adjuster, may be expressed as:

$$PM = PmtMult_{gender} * PmtMult_{BSA} * PmtMult_{HepB} * PmtMult_{GIBleed} * PmtMult_{LV}$$
$$= 1.132 * 1.0902 * 1.089 * 1.316 * 1.202$$
$$= 2.1259$$

The ESRD PPS payment rate per treatment applicable to Mary would be:

$206.22 * 2.1259 = $438.40

Example 5—Aged ESRD Patient With Low BMI (< 18.5kg/m^2) and History of Hospitalization

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 2004. The patient has coronary artery disease and peripheral vascular disease. In January 2008 Agnes began dialyzing with an upper arm AV fistula, which had been created in 2006. In March 2009, 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 suffering an observed cardiac arrest during outpatient dialysis. She was diagnosed with myocardial infarction, and underwent coronary artery angioplasty and coronary artery stent placement during that hospitalization. Agnes was again admitted to the hospital on January 3, 2011 for congestive heart failure, and discharged January 11. She resumed outpatient dialysis on January 13, 2011.

We must first use Agnes' height and weight to determine if a case-mix adjustment for low BMI applies, and the magnitude of the case-mix adjustment for BSA. The patient's BMI is computed as follows:

$$BMI = weight_{kg}/height(m^2)$$
$$= 45.36/1.6002^2$$
$$= 45.36/2.5606$$
$$= 17.71$$

Agnes' BMI is less than 18.5. Therefore, her PM will include a 2.0 percent case-mix adjustment for underweight status.

The formula for calculation of a patient's BSA is:

$$BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}$$

Agnes' BSA is computed as:

$$BSA_{Agnes} = 0.007184 * 160.02^{.725} * 45.36^{.425}$$
$$= 0.007184 * 39.6302 * 5.0592$$
$$= 1.4404$$

Using the Table 29 multiplier of 1.034, Agnes' case-mix adjustment based on her BSA of 1.4404 is calculated as follows:

$$PmtMult_{BSA} = 1.034^{(1.4404-1.87)/0.1}$$
$$=1.034^{(-4.296)}$$
$$= .8662$$

Agnes's PM would reflect the applicable case-mix adjustments from Table 29 for age, gender, BSA, low BMI, and cardiac arrest. It may be expressed as:

$$M = PmtMult_{age} * PmtMult_{gender} * PmtMult_{BSA} * PmtMult_{BMI} * PmtMult_{CardArrest}$$
$$= 1.076 * 1.132 * .8662 * 1.020 * 1.032$$
$$= 1.1106$$

The ESRD PPS payment rate per treatment for Agnes would be:

$206.22 * 1.1106 = $229.03

Example 6—Pediatric ESRD Patient With 2 Co-morbidities; no Outlier Payments Apply

Jonathan, a 24-month old male, began dialysis 8 months ago due to autosomal recessive polycystic kidney disease. Jonathan inherited HIV/AIDS from his mother, who has a history of drug abuse. Jonathan also has diabetes. The patient undergoes PD, with the assistance of a cycler.

Table 33 reveals that Jonathan has two qualifying co-morbidities, diabetes and HIV/AIDS. Because Jonathan is less than 13 years old, and undergoes PD, his pediatric classification group is category 2, for which the PM is 0.980. Jonathan's ESRD PPS payment rate per treatment would be:

$206.22 * 0.980 = $202.10

For as long as Jonathan is on PD, his treating dialysis facility would receive 3 times $202.10 or $606.30 weekly.

Example 7—Pediatric ESRD Patient With 1 Co-morbidity; Outlier Payments Apply. (For a Description of the Outlier Payment Methodology, See Section X.)

Timmy is a 16 year old male with ESRD due to renal hypoplasia. The patient was on PD until 2005, when he received a deceased donor kidney transplant. Timmy's transplant failed in August 2007, and he has been on HD since that time. The patient receives dialysis through an AV fistula. 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 one month ago with Klebsiella 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 facility submitted a bill for allowable SB drugs and biologicals, laboratory tests, and supplies totaling $3250.00.

Table 33 reveals that Timmy has 1 qualifying co-morbidity, diabetes. Because Timmy is 16 and undergoes HD, his pediatric classification group is category 8, for which the PM is 1.215. Timmy's payment rate per treatment, without regard to outlier payments, would be:

$206.22 * 1.215 = $250.56

Timmy's dialysis facility would receive $250.56 for each of the 12 treatments it furnished in January. Based on the total allowable billed SB services of $3250, the SB MAP per

treatment averaged $3250/12 or $270.83 per session. We must determine if Timmy's dialysis facility would be eligible for outlier payments.

Using Table 33, we must calculate the case-mix adjusted predicted SB MAP. (See section X.A.1.b)

SB MAP * PmtMult = $64.54 * 1.272 = $82.09

The fixed dollar loss amount for the predicted SB MAP is:
$82.09 + $174.31 = $256.40

Because Timmy's average SB MAP for services furnished was $270.83, which exceeds the case-mix adjusted fixed dollar loss amount of $256.40, Timmy's ESRD facility is eligible for outlier payments beyond the otherwise applicable $250.56 ESRD PPS amount. The outlier payments are computed as follows:

Amount in excess of fixed dollar loss amount

($270.83—$256.40) = $14.43
Loss sharing ratio 80%

Outlier payments per treatment

($14.43 * .80) = $11.54 $11.54

Outlier payments

($11.54 * 12) = $138.48 $138.48

The total ESRD payments to this facility on behalf of Timmy for January would be:

Regular ESRD payments

($250.56 * 12) = $3006.72 $3006.72

Outlier payments 138.48
Total payments $3145.20

XII. ESRD Bundled Market Basket

Under section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor minus 1.0 percentage point. 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. As noted in section VII.B of this proposed rule, under section 1881(b)(14)(F)(ii) of the Act, the ESRD bundled rate market basket will also be used to update the composite rate portion of ESRD payments during the PPS phase-in period from 2011 through 2013.

As required under section 1881(b)(14) of the Act, effective for CY 2012, 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 we are proposing a single payment rate for both operating and capital-related costs, the proposed ESRDB market basket for ESRD facilities includes both operating and capital-related costs.

The following discussion includes an explanation of the methodology and results of the proposed ESRDB market basket. First, we describe the methodology behind the development of the proposed cost category weights. Next, we explain the basis for the selection of each price measure used to proxy the rate of price change for each expenditure or cost category. Next, we present the results of the proposed ESRDB market basket, and finally we propose our definition of the ESRDB labor-related share.

The ESRDB market basket is constructed in three steps. First, a base period is selected and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories. Then, the proportion of total costs that each category represents is determined. These proportions are called cost or expenditure weights. Each expenditure weight category is then matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are price index levels derived from publicly available statistical series that are published on a consistent schedule, preferably at least on a quarterly basis. Finally, the expenditure weight for each category is multiplied by the index level of the respective price proxy to arrive at a weighted index level for each cost category. The sum of the products (that is, the expenditure weights multiplied by the price levels) for all cost categories yields the aggregate index level of the market basket in a given year. Repeating this step for different time periods produces a series of market basket index levels over time. Dividing an index level in one period by an index level in an earlier period produces a rate of growth in the input price index over that time period.

We are proposing to use CY 2007 as the base year for the development of the ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities.

We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2007 = 100. Source data included CY 2007 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 2007 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 published by the U.S. Department of Labor, Bureau of Labor Statistics (BLS). We are proposing to use CY 2007 because it is the most recent year that both relatively complete Medicare cost report data and supplemental BES data is available. Analysis of Medicare cost reports for CY 2002 through CY 2006 showed little difference in cost weights compared to CY 2007. Medicare cost reports from hospital-based ESRD providers were not used to construct the proposed ESRDB market basket because data from independent ESRD facilities tend to better reflect the actual cost structure faced by the ESRD facility itself, and are not influenced by the allocation of overhead over the entire institution, as can be the case with hospital-based providers. This approach is consistent with our standard methodology used in the development of other market baskets, particularly those used for updating the skilled nursing facility PPS and home health PPS.

Cost Category Weights

Using Worksheets A, A2, and B from the CY 2007 Medicare cost reports, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits for direct patient care, Pharmaceuticals, Supplies, Laboratory Services, Blood Products, Administrative and General and Other (A&O), Housekeeping and Operations, and Capital-Related costs. 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 3,572 independent ESRD facilities' cost reports from an available pool of 3,970 cost reports. Expenditures for the nine cost categories as a proportion of total expenditures are shown in Table 38.

Table 38
Initial 2007-Based End-Stage Renal Disease Bundled Rate Major Cost Categories and Weights Determined from the Medicare Cost Reports

Expense Category	CY 2007-Based Weights
Wages and Salaries	25.106%
Benefits for Direct Patient Care	5.076%
Pharmaceuticals	28.775%
Blood products	0.043%
Supplies	9.409%
Laboratory Services	0.330%
Housekeeping and Operations	3.353%
Administrative and General, and Other	17.847%
Capital-Related Costs	10.061%
Total	100.000%

Note: Totals may not sum to 100 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 drugs currently covered by Medicare Part D, as well as with additional lab expenses. The estimates for both of the aforementioned expenditures were provided by KECC. There are also costs that are reported on the Medicare cost report, but are not included in the ESRD bundled payment. As a result, we removed the expenses related to vaccine costs from total expenditures since these are excluded from the ESRD bundled payment, but reported on the Medicare cost report.

We are proposing to expand 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 separately break out 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 proposed rule.

Wages and Salaries

The weight for wages and salaries for direct patient care 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 market basket cost weight. This was accomplished in the following steps.

(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, blood and blood products, 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 20.965 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 25.106 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 38.

When we add the expenditures related to lab expenses that were previously paid for under the Medicare fee schedule and not included in the Medicare cost report and the ESRD-related drug expenditures currently covered under Part D that were 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 22.798 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 24.516 percent.

Benefits

The Benefits weight was derived from the 2002 BES data aged forward to 2007 as a benefit share for all employees is not available from the ESRD Medicare cost report. The cost report only reflects benefits for 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 0.672 percentage point larger (5.748 vs. 5.076) 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 0.672 percentage point for Benefits from Pharmaceuticals, Biological Products, 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 6.177 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 the 2002 utility expenditures to 2007. 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 drugs 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 0.586, 0.111, and 0.483 percent, respectively, yielding a combined Utilities cost weight of 1.180 percent.

Pharmaceuticals

The proposed ESRDB market basket includes expenditures for all drugs, including separately billable drugs and ESRD-related drugs 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 proposed 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. 2007 expenditures for ESRD-related drugs currently covered under Part D were added to cost report totals.

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 a proposed ESRDB market basket weight for Pharmaceuticals of 30.743 percent. EPO expenditures accounted for 19.351 percentage points of the Pharmaceuticals weight, ESRD-related drugs currently covered under Part D accounted for 4.681 percentage points of the Pharmaceuticals weight, and all other drugs accounted for the remaining 6.710 percentage points of the Pharmaceuticals weight.

Blood Products

We calculated the weight for Blood Products in the ESRDB market basket using the separately billable expenditure amounts for the Whole Blood and Packed Red Blood Cells cost center on Worksheet A of the Medicare cost report. We then added the expenditures for A&O for Whole Blood and Packed Red Blood Cells from Worksheet B to the net expenses from worksheet A to arrive at a total expenditure amount for Blood Products. This total was divided by total expenses to derive a weight for the Blood Products component in the bundled rate market basket. Similar to other expenditure category adjustments, we reduced the computed weight to exclude non-direct patient care salaries and benefits associated with the Blood cost centers. The proposed adjusted Blood Products market basket weight is 0.035 percent.

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 proposed market basket weight for Supplies is 8.543 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. For 2007, we increased the laboratory expenditures by a factor of 16.298, as estimated by KECC. 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 proposed

market basket weight for Laboratory Services is 4.875 percent.

Housekeeping and Operations

We developed a market basket 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 proposed market basket weight for Housekeeping and Operations is 1.766 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 category. 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 13.617 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 2007. 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 1.692 percent. This proposed cost weight is then separated into Labor-related Professional Fees (1.478 percent) and Nonlabor-related Professional Fees (0.214 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 2007. 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 proposed market basket cost weight for Telephone Services is 0.590 percent.

All Other Labor-related Services

A separate weight for All Other Labor-related Services was developed using the 2002 BES data aged to 2007. 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 proposed market basket cost weight is 1.163 percent.

All Other Nonlabor-related Services

A separate weight for All Other Nonlabor-related Services was developed using the 2002 BES data aged to 2007. 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 proposed market basket cost weight is 10.172 percent.

Capital

We developed a market basket 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 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 felt that separate price proxies would be more appropriate to track price changes for the different capital-related categories over time. The resulting proposed market basket weights for Capital-related Buildings and Equipment and Capital-related Machinery are 6.653 and 1.894 percent, respectively.

Table 39 lists all of the expenditure categories in the ESRDB market basket and their corresponding CY 2007 cost weights and proxies, as developed in accordance with the methodology described above.

TABLE 39—ESRDB MARKET BASKET COST CATEGORIES, PRICE PROXIES, AND COST WEIGHTS

Cost	Price/wage	ESRDB market basket
Category	Variable	CY 2007 weights
		(Percent)
Total Compensation		30.693
Wages and Salaries	ECI—Health Care and Social Assistance (Civilian)	24.516
Employee Benefits	ECI—Benefits Health Care and Social Assistance (Civilian)	6.177
Utilities		1.180
Electricity	PPI—Commercial Electric Power	0.586
Natural Gas	PPI—Commercial Natural Gas	0.111
Water and Sewerage	CPI—Water & Sewerage	0.483
All Other Materials		44.196
Pharmaceuticals	PPI—Prescription Drugs	30.743
Blood Products	PPI—Blood and Organ Banks	0.035
Supplies	PPI- Medical, surgical, and personal aid devices	8.543
Laboratories	PPI—Medical Laboratories	4.875
All Other Services		15.383
Telephone	CPI—Telephone Services	0.590
Housekeeping and Operations	PPI—Building, cleaning, and maintenance	1.766
Labor-Related		2.641
Professional fees Labor-Related	ECI—Compensation Professional and Related (Priv.)	1.478
All Other Labor-Related Services	ECI—Compensation Service Occupations (Priv.)	1.163
Nonlabor-Related		10.386
Professional fees Nonlabor-Related	ECI—Compensation Professional and Related (Priv.)	0.214
All Other Nonlabor-Related Services	CPI—All items less food and energy	10.172
Capital Costs		8.547
Capital Related-Building and Equipment	CPI—Residential Rent	6.653
Capital Related-Machinery	PPI–Electrical Machinery and Equipment	1.894

Price Proxies

Once we determined the proposed CY 2007 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:

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.

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.

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 propose to use meet these criteria.

Wages and Salaries

We propose to use the ECI (Wages and Salaries) for Health Care and Social Assistance Workers (Civilian) as the measure of price growth for Wages and Salaries in the ESRDB market basket. We feel that this price proxy most closely reflects both the types of occupations employed by ESRD facilities, and the competitive nature of the dialysis and health services labor markets.

Benefits

We propose to use the ECI for Employee Benefits for Health Care and Social Assistance Workers (Civilian) as the measure of price growth for Benefits in the ESRDB market basket. We selected this price proxy because it most accurately represents the labor conditions associated with ESRD facilities' employee benefit costs, similar to our finding for wages and salaries.

Professional Fees

We propose to use the ECI (Compensation) for Professional and Related Occupations (Private) 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 propose to use the PPI for Commercial Electric Power and the PPI for Commercial Natural Gas as the proxies for the Electricity and Natural Gas cost categories, respectively. We propose to use the CPI for Water and sewerage as the price proxy for the water and sewerage cost category.

Capital-Related—Building and Equipment

We propose to use the CPI for Residential Rent as the price proxy for the Capital-related Building and Equipment cost category. 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. Thus, 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 an adequate proxy for the changes in capital costs facing ESRD facilities.

Capital-Related—Machinery

We propose to use the PPI for Electrical Machinery and Equipment 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 Aranesp© (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 proposed ESRDB market basket, we propose to use the PPI for Prescription Drugs as the price proxy for the Pharmaceuticals category. We propose the use of 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 proposed ESRD 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.

Blood Products

We propose to use the industry PPI for Blood and Organ Banks as the price proxy for this cost category. This is the price proxy that we recently proposed to use in the 2006-based inpatient hospital market basket (74 FR 24157).

Supplies

We propose to use the commodity-based PPI for Medical, Surgical, and Personal Aid Devices 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 propose to use the PPI for Medical Laboratories 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 medical labs PPI). 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 the medical labs PPI).

Telephone

We propose to use the CPI for Telephone Services 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 propose to use the PPI for Building Cleaning and Maintenance Services as the price proxy for the Housekeeping and Operations cost category. 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 propose to use the ECI (compensation) for Service Occupations (Private) 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 propose to use the CPI for All Items Less Food and Energy 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 proposed ESRDB market basket reflects the combination of weights and proxies discussed above. Table 40 contains the forecasted rate of growth for CY 2009 through CY 2019 for the ESRDB market basket. Over this time period, the ESRDB market basket average increase is projected to be 2.7 percent.

TABLE 40—FORECAST OF THE 2007-BASED ESRD BUNDLED RATE MARKET BASKET PERCENT CHANGE, 2009 THROUGH 2019

Cy beginning January 1st	ESRDB
CY2009	3.4
CY2010	2.3
CY2011	2.5
CY2012	2.6
CY2013	2.6
CY2014	2.7
CY2015	2.7
CY2016	2.7
CY2017	2.7
CY2018	2.7
CY2019	2.7

Note: These percent changes do not reflect the −1 percentage point update in the market basket as mandated by MIPPA.

Source: 2009 2nd 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 2007-based ESRDB market basket costs to determine the proposed labor-related share for ESRD facilities under a bundled system. Under the proposed ESRDB market basket, the labor-related share for ESRD facilities is 38.160 percent; as shown in Table 41 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 41—ESRDB MARKET BASKETS LABOR-RELATED

Share cost category	2007-based ESRDB labor-related share (percent)
Wages	24.516
Benefits	6.177
Housekeeping and operations	1.766
All other labor-related services	1.163
Professional fees labor-related	1.478
Capital labor-related	3.060
Total	38.160

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. 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. Thus, we are proposing to include 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).

XIII. Proposed Implementation for the ESRD PPS

A. 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 prospective payment system, or the 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 proposed rule, we will 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. In addition, 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 is discussed further in section VII.E.

In accordance with section 1881(b)(14)(E) of the Act, we propose to implement the transition from the current basic case-mix adjusted composite payment system in equal increments, with renal dialysis services and home dialysis furnished on or after January 1, 2014, paid entirely based on the payment amount under the ESRD PPS. Specifically, we propose that for renal dialysis services and home dialysis services provided during the transition period beginning January 1, 2011 and ending December 31, 2013, ESRD facilities 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. Therefore, because ESRD facilities would receive an all-inclusive payment during the transition for all renal dialysis services and home dialysis items and services, other entities, such as Method II DME suppliers, laboratories, and Part D plans would no longer bill Medicare beginning January 1, 2011. To the extent these entities furnish items or services to ESRD patients, the entities would need to seek payments from the patient's ESRD facility. Further discussion on Method II DME suppliers, laboratories, and Part D plans can be found below.

For CY 2011, we are proposing 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 are proposing 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 are proposing 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 propose that payment to ESRD facilities be based on 100 percent of the payment amount under the ESRD PPS.

In particular, we propose 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 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. In addition to the above components of the basic case-mix adjusted payment system, as part of the transitional budget neutrality adjustment (describe in section VII.E.), we are also proposing to include a 14 dollar adjustment to the portion of the blended rate related to the basic case-mix adjusted payment system during the transition. The 14 dollar adjustment to the portion of the blended payment amount related to the basic case-mix adjusted payment system accounts for the ESRD related drugs and biological that are currently separately paid under Part D and are being proposed to be included in the ESRD PPS base rate.

For the years during which the phase-in (transition) is applicable, section 1881(b)(14)(F)(ii) of the Act requires the Secretary to annually increase the portion of the proposed ESRD PPS that is based on the composite rate that would otherwise apply if the ESRD PPS had not been enacted. In particular, section 1881(b)(14)(F)(ii)(II) of the Act requires the composite rate portion of the blended payment to be updated annually by the ESRDB market basket minus 1.0 percentage point. Our interpretation of section 1881(b)(14)(F)(ii) of the Act is that the ESRDB market basket minus 1.0 percentage point would be applied only to the composite payment rate portion of the blended payment amount for each year of the transition (which includes CY 2011). A full description of the ESRDB market basket is presented in section XII.

Therefore, for each year of the transition, we are proposing that the composite payment rate portion of the blended amount would be updated by a case-mix adjustment, the drug add-on adjustment, the current wage index, the ESRDB market basket minus 1.0 percentage point, and an adjustment to account for former ESRD-related Part D drugs to maintain transitional budget neutrality. Payments for items and services furnished to dialysis patients that are paid separately under Part B with regard to 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.

We note 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 (further discussion of exceptions under the basic case-mix adjustment composite payment system can be found in section I.B.3). Any existing exception amount would not be updated by the ESRDB market basket throughout the transition.

The portion of the blended rate based on the payment amount under the ESRD PPS includes the base rate and all applicable patient-level and facility-level adjustments, as would be determined under proposed § 413.231 and § 413.235. As set forth in proposed § 413.237, we propose that the ESRD PPS portion of the blended rate would also include outlier payments.

As specified in proposed § 413.178, bad debt is paid separately from the ESRD PPS and any payment for bad debt would occur at the time a FI/MAC reviews an ESRD facility's cost report and makes a final determination on if there are any overpayments/underpayments due to the ESRD facility/Medicare. For more information regarding bad debt payments see section XIV.D.

As previously noted, 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. 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 adjust their operations accordingly. We believe ESRD facilities will choose to be excluded from the transition if they conclude that they would benefit financially from the payment amount under the ESRD PPS.

Section 1881(b)(14)(E)(ii) of the Act requires that ESRD facilities wishing to be excluded from the transition make their election prior to January 1, 2011, in the form and manner specified by the Secretary. We are proposing that ESRD facilities notify CMS of their election choice in a manner established by their respective FI/MAC no later than November 1, 2010 regardless of any postmarks or anticipated delivery dates. A timeframe of 60 days before implementation is consistent with the timeframe that a FI/MAC is given to incorporate any updates to rates. We are also proposing that those 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 their 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. We note that section 1881(b)(14)(E)(ii) of the Act provides that all ESRD facilities wishing to be excluded from the transition must make an election to be excluded from the transition. We therefore are further proposing that those ESRD facilities that fail to affirmatively make an election by November 1, 2010, would be paid based on the blended amount under the transition. 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. All ESRD facilities wishing to be excluded from the transition should submit their election choice by the proposed deadline if they wish to be excluded from the transition and paid entirely based on the payment amount under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. Instruction as to how the FIs/MACs would implement the proposed ESRD PPS would be provided in future guidance. If the FIs/MACs express concern about the November 1, 2010 date, we would revisit the deadline in the ESRD PPS final rule. The proposed transition period policy is set forth in proposed § 413.239.

We are requesting public comment regarding our proposed blended payment rates and our proposed process for making the election to be excluded from the transition period.

1. New ESRD Facilities

Although the first sentence of section 1881(b)(14)(E)(i) of the Act permits ''a provider of services or renal dialysis facility'' to make a one-time election to be excluded from the transition, the second sentence provides that this election must be made prior to January 1, 2011. Reading these two sentences together, we believe that only ESRD facilities providing renal dialysis services to Medicare beneficiaries before January 1, 2011, should have the option to choose whether to be paid under the

transition or under the ESRD PPS. We further note that the transition period provided for under section 1881(b)(14)(E)(i) of the Act is intended to provide existing ESRD facilities time to adjust from payments based on the current basic case-mix adjusted composite payment methodology to bundled payments under the ESRD PPS. New ESRD facilities that begin providing renal dialysis services and home dialysis to Medicare beneficiaries on or after January 1, 2011, would not have received payment under the current basic case-mix adjusted composite payment system; therefore, we do not believe new ESRD facilities require a transition period in order to make adjustments to their operating procedures. Accordingly, we propose that ESRD facilities that are certified for Medicare participation and begin providing renal dialysis services and home dialysis on or after January 1, 2011, 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 propose that new ESRD facilities be paid based on 100 percent of the payment amount under the ESRD PPS.

As set forth in § 413.171 of this proposed rule, we are proposing to define a new ESRD facility as an ESRD facility that is certified for Medicare participation on or after January 1, 2011.

2. Limitation on Beneficiary Charges Under the Proposed ESRD PPS and Beneficiary Deductible and Coinsurance 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 coinsurance 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).

In this rule, we have proposed the items and services that would be considered renal dialysis services included in the ESRD PPS payment such as the composite rate related services, certain separately billable drugs, former Part D drugs used in the treatment of ESRD, laboratory testing, etc. We understand that certain items and services such as laboratory tests and Part D drugs have different beneficiary coinsurance structures. However, 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, a 20 percent beneficiary coinsurance 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, geographic wage index, outlier, etc.

Thus, we are proposing that an ESRD facility receiving an ESRD PPS payment may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts as specified in § 413.176. The beneficiary coinsurance amount for the ESRD PPS base rate is 20 percent of the total ESRD PPS payment (including payments made under the transition). We note that the amount of coinsurance is based on the proposed ESRD PPS payment for renal dialysis services and home dialysis in 42 CFR part 413. In general, facilities are paid monthly by Medicare for the ESRD services they furnished to a beneficiary even though payment is on a per treatment basis. We are proposing to continue this practice to pay ESRD facilities monthly for services furnished to a beneficiary beginning January 1, 2011. 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 of the prospective payment system in effect prior to January 1, 2011, and the ESRD PPS payment amount for services furnished to a beneficiary. ESRD Facilities would receive a monthly payment that is a blended payment amount for services furnished to a beneficiary. The services included in this blended monthly payment amount would be subject to a 20 percent beneficiary coinsurance.

Additionally, in accordance with section 1881(b)(1) of the Act and consistent with other established prospective payment systems policies, we are proposing 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.

B. Claims Processing

As indicated above, 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 related to home dialysis. For example, those services would include supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, and support services.

Implementation of the proposed ESRD PPS will require a significant amount of changes to the way we process claims. Some of the changes could entail consolidated billing rules and edits and the data elements reported on claims, as discussed below.

1. Consolidated Billing

Since the ESRD PPS payment model represents an all-inclusive payment for renal dialysis services and home dialysis items and services, the ESRD facility itself is responsible for virtually all of the services mentioned above that its patients receive. It is important that billing and payment for these services, which could be provided by other entities, such as laboratories, is made only to the ESRD facility so that duplicate payment is not made by Medicare. Therefore, as stated previously in section XIII.B, suppliers, laboratories, and Part D plans would not be permitted to bill Medicare for renal dialysis services and home dialysis items and services that they furnish to ESRD beneficiaries. The consolidated billing approach essentially confers to the ESRD facility itself the Medicare billing responsibility for all of the renal dialysis services that its patients receive.

a. Laboratory Tests

ESRD patients generally have many co-morbid conditions and are treated by other specialists for those conditions. As such, many of the same laboratory tests ordered by a physician to monitor a patient's ESRD, could also be ordered by other physician specialists treating the ESRD patient for other medical conditions. Therefore, it is difficult to differentiate between an ESRD related laboratory test and a test ordered for another condition. While the ideal scenario would be to require that payment for all potential ESRD related laboratory tests be made only to the ESRD facility, ESRD facilities may not be able to control the ordering of tests by physicians not treating the patient's renal disease. A consolidated billing approach could identify the source of a given laboratory test to allow separate payment when the test was not ordered in connection with the patient's ESRD condition. In order to ensure proper payment in all settings, we are exploring the use of modifiers to identify those services furnished to ESRD beneficiaries, which are excluded from the proposed ESRD PPS.

b. Drugs and Biologicals

Certain drugs and biologicals routinely furnished to ESRD beneficiaries that are paid under the Medicare ESRD benefit are included in the current basic case-mix adjusted composite rate. Other ESRD-related injectable drugs are separately paid under Medicare Part B. However, as mentioned above, section 1881(b)(14)(B) of the Act requires the inclusion of all drugs and biologicals used for the treatment of ESRD, including drugs and biologicals that were formerly covered under Medicare Part D. Therefore, we would include these drugs as part of the consolidated billing mechanism discussed above. As a result of including these former Part D ESRD drugs and biologicals in the proposed ESRD PPS, we are proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. Such arrangements would prevent potential Medicare overpayments made under both Parts B and D. Further discussion regarding payment for former Part D drugs and biologicals can be found in section III.C.

c. Home Dialysis

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 proposed ESRD PPS. Thus, we are proposing that the Method II home dialysis approach in its present form would no longer exist under the proposed ESRD PPS effective January 1, 2011. This proposal does not eliminate Method I in its present form. Therefore, a supplier could only furnish, under arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary, and the supplier would have to look to the ESRD facility for payment. We believe that this approach is simpler and would reduce the administrative burden of maintaining two payment methods for home dialysis patients, as we believe that section 1881(b)(14)(A)(i) of the Act requires that all Medicare home dialysis supplies and services be paid under the proposed ESRD PPS and such payment be made to the ESRD facility. Further discussion of this proposal and information on home dialysis can be found in section III.E.

2. Expansion of the Data Elements Reported on Claims

Under the current basic case-mix composite adjusted payment system, ESRD facilities are paid a composite rate for each dialysis treatment performed. Currently the composite rate includes a number of items and services beyond the dialysis treatment itself. The services that are billed on the claim do not provide any detail of the composite rate items and services that are furnished to the patient beyond the treatment itself. Examples of additional types of items and services that are included in the composite rate but are not captured on the claims and that we believe would be helpful in our ability to predict composite rate costs are: time on machine, nutritional services, social work services, and nursing services. We are not proposing additional reporting requirements at this time, but we believe that collecting additional data at patient-level is necessary for refinements to the proposed case-mix adjustments of the proposed ESRD PPS payment model.

In the future, we may implement new reporting requirements where data elements, such as time on machine, nutritional services, social work services, and nursing services, would be relevant for case-mix refinements. We are requesting public comment regarding these data elements and other claim-based information that would identify patients who are high cost. Identifying other factors that explain costs could assist us in developing future patient-level adjusters that would further refine the model that we used to develop the proposed ESRD PPS. Detailed instruction as to how claims would be processed under the proposed ESRD PPS will be provided in future guidance.

C. Operational Issues Surrounding Payment for Self Administered ESRD–Related Drugs and Biologicals

As we discussed in section III. of this 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 Parts B and D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

As described in section III. of this proposed rule, we are proposing to include renal dialysis service drugs formerly covered under Part D under the proposed ESRD PPS. As a result, we are further proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. Regardless of the mechanism by which these drugs would be furnished (directly or under arrangement), as ESRD facilities assume responsibility for the provision of these drugs that were formerly furnished by the Part D plans, we believe that some of the Part D provisions set forth in the 42 CFR Part 423, would become relevant for ESRD facilities. We are particularly interested in assuring beneficiary access to these drugs. As such, we request public comment on the extent to which Part D access requirements including, but not limited to, pharmacy networks and formularies may be relevant in the context of ESRD facilities' provision of renal dialysis service drugs.

In addition, consistent with the patients' rights processes set forth in § 494.70(a) and the condition: governance processes set forth in § 494.180(e) of the conditions for coverage for ESRD facilities, we would expect that the ESRD facilities would update their grievance processes to account for all self-administered ESRD-related drugs. Patients would continue to have access to both internal and external grievance processes including the ESRD Network and the State survey agency.

In the case of any ESRD facility that would seek to furnish drugs directly by dispensing on-site, we would expect that such facility comply with state pharmacy licensure requirements. As an alternative, we believe that 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. Under this scenario, the patient's MCP physician would prescribe the drugs or biologicals. The patient would obtain these drugs from a retail or mail order pharmacy with which the ESRD facility has contracted. We would expect 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.

As indicated in proposed § 413.241 of this proposed rule, we would further expect 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 would expect 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 would expect 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.

To prevent duplicate payment under both Part D and Part B for bundled drugs and biologicals formerly covered under Part D, we are 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. For example, similar to the Part D requirements in § 423.120(c), ESRD facilities could issue a card or other type of technology that its enrollees may use to access renal dialysis service drugs through pharmacies with which they have established arrangements.

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 coinsurance amount, nor treat these drugs in accordance with the Part D rules. As discussed in section XIII.A.2. of this proposed rule, the ESRD facility would collect applicable beneficiary coinsurance that is based on the proposed ESRD PPS per treatment payment amount.

As discussed in section VII. of this proposed rule, the cost of the drugs and biologicals currently separately payable under Part D that we propose 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. In addition, the mechanism by which we propose to address payment for these drugs during the transition as an adjustment to the blended payment related to basic case-mix adjusted composite payment system is discussed in section VII.D.b. of this proposed rule.

XIV. Evaluation of Existing ESRD Policies and Other Issues

We reviewed existing ESRD policies to determine their applicability to the proposed ESRD PPS. We propose to eliminate the exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities that exist under the case-mix adjusted composite payment system. We would maintain the current erythropoeisis stimulating agent monitoring policy, bad debt policy, reporting requirements for circumstances whereby Medicare is the secondary payer (MSP), and the 50-cent deduction to fund the ESRD Networks. We also propose to set forth in § 413.195 the limitation on review with regard to the ESRD PPS. In addition, we are considering the extent to which the laboratory services 50 percent rule would continue to apply under the proposed ESRD PPS.

A. 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, but did allow the continuation of the existing exceptions as long as the exception rate exceeded the applicable composite payment rate. 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 calendar year (CY) 2005 Physician Fee Schedule (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 that when computing an exception amount, the facility's patient population and the higher costs relating to case-mix are taken into consideration. We indicated 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. 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. We indicated 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.

While section 153 of the MIPPA does not directly address exceptions, we believe that the ESRD PPS under 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. We also believe that we have addressed the higher costs relating to case-mix through the patient characteristic adjustments and outlier payments that are discussed in detail in sections VIII.B and X.A. Therefore, we are proposing 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 elects to receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, any existing exceptions would no longer be recognized. In the event that an ESRD facility elects to receive payment under the transition period, any existing exceptions would be recognized for purpose of the basic case-mix adjusted composite payment system portion of the blended payment through the transition. We propose 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 point out that such appeals apply only to exceptions to the composite rate granted before January 1, 2011.

B. Erythropoiesis Stimulating Agent (ESA) Monitoring Policy

In 2003, we solicited input from the ESRD community, in order to develop an erythropoiesis stimulating agent (ESA) Monitoring Policy. After input from the community, we implemented, through administrative issuance, the first iteration of the monitoring policy effective for services provided on or after April 1, 2006. On July 20, 2007, we issued through administrative issuance, a revised policy effective for services

furnished on or after January 1, 2008. We are currently evaluating the extent to which we could continue the ESA Monitoring Policy for renal dialysis services furnished on or after January 1, 2011. Specifically, at the current time it is not known how the reduction in payment that is currently applied to the separately billed ESAs would be applied under the proposed ESRD PPS. As discussed in section X.A, we are also continuing to evaluate how to establish eligibility for outlier payments in instances where the ESA Monitoring Policy is implicated. We request public comments on this issue to inform our evaluation.

C. ESRD Facility Network Deduction

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. The methodology for calculating the reduction is described in the Medicare Claims Processing Manual, Pub. 100–04, Ch. 8, section 110. We would continue this deduction with the ESRD PPS effective for services provided on or after January 1, 2011, 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 (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). For facilities that elect to receive ESRD payment during the transition, we would apply the reduction methodology as described above to the blended payment amount during the transition.

D. Bad Debt

Section 413.89 of the regulations 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.

Under the basic case-mix adjusted 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 coinsurance, 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 the 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 § 413.178 and § 413.89 of the regulations and Chapter 3 of this proposed rule.

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.

In developing the proposed changes to the ESRD payment system described in this proposed rule, 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, under the proposed ESRD PPS, 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 proposed single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we are proposing to use only the composite rate portion of the proposed single ESRD payment rate to determine bad debt payments. We are proposing that bad debt payments for ESRD facilities would continue to be capped as required under § 413.178(a). The Medicare cost report and instructions in the PRM, Part 2 (CMS Pub. 15–2) may 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 are proposing to make a conforming change to regulation text at § 413.178(d) regarding ESRD bad debt payment made under the proposed ESRD payment system described in this proposed rule. We are also including a cross-reference to § 413.178 in § 413.89(h) and (i).

E. Limitation on Review

In addition to requiring the establishment of the ESRD PPS, 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 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 propose to codify this limitation on review in § 413.195 of the regulations.

F. 50 Percent Rule Utilized in Laboratory Payments

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 in addition to the composite rate is made for any of the separately billable 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. When ordering ESRD-related AMCC tests, ESRD facilities identify, for a particular date of service, each test that is included in the composite rate and each test that is not included. A ''non-composite rate test'' is defined as ''any test separately payable outside the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.''

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. Under the proposed consolidated billing provisions discussed further in section XIII B. of this proposed rule, the ESRD facility itself would assume the Medicare billing 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.

As described in section X of this proposed rule, under the proposed ESRD PPS, 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.

In addition, preliminary analyses reveal a small impact upon removing from eligibility for outlier services the AMCC tests to which the 50 percent rule applies. As a result, we are considering excluding AAMC tests to which the 50 percent rule applies from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS. We plan to continue to evaluate the impact of this approach and include further discussion in the final rule. We request 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.

G. Medicare as a Secondary Payer

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. At this time, we are 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 are exploring how it will be utilized and managed under the proposed ESRD prospective payment system. We believe that while there may need to be system changes in order to process MSP claims under the Proposed ESRD prospective payment system, there should be no impact on ESRD providers and on primary payers. We will issue through administrative issuance, any changes in the manner of reporting information, should that be required. We are soliciting public comment on the operational issues of MSP under the proposed ESRD payment system.

XV. Quality Incentives in the End-Stage Renal Disease (ESRD) Program

A. Introduction

Section 1881(h) of the Social Security Act (the Act), as added by section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), requires the Secretary to develop a quality incentive program (QIP) that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established with respect to certain specified measures. As provided under section 1881(h) of the Act, the payment reductions, which will be up to 2.0 percent of the payments otherwise made to providers and facilities under section 1881(b)(14), will apply to renal dialysis services furnished on or after January 1, 2012, and the total performance score that providers and facilities must meet or exceed in order to receive their full payment will be based on a specific performance period prior to this date. The payment reductions will apply with respect to the year involved and will not be taken into account when computing future payment rates.

The CMS is committed to developing and implementing an ESRD QIP, and we intend to issue a subsequent proposed rule that makes detailed proposals regarding how we plan to implement section 1881(h) of the Act. However, in the interim, with one exception described below, we believe it is important to describe the QIP conceptual model that CMS is considering proposing for purposes of the payment reduction that will apply with respect to renal dialysis services furnished on or after January 1, 2012. Therefore, we will present the model below so that the public has an opportunity to comment on it, and we will use the comments to inform our evaluative, analytic, and guidance efforts during the development of the QIP.

The one exception mentioned above is the measure set that will apply for purposes of the CY 2012 payment reduction. We are making specific proposals with respect to that measure set in this proposed rule so that the public will be informed as early as possible regarding the measures on which the performance standards will be based.

B. Background

Quality monitoring and provider accountability is important in the ESRD payment system and has been done for over 30 years. We will describe the evolution of our ESRD quality monitoring initiatives by category below:

1. ESRD Network Organization Program

In the End-Stage Renal Disease Amendments of 1978 (Pub. L. 95–292), Congress required the formation of ESRD Network Organizations to further support the ESRD program. CMS currently contracts with 18 ESRD Networks throughout the United States to perform oversight activities and to ensure that dialysis patients are provided appropriate care. The Networks' responsibilities include monitoring the quality and improvement of care received, providing technical assistance to patients who have ESRD and providers/facilities that treat ESRD patients, and addressing patient grievances. In 1994, CMS and the Networks, with input from the renal community, established the ESRD Core Indicators Project (CIP). The ESRD CIP was CMS's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD. This project established the first consistent clinical ESRD database. Information included in the database included clinical measures thought to be indicative of key components of care surrounding dialysis.

2. Clinical Performance Measures (CPMs)

Section 4558(b) of the Balanced Budget Act of 1997 required CMS to develop and implement, by January 1, 2000, a method to measure and report the quality of renal dialysis services furnished under the Medicare program. To implement this legislation, CMS developed the ESRD Clinical Performance Measures (CPM) Project, based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (NKF–DOQI) Clinical Practice Guidelines. The purpose of the ESRD CPM Project is to provide comparative data to ESRD facilities to assist them in assessing and improving the care furnished to ESRD patients. Sixteen CPMs were developed in 1998 to measure and report the quality of dialysis services furnished under Medicare in the areas of hemodialysis and peritoneal dialysis adequacy, anemia management, and vascular access management. The first data collection effort for the ESRD CPMs began in 1999. These CPMs are calculated using information contained in patients' records. CPMs are collected on a national random sample of adult in-center hemodialysis patients, all in-center hemodialysis patients less than 18 years of age, and a national random sample of peritoneal dialysis patients. Data are collected annually and submitted to CMS via a predominantly paper-based process. The CPMs are calculated and released in the Department of Health and Human Services' Annual Report on the ESRD CPM Project.

3. Dialysis Facility Compare (DFC)

Also in response to the Balanced Budget Act of 1997, we created Dialysis Facility Compare (DFC) as a new feature on *http://www.medicare.gov* that was modeled after Nursing Home Compare. We worked with a contractor and a consumer workgroup to identify dialysis facility-specific measures that could be provided to the public for consumer choice and information purposes. This tool was launched in January 2001 on the *http://www.medicare.gov* Web site to provide information to the public for comparing the quality of dialysis facilities and providers across the country, including specific information about services and the quality of care furnished by a specific dialysis facility/provider. DFC captures administrative and quality related data submitted by dialysis facilities and providers.

The key quality measures captured in this tool include facility-level measures of anemia control, adequacy of hemodialysis treatment and patient survival. Medicare claims data are used to calculate the anemia management and dialysis adequacy rates and administrative data (non-clinically based data such as demographic data, and data acquired from the Social Security Administration and obtained from the CMS forms 2728 and 2746) used to determine the patient survival rates. The anemia measure shows the raw number or the percentage of patients at a given facility/provider whose anemia (low red blood cell count) was not controlled. More specifically, the anemia measure is the percentage of patients whose hematocrit levels are at 33 percent (33 percent out of 100 percent) or more (or hemoglobin levels of 11 g/dL or more). The dialysis adequacy measure shows the raw number or the percentage of in-center hemodialysis patients at a facility that get effective treatments during dialysis. More specifically, the measure is the percentage of patients with urea reduction ratio (URR) levels of 65 percent or more. The patient survival measure shows whether patients treated at a certain facility generally live longer, as long, or not as long as expected. These measures are updated annually on the DFC Web site, usually at the end of the year, using data from the previous year for the dialysis adequacy and anemia measures and data from the past four years for the patient survival measure.

In November 2008, the anemia management measure was updated using facility and claims data from 2007. Recent evidence about increased risk of certain adverse events associated with the use of erythropoiesis-stimulating agents (ESAs), which are used to treat anemia, raised concerns about patients who have hemoglobin levels too high, as well as patients whose hemoglobin levels are too low. The Food and Drug Administration (FDA) responded by requiring manufacturers to develop a Medication Guide (*http://www.fda.gov/cder/drug/advisory/RHE200711.htm*) and to ensure that this information is provided to patients. The labeling guideline 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'' (*http://www.fda.gov/cder/drug/advisory/RHE200711.htm*). As a result of this guideline, DFC was revised to include two anemia measures: one measure shows the percentage of patients whose hemoglobin levels are considered too low (that is, below 10 g/dL), and a second measure shows the percentage of patients whose hemoglobin levels are too high (that is, above 12 g/dL). In addition, CMS has updated the way it reports patient survival rates on DFC to reflect whether patients treated at a provider/facility generally live longer than, as long, or not as long as expected.

4. ESRD Quality Initiative

In 2004, the ESRD Quality Initiative was launched. The objective was to stimulate and support significant improvements in the quality of dialysis care. The initiative aimed to refine and standardize dialysis care measures, ESRD data definitions, and data transmission to support the needs of the ESRD program; empower patients and consumers by providing access to facility service and quality information; provide quality improvement support to dialysis providers; assure compliance with conditions of coverage; and build strategic partnerships with patients, providers, professionals, and other stakeholders. Components of this Quality Initiative included the DFC, the CPM Project, and the Fistula First Breakthrough Initiative.

5. ESRD Conditions for Coverage

The ESRD Conditions for Coverage final rule published on April 15, 2008, and contains revised requirements that dialysis providers and facilities must meet in order to be certified under the Medicare program. As part of the revised requirements, dialysis providers and facilities are required to implement a quality assessment and performance improvement program. In addition, providers and facilities are required to submit the CPMs electronically on all their patients on an annual basis. The CPMs were updated and expanded in April 2008 through a National Quality Forum (NQF) endorsement process. The current CPMs include 26 measures in the areas of anemia management; hemodialysis adequacy; peritoneal dialysis adequacy; mineral metabolism; vascular access; patient education/perception of care/quality of life; and patient survival. The anemia management measures for patients receiving erythropoiesis-stimulating agents (ESAs) and the urea reduction ratio (URR) measure (in-center hemodialysis) are not NQF endorsed.

6. CROWNWeb

CMS has developed a new Web-based system, Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) for the purposes of collecting CPM data electronically from dialysis facilities. Use of the CROWNWeb system will increase the efficiency of data collection for both CMS and providers/facilities, improve data quality, and provide a more stable and accessible platform for continual improvements in functionality. In February 2009, CMS began implementing the CROWNWeb system with a number of providers/facilities and plans to expand reporting to additional providers/facilities as soon as practicable.

C. The ESRD Quality Incentive Program as Authorized by Section 1881(h) of the Act

Recognizing the need for additional quality monitoring in an ESRD payment system, Congress required in section 153 of MIPPA that the Secretary implement an ESRD quality incentive program (QIP). We believe that the QIP is the next step in the evolution of the ESRD quality program because it measures provider/facility performance versus being focused on reporting outcome data.

Specifically, section 1881(h) of the Act, as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established with respect to certain specified measures. As provided under this section, the payment reductions, which will be up to 2.0 percent of payments otherwise made to providers and facilities under section 1881(b)(14), will apply to renal dialysis services furnished on or after January 1, 2012, and the total performance score that providers and facilities must meet

or exceed in order to receive their full payment will be based on a specific performance period prior to this date. Under section 1881(h)(1)(C), the payment reduction will only apply with respect to the year involved and will not be taken into account when computing future payment rates.

For the ESRD quality incentive program, section 1881(h) of the Act generally requires the Secretary to: (1) Select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures for a performance period; and (5) apply an appropriate payment reduction to providers and facilities that do not meet or exceed the established total performance score.

We view the ESRD QIP required by section 1881(h) of the Act as the next step in the evolution of the ESRD quality program that began more than 30 years ago. Our vision is to develop a robust, comprehensive ESRD QIP that builds on the foundation that has already been established. As we move towards this larger goal, we understand the importance of giving providers and facilities time to prepare for the implementation of this new quality incentive program and to assess how the new program will affect them.

Therefore, we are outlining below a conceptual model that describes various components of an ESRD QIP that we are considering proposing in a future proposed rule. We want to make clear that this is only a model, with one exception. The exception, more fully described below, is that we are proposing to initially adopt for the QIP three measures, two of which assess anemia management and one which assesses hemodialysis adequacy, which can be calculated using Medicare claims data.

Our goal is to propose to implement other components of the QIP in future rulemaking. Our purpose in describing a model in this proposed rule is to notify the public regarding what we believe at this time to be essential components of the QIP in the hope of receiving detailed comments on those components. We also note that the model described below represents our thinking on what we are considering implementing only for payment consequence year 2012 because we anticipate that the program will evolve as we conduct additional analyses, gather experience, and respond to industry feedback.

1. Proposed Anemia Management and Dialysis Adequacy Measures

Section 1881(h)(2)(A)(i) of the Act requires that the measures specified for the QIP include measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management, and measures on dialysis adequacy. To implement this section, we are proposing that for the first QIP performance period, we will adopt the two anemia management measures and one hemodialysis adequacy measure that are currently used for DFC. Data needed to calculate these measures can be collected from Medicare claims submitted by ESRD providers and 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 at a provider/facility whose hemoglobin levels were less than 10 g/dL, and (2) the percentage of patients at a provider/facility whose hemoglobin levels were greater than 12 g/dL.

Section 1881(h)(2)(A)(i) of the Act provides that the anemia management measures must reflect the labeling approved by the FDA for such management. The current FDA labeling guideline released November 8, 2007 for the administration of erythropoesis-stimulating agents (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.''

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. These data will also allow us to calculate the percentage of patients who have hemoglobin levels within the 10 through 12 range g/dL. Therefore, we propose to adopt these two anemia management measures for the QIP.

Anemia data has been reported on Dialysis Facility Compare (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 are proposing to use the same methodology we use to calculate the anemia management measures for purposes of DFC to calculate them for purposes of the QIP because the methodology is consistent with how we have calculated that data since 2001. 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 or greater than 20 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 we are proposing to use to calculate the anemia measures are available on the University of Michigan Kidney Epidemiology and Cost Center Web site at *http://www.sph.umich.edu/kecc/assets/documents/facguide.pdf.*

The hemodialysis adequacy measure (urea reduction ratio [URR]) that we are proposing to adopt 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 their in-center hemodialysis). Specifically, this measure assesses the percentage of 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 on the DFC Web site at *http://www.medicare.gov.* This measure has been endorsed by the National Quality Forum (NQF), an organization that endorses quality measures through a public consensus process, although we note that NQF

endorsement of dialysis adequacy measures is not a requirement under section 1881(h)(2)(A)(i).

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, and we are proposing 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. Under this methodology, we will 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. Technical details about the methodology we are proposing to use to calculate the hemodialysis adequacy measure are available on the University of Michigan Kidney Epidemiology and Cost Center Website at *http://www.sph.umich.edu/kecc/assets/documents/facguide.pdf.*

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 and facility level data set available to CMS at this time. For this reason, we are proposing 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) states that the measures shall include ''measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy,'' only one dialysis adequacy measure is collected nationally and available to determine provider and facility-specific values. For this reason, we are proposing at this time to adopt only one dialysis adequacy measure. We also note that section 1881(h)(2)(A)(iii) 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 (including for maximizing the placement of arterial venous fistula). CMS is not proposing to adopt any measures in these categories at this time since we are not currently collecting data that would allow determination of provider and 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. Finally, it is not feasible to propose a patient satisfaction measure at this time because there is no validated data collection tool available to collect relevant and industry accepted patient satisfaction measure data. Therefore, it is not feasible to propose more than the aforementioned measures at this time because of the lack of complete and accurate data. Subsequent rulemaking will address other measures.

2. Performance Standards for the ESRD QIP Measures

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the QIP for a performance period with respect to a year. Section 1881(h)(4)(B) provides that the performance standards shall include levels of achievement and improvement, as determined appropriate by the Secretary. However, in our model, for the first performance period, we would establish a performance standard for the proposed anemia management and hemodialysis adequacy measures based on the special rule in Section 1881(h)(4)(E). This provision requires the Secretary to ''initially'' use as a performance standard for the anemia management and dialysis adequacy measures the lesser of a facility-specific performance rate in the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii), or a standard based on the national performance rate for such measures in a period determined by the Secretary. We would not include in this performance standard levels of achievement or improvement because we do not believe that section 1881(h)(4)(E) requires that we include such levels. In addition, we would interpret the term ''initially'' to apply only to the performance period applicable for payment consequence year 2012. For subsequent performance periods, we plan to propose performance standards under section 1881(h)(4)(A). Such standards will include levels of achievement and improvement, as required under section 1881(h)(4)(B).

As stated above, to implement the special rule for the proposed anemia management and hemodialysis adequacy measures, we would need to compare the performance of a provider or facility on these measures during the year selected by the Secretary for purposes of calculating the ESRD bundle with the performance of the provider or facility using a performance standard based on the national performance rates for these measures in a period determined by the Secretary. For purposes of making this comparison in our model, the provider/facility-level performance year referenced in section 1881(h)(4)(E)(i) would be 2007, 2008, or 2009, depending on which of those years is selected by the Secretary for purposes of calculating the ESRD bundle. We would refer to this year as the ''base utilization year.'' The provider/facility-specific rates for 2007 are currently posted on the DFC Web site.

In terms of establishing a performance standard based on national performance rates as required under section 1881(h)(4)(E)(ii), we are considering adopting a standard that is equal to the average performance of all dialysis providers and facilities based on 2008 data. These data for the anemia management and hemodialysis adequacy measures will be posted on DFC in November 2009.

Although the 2008 data are not yet available on DFC, the national averages currently posted on the DFC website for 2007 are

- For the proposed anemia management measure (Anemia Management Measure less than 10)—the percentage of Medicare patients who have an average hemoglobin value less than 10.0 g/dL in a provider/facility: *2 Percent*
- For the proposed anemia management measure (Anemia Management Measure more than 12)—the percentage of Medicare patients who have an average hemoglobin value greater than 12.0 g/dL in a provider/facility: *44 Percent*
- For the proposed hemodialysis adequacy measure (Hemodialysis Adequacy One)—the percentage of Medicare patients in a provider/facility with URR levels above 65 percent: *95 Percent.*

We expect that these averages will change for 2008.

This means that, for purposes of implementing the special rule in our model for the proposed anemia management and hemodialysis adequacy measures, the performance standard for the initial performance period would be the lesser of (1) the provider/facility-specific rate for the base utilization year, or (2) the national average results from 2008 claims data. If a provider or facility performed below the national average, then we would

look at the provider/facility-specific rate for the base utilization year to determine whether the provider/facility's performance during the initial performance period meets or exceeds the performance standard.

We note that the proposed hemodialysis adequacy measure would assess hemoglobin values only in hemodialysis patients who receive treatment at a provider or facility (and not in hemodialysis or peritoneal dialysis patients treated at home). In addition, the proposed hemodialysis adequacy measure would not assess hemoglobin values in pediatric dialysis patients. Therefore, we are seeking public input about this issue and ideas about whether and how we could assess dialysis adequacy for home dialysis (home hemodialysis and peritoneal dialysis) and pediatric dialysis.

3. Performance Period for the ESRD QIP Measures

Section 1881(h)(4)(D) of the Act requires the Secretary to establish a performance period with respect to a year, and for that performance period to occur prior to the beginning of such year. Because we are required under section 1881(h)(1)(A) to implement the payment reduction beginning with renal dialysis services furnished on or after January 1, 2012, the first performance period would need to occur prior to that date.

In selecting a performance period, we need to allow sufficient time to calculate the provider/facility-specific scores, determine whether providers and facilities meet the performance standards and prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012. Among potential performance periods in our model would be all or portions of 2010. However, we are also considering other performance periods. We seek public comments about performance periods and will propose a specific performance period in future rulemaking.

4. Methodology for Calculating the Total Performance Score for the ESRD QIP Measures

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures selected for a performance period. Section 1881(h)(3)(A)(iii) states that the methodology must also include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary. In addition, section 1881(h)(3)(B) requires the Secretary to calculate separate performance scores for each measure.

Finally, under section 1881(h)(3)(A)(ii), for those providers and facilities that do not meet (or exceed) the total performance score, the Secretary is directed to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments to providers and facilities, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

As discussed earlier, we are proposing to adopt for the initial performance period two anemia management measures and one hemodialysis adequacy measure that are currently used for DFC. In our model, for purposes of calculating the total performance of each provider and facility during the initial performance period, we are considering assigning 10 points to each of these measures. That is, if a provider or facility meets the performance standard for one measure, then it would receive 10 points for that measure, and if the provider or facility meets the performance standards for all three measures, it would receive a total performance score of 30 points.

In our model, we are considering, for scoring purposes, that a provider or facility that does not meet the performance standard set for a measure would receive fewer than 10 points, with the exact number of points corresponding to how far from the set standard the provider/facility's performance falls. Specifically, we are considering implementing a scoring methodology that subtracts 2 points for each 2 percentage point increment range the provider or facility's performance falls from the set performance standard. For example, if we used as the performance standard during the initial performance period the national average of 44 percent (based on 2007 DFC data) for one of the proposed anemia management measures (percentage of patients whose hemoglobin levels are greater than 12 g/dL), and a particular provider/facility had 46 percent of patients with hemoglobin levels greater than 12 g/dL during that period, the provider/facility would receive 8 points for its performance on the measure because 46 percent is within the first 2 percentage point increment range from 44 percent (see Table 42 below). However, applying the special rule for the initial performance period, as required by section 1881(h)(4)(E), the provider/facility's performance of 46 percent would become the performance standard for scoring purposes, and the provider/facility would receive 10 points for this measure (see Table 43 below).

Under our model, providers and facilities that exceed the performance standards based on the national average for the period that the Secretary has determined and if their performance rate improved from the ''base utilization year'' then the provider or facility would receive additional points. Using the 2007 DFC data again to illustrate, if a provider/facility had 43 percent of patients with hemoglobin levels greater than 12 g/dL during the initial performance period, the provider/facility's performance would be better than the 2007 national average of 44 percent. In addition, if the provider/facility had a performance rate of 46 percent in the base utilization year then the provider/facility's performance of 43 percent for the initial performance period would also be better. Therefore, the provider/facility would receive 12 points, which is an additional 2 points or a ''bonus'' (maximum bonus in this conceptual model) above the 10 points that could be received for meeting the performance standard of a measure. We believe providers and facilities should only receive additional points if they achieve higher levels of performance, that is, their actual performance exceeds the performance standard for the national average for the period that the Secretary has determined and improves above the base utilization year.

As we noted above, the right side of Table 42 that represents the percentage of patients whose hemoglobin levels are greater than 12 g/dL, illustrates how this scoring methodology could work for a provider/facility for which, after applying the special rule, the performance standard for the proposed anemia management measures is the national performance rates for 2007. Likewise, Table 43 shows an example using a provider/facility-specific rate as the performance standard (after applying the special rule) for the proposed anemia management measures. In addition, Table 44 illustrates how the scoring methodology would work using the national performance rate for 2007 as the performance standard (after applying the special rule) for the proposed hemodialysis adequacy measure, and Table 45 shows an example of the scoring for the proposed hemodialysis adequacy measure using a facility-

specific rate as the performance standard (after applying the special rule).

Note that the bolded rows show the performance standard for the applicable measure.

TABLE 42—MODEL SCORING METHODOLOGY FOR PROPOSED ANEMIA MANAGEMENT MEASURES USING NATIONAL PERFORMANCE RATES IN 2007 AS THE PERFORMANCE STANDARDS

Points	Proposed anemia management measures			
	Percentage of patients whose hemoglobin levels are less than 10 g/dL		Percentage of patients whose hemoglobin levels are greater than 12 g/dL	
	Percentage	Distribution of facilities	Percentage	Distribution of facilities
12 points**	Below 2 percent	2,523	Below 44 percent	2,283
10 points	**2 percent**	**657**	**44 percent**	**73**
8 points	3 to 4 percent	884	45 to 46 percent	155
6 points	5 to 6 percent	358	47 to 48 percent	143
4 points	7 to 8 percent	149	49 to 50 percent	228
2 points	9 to 10 percent	54	51 to 52 percent	76
0 point	Over 11percent	119	Over 53 percent	1,786

* Provider/Facility must be above both performance standards to receive the bonus points for the anemia management measures.

TABLE 43—MODEL SCORING METHODOLOGY FOR PROPOSED ANEMIA MANAGEMENT MEASURES USING FACILITY-SPECIFIC RATES AS THE PERFORMANCE STANDARDS

Points	Proposed anemia management measures	
	Percentage of patients whose hemoglobin levels are less than 10 g/dL	Percentage of patients whose hemoglobin levels are less than 12 g/dL
	Percentage	Percentage
12 points*	Below 3 percent	Below 46 percent.
10 points	**3 percent**	**46 percent**
	(Example of a facility-specific score)	**(Example of a facility-specific score).**
8 points	4 to 5 percent	47 to 48 percent.
6 points	6 to 7 percent	49 to 50 percent.
4 points	8 to 9 percent	51 to 52 percent.
2 points	10 to 11 percent	53 to 54 percent.
0 point	Over 12 percent	Over 55 percent.

* Provider/Facility must be above both performance standards to receive the bonus points for the anemia management measures.

TABLE 44—MODEL SCORING METHODOLOGY FOR PROPOSED HEMODIALYSIS ADEQUACY MEASURE USING NATIONAL PERFORMANCE RATES IN 2007 AS THE PERFORMANCE STANDARD

Points	Proposed hemodialysis adequacy measure	
	Percentage of patients whose URR levels are greater than 65 percent	Distribution of facilities
12 points**	Over 95 percent	3,142
10 points	**95 percent**	**296**
8 points	93 to 94 percent	417
6 points	91 to 92 percent	245
4 points	89 to 90 percent	181
2 points	87 to 88 percent	102
0 point	Below 86 percent	296

** Provider/Facility must be above both performance standards to receive the bonus points for the hemodialysis adequacy measure.

TABLE 45—MODEL SCORING METHODOLOGY FOR PROPOSED HEMODIALYSIS ADEQUACY MEASURE USING THE FACILITY-SPECIFIC RATES AS THE PERFORMANCE STANDARD

Points	Proposed hemodialysis adequacy measure
	Percentage of patients whose URR levels are greater than 65 percent
12 points**	Above 92 percent.
10 points	92 percent (Example of a facility-specific score).
8 points	90 to 91 percent.
6 points	88 to 89 percent.
4 points	86 to 87 percent.
2 points	84 to 85 percent.
0 point	Below 83 percent.

Provider/Facility must be above both performance standards to receive the bonus points for the hemodialysis adequacy measure.

Another example of how the scoring methodology might work follows below. The example assumes that Facility A achieves the following results during the initial performance period:

1. Anemia Management (less than 10 g/dL): Percentage of patients whose hemoglobin levels are less than 10 g/dL is *4 percent*.

2. Anemia Management (more than 12 g/dL): Percentage of patients whose hemoglobin levels are greater than 12 g/dL is *43 percent*.

3. Hemodialysis Adequacy: Percentage of patients whose URR levels are greater than 65 percent is 93 percent.

The total performance score for Facility A would be 30 points. Facility A would receive bonus points for the anemia management (more than 12 g/dL) because the facility was above the national performance standard for the period determined by the Secretary, which in this example is 2007, and improved above the base utilization year, which is also 2007 in this example. However, the facility would not receive bonus points for the hemodialysis adequacy measure even though it improved from its base utilization year because it did not receive a percentage higher than the national average so the facility would receive a score of 10 points. Table 46 shows how the total performance score would be calculated for Facility A.

TABLE 46—EXAMPLE OF TOTAL PERFORMANCE SCORE METHODOLOGY USING FACILITY A

Measure	Facility performance rate	Performance standard using special rule	Score
Anemia Management: Percentage of patients whose hemoglobin levels are less than 10 g/dL.	4 percent	3 Percent ..... (Use Table 43).	8 points.
Anemia Management: Percentage of patients whose hemoglobin levels are greater than 12 g/dL.	43 percent	44 Percent and 46 Percent ..... (Use Tables 42 and 43).	12 points.
Hemodialysis Adequacy: Percentage of patients whose URR levels are greater than 65 percent.	93 percent	92 Percent ..... (Use Table 45).	10 points.
Total			30 points.

We believe this total performance score methodology is appropriate for the initial performance period in the new ESRD QIP because it is basic and straightforward, allowing providers and facilities to familiarize themselves with the new pay-for-performance quality system. We plan to propose a total performance scoring methodology using the applicable set of measures in future rulemaking. However, we are seeking input on this model of a total performance score methodology to be applied for payment consequence year 2012.

In our model, the initial scoring method weights each of the three proposed measures equally. As we stated above, we also plan to implement performance standards that include levels of achievement and improvement after the initial performance period. From a clinical perspective, we believe that providers and facilities may be concerned about whether they have as much opportunity to improve their performance on one of the proposed anemia management measures (hemoglobin levels less than 10 g/dL) as they might with the other two proposed measures. We are specifically soliciting comments on whether this is truly a concern among providers and facilities and, if so, whether we should consider assigning less weight to the measure based on that concern. We are also soliciting comments on how reassigning weights to measures in general (that is, less to some, more to others) might affect providers and facilities in terms of the payment consequence.

5. Application of Payment Reductions Using the Total Performance Score

With respect to the providers/facilities that do not meet (or exceed) the total performance score, section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

Under our model, for payment consequence year 2012, we are thinking about implementing a sliding scale of payment reductions, where the payment reduction for the lowest total performance score would be 2.0 percent.

Under our model, the minimum total performance score that providers and facilities would need to achieve in order to avoid a payment reduction would be 28 points. The range for the payment reductions is shown in Table 6:

TABLE 47—MODEL RANGE OF PAYMENT REDUCTIONS

Total performance score	Percent of payment reduction
28 to 30 Points	0 Percent.
24 to 26 Points	.25 Percent.
20 to 22 Points	.50 Percent.
16 to 18 Points	.75 Percent.
12 to 14 Points	1.0 Percent.
8 to 10 Points	1.25 Percent.
4 to 6 Points	1.50 Percent.
2 Points	1.75 Percent.

TABLE 47—MODEL RANGE OF PAYMENT REDUCTIONS—Continued

Total performance score	Percent of payment reduction
0 Points	2.0 Percent.

Based on our example involving Facility A above, this facility would not receive a payment reduction in 2012 because it achieved a total performance score of 30 points.

We recognize that under our model, a provider or facility that scores poorly on one measure could nonetheless receive no reduction in payment because the provider or facility also exceeded the performance standard for one or both of the other two measures. We are concerned about this possibility and are considering proposing that, for any measure for which a provider or facility receives 4 points or less, the provider/facility receive a 0.25 percent payment reduction even if it receives a total performance score of 28 points. We are seeking comments on our modeled methodology for applying payment reductions in 2012.

6. Public Reporting of Measures

Section 1881(h)(6) requires the Secretary to establish procedures for making information regarding performance under the QIP available to the public, including information on the total performance score and performance scores for individual measures achieved by each provider and facility. Providers and facilities are required to have an opportunity to review this information prior to it being made public. The Secretary is also directed in section 1881(h)(6)(D) to post a list of providers and facilities on the CMS Web site that indicates the total performance score and the performance scores for individual measures achieved by each provider and facility. In addition, under section 1881(h)(6)(C), the Secretary is required to provide certificates to providers and facilities that indicate the total performance score achieved by the provider or facility, and the provider or facility must prominently display the certificate in patient areas.

We plan to establish procedures for making information available to the public in a future rulemaking, but welcome comments on how to best implement these statutory requirements.

XVI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We are soliciting 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 this proposed rule, to receive the low-volume adjustment, we propose 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.

The burden associated with the requirement is 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. 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 estimate 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. We further estimate several dozen additional ESRD facilities may meet the criteria of a low-volume facility prior to implementation of the ESRD PPS and therefore, we round the total number of estimated low-volume facilities to 200. Therefore, we estimate that the total initial ESRD facility burden would be 16.6 hours.

B. ICRs Regarding Transition Period (§ 413.239)

As discussed in section XIII.A. of this 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. That is, a facility may elect to be paid entirely based on the proposed ESRD PPS beginning January 1, 2011. Proposed § 413.239(b) states that 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 specifies that such election must be submitted to the facility's Medicare administrative contractor or fiscal intermediary no later than November 1, 2010.

We estimate 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. In addition, for those facilities electing to be excluded from the four-year transition, the burden associated with the requirement in proposed § 413.239(b) is the time and effort necessary to develop an election and submit it to the Medicare administrative contractor or fiscal intermediary. We estimate 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 estimate 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 estimate that the total one-time ESRD facility burden would be 448.5 hours.

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
413.232	None	488	200	.083	16.6
413.239(b)	None	4,921	1,794	.25	448.5

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

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

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS 1418–P. Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.gov.*

XVII. 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 proposed 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 proposed 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 proposed rule. We request comments on the economic analysis provided in this proposed rule.

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 21 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 21 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 48. Using the definitions in this ownership category, we consider the 550 facilities that are independent and the 471 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 2.4 percent increase in payments under the new ESRD PPS for 2011. An independent facility (as defined by ownership type) is estimated to receive a 0.0 percent increase in payments under the proposed ESRD PPS for 2011. Therefore, the Secretary has determined that this proposed 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 proposed 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 48.

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 initial 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule has a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 188 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 189 rural hospital-based dialysis facilities will experience an estimated 1.7 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 proposed 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 2009, that threshold is approximately $133 million. While dialysis facilities will be paid approximately $200 million less, we do not believe that this proposed 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 proposed 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 proposed changes to the ESRD bad debt payment in this proposed 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 proposed 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 proposed 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 48 shows the impact of the proposed 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 48 indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions).

TABLE 48—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2011 ESRD PPS

[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
	A	B	C	D
All Facilities	4,921	36.5	−2.0%	−2.0%
Type:				
Freestanding	4,330	32.7	−2.5%	−2.6%
Hospital based	591	3.8	2.1%	3.7%
Ownership Type:				
Large dialysis organization	2,987	23.3	−3.1%	−3.7%
Regional chain	753	5.9	−1.3%	−0.3%
Independent	550	4.0	0.0%	1.3%
Unknown	160	0.3	−1.2%	0.0%
Hospital based [2]	471	3.0	2.4%	4.0%
Geographic Location:				
Urban	3,794	30.3	−1.9%	−1.7%
Rural	1,127	6.3	−2.5%	−3.4%
Census Region:				
East North Central	778	5.8	−2.4%	−2.4%
East South Central	384	2.8	−3.0%	−4.4%
Middle Atlantic	577	4.6	0.1%	1.2%
Mountain	267	1.6	−0.6%	0.8%
New England	156	1.2	−1.3%	0.1%
Pacific	556	4.5	−1.9%	−1.0%
South Atlantic	1,116	8.3	−2.5%	−3.3%
West North Central	374	2.0	−1.2%	−0.2%
West South Central	679	5.2	−3.1%	−3.8%
Puerto Rico and Virgin Islands	34	0.4	−2.9%	−6.6%
State:				
Alaska	4	0.0	−2.4%	0.3%
Hawaii	20	0.2	−2.3%	−0.2%
Other	4,897	36.3	−2.0%	−2.0%
Facility Size:				
Less than 3,000 treatments [3]	489	0.9	5.1%	6.0%
3,000 to 9,999 treatments	2,170	10.7	−2.5%	−3.1%
10,000 or more treatments	2,206	24.8	−2.0%	−1.8%

TABLE 48—IMPACT OF PROPOSED CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2011 ESRD PPS—Continued

[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
	A	B	C	D
Unknown	56	0.1	−1.4%	−1.4%
Percentage of Pediatric Patients:				
Less than 2%	4,808	36.1	−2.0%	−2.0%
Between 2% and 19%	56	0.4	1.0%	2.3%
Between 20% and 49%	12	0.0	−1.9%	−4.9%
More than 50%	45	0.1	−3.6%	−11.7%
Prior Composite Rate Exception (IEF, Atypical):				
Yes[4]	37	0.1	5.2%	4.6%
No	4,884	36.4	−2.0%	−2.0%

[1] Assumed that 1794 out of 4921 Facilities choose to be excluded from the transition based on comparison of payments under current system to payments under proposed 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 489 Facilities with less than 3,000 treatments, only 166 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress.

The impact to these Low volume Facilites is a 16.6% increase in payments.

[4] These facilities that choose to retain their exception rate (either IEF or atypical) rather than be paid under the current basic case-mix adjusted composite payment system.

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 (see section VII.E of this proposed rule for details of this statutory provision). 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 proposed 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 proposed 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 are proposing to estimate both the aggregate payments for each ESRD facility under the proposed 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 proposed 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 proposed ESRD PPS would elect to be paid based on 100 percent of the payment amount under the proposed 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 proposed 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 36 percent of ESRD facilities would choose to be excluded from the transition and we estimate that 64 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 proposed rule, we are proposing 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 0.970. 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 proposed 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 proposed ESRD PPS, which includes blended payments and payments that are computed using our assumption that 36 percent of ESRD facilities would elect to be paid 100 percent ESRD PPS and 64 percent of ESRD facilities would elect to go through the transition. These payments have also been adjusted to reflect the proposed 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 2.1 percent increase because as a group they receive higher payments under the proposed ESRD PPS than they would receive under the current system. We believe that the model used to create the proposed ESRD PPS adjustment factors more accurately predicts costs for this provider category. Facilities with less than 3,000 treatments show a 5.1 percent increase in payments under the proposed ESRD PPS because many of these facilities are eligible to receive the low-volume adjustment, which is a 20.2 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 show a 5.2 percent increase in payments under the proposed 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 proposed ESRD PPS more accurately accounts for the higher costs of these facilities as a group. The largest decrease in payments under the proposed ESRD PPS is for facilities with more than 50 percent pediatric patients which will experience a 3.6 percent decrease. We believe this decrease may be a result of the current system overpaying for pediatric patients, rather than the proposed ESRD PPS underpaying this group of facilities. As described in more detail in section IX of this proposed rule, the current system provides a 1.62 increase factor for pediatric patients. This factor was developed using cost per treatment for pediatric facilities that had applied for and received an exception under the current system. The current 1.62 adjustment factor was intended as a temporary adjustment and we stated our intention to refine this adjustment (69 FR 66327). We believe that the proposed pediatric patient adjustments under the proposed ESRD PPS provide a more accurate estimate of costs for these pediatric patients and therefore this provider category because they are now empirically driven and tied to the proposed ESRD PPS base rate. While this provider category will experience a decrease in payments under the proposed ESRD PPS as compared to the current system, we believe the transition to the ESRD PPS will provide a more gradual decrease.

Column D shows the effect if all ESRD facilities were paid 100 percent of the proposed 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 proposed 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, we do not need to 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 proposed ESRD PPS, as well as the effect of the transition budget neutrality factor. Generally, providers that do well under the proposed 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 proposed ESRD PPS and providers that are estimated to receive lower payments under the proposed ESRD PPS. We believe the comparison of columns C and D also shows that our proposal to apply 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 proposed expanded bundle in the proposed 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 proposed ESRD PPS, Medicare is paying ESRD facilities one combined payment for services that may have been separately paid by Medicare in the past. As discussed in more detail in section X.B of this proposed rule, the other provider types noted above may continue to provide certain ESRD-related services, 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 over the next five years would be as follows:

TABLE 49—ESTIMATED PAYMENTS

Calendar year	Estimated payments ($ in billions)
2011	7.9
2012	8.2
2013	8.5
2014	8.9
2015	9.2

These estimates are based on current estimates of annual increases in the ESRDB market basket (discussed in detail in section XII of this proposed rule) of 2.6 percent for CY 2012 and CY 2013, and 2.7 for CY 2014 and CY 2015. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 1.8 percent in CY 2011, 2.4 percent in CY 2012, 2.5 percent in CY 2013, 2.4 percent in CY 2014 and 2.3 percent in CY 2015.

Consistent with the requirement for 98 percent budget neutrality in the initial year of implementation, we intend for estimated aggregate payments under the proposed ESRD PPS to equal 98 percent of the estimated aggregate payments that would have been made if the proposed 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

Medicare beneficiaries are responsible for 20 percent coinsurance on Part B renal dialysis services. The overall effect for all ESRD facilities in aggregate is a 2 percent reduction in payments, which reflects the statutory 98 percent budget neutrality provision. Since Medicare beneficiaries are responsible for 20 percent coinsurance on Part B renal dialysis services, this overall 2 percent reduction translates to a 2 percent reduction to beneficiary coinsurance.

C. Alternatives Considered

In developing this proposed 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 proposed 1 percentage policy. We also considered a monthly payment, but instead proposed a per treatment payment.

We have discretion on some of the adjustments we are proposing, however this has no impact on the aggregate amount of spending in the first year of

the ESRD PPS (CY 2011). 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 an outlier policy. These issues are discussed in sections VIII.C and X.A, respectively. The sections referenced also discuss our rationale for the policy decisions we made.

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 proposed rule.

Table 50, 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 proposed rule based on the best available data. The expenditures are classified as a transfer to the Federal Government of $160 million dollars (or as a savings to the Medicare Program) and as a transfer to beneficiaries of $40 million.

TABLE 50

Category	Primary estimate
Transfers:	
Annualized monetized transfers: "on budget".	−$200 million.
From whom to whom?	Federal Government & Beneficiaries to ESRD Facilities.

Note: The −$200 million from the Federal Government and Beneficiaries to ESRD Providers is distributed as −$160 million from the Federal Government to the ESRD Provider, and −$40 million from the Beneficiaries to the ESRD Provider.

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 the reasons set forth in the preamble, the Center for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

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 described in § 413.230, 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 rate established under section 1881(b)(7) and section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system.

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 furnishes 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 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.

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), and any oral equivalent form of such drug and biological;

(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.

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, 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) introductory text, 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 paragraph (f)(5).

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, under section 1881(b)(7) and section 1881(b)(12) of the Act;

(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. Effective January 1, 2011, as specified in section 1881(b)(14) of the Act, payment to an ESRD facility for certain ESRD-related drugs and biologicals 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.

* * * * *

(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 biologicals furnished by independent ESRD facilities is based on the methodology specified in § 414.904 of this chapter.

(5) Effective January 1, 2011, payment for drugs and biologicals furnished by ESRD facilities as defined in § 413.171(c) is included in the ESRD prospective payment system rate established in § 413.230.

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 prospective 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 exceptions to the prospective payment rate as defined in § 413.180(l).

(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 prospective payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in § 413.235(a) of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities is used as the payment amount in place of the composite rate, for exceptions in effect prior to January 1, 2011 and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with § 413.235(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 is prohibited of 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, 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 minus 1.0 percentage point.

(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 1.0 percentage point.

(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 read as follows:

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

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 of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount for items and 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) The per-treatment payment amount is the product of the per treatment base rate described in § 413.220 plus the applicable adjustments described in § 413.231 through § 413.237 of this part.

(c) 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 items and 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 for calendar years 2007, 2008, or 2009.

(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.* 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) *Average payments in CY 2007, 2008 or 2009.* CMS computes the average Medicare allowable payment for composite rate items and services and separately billable items and services furnished in CY 2007, 2008 or 2009 to yield a per treatment base rate for 2007, 2008 or 2009 and selects 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 § 413.237 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 § 413.210 through § 413.239 of this part were not implemented.

(6) *First Four Years of the ESRD Prospective Payment* System. During the first four years of ESRD prospective payment system (January 1, 2011 to December 31, 2014), 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 product of the per treatment base rate established in § 413.220, the facility-level and patient-level adjustments described in § 413.231, § 413.232 and § 413.235 of this part, and any outlier payment under § 413.237.

19. Section 413.231 is added to subpart H to read as follows:

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor 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 3,000 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 be equal to 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 the fiscal intermediary/MAC that the facility has met all the criteria as established in paragraphs (a), (b), (c), and (d) of this section.

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, patient sex (female), 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, treatment modality, and the presence of co-morbidities.

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 separately billable items and services as defined in § 413.171 of this part and renal dialysis service drugs proposed for inclusion in the ESRD prospective payment system that currently are covered under Medicare Part D.

(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 as defined in § 413.171.

(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 as defined in § 413.171.

(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:* 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(c)(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 items and 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, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after November 1, 2010 will not be accepted. 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 CMS 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 contractor (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, provided during the transition, 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 first 3 years of the transition (January 1, 2011 through December 31, 2013), 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, the ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs must ensure that the pharmacy is located such that it has the capability to provide all classes of renal dialysis service drugs 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. Section 414.335 is amended by revising paragraph (a) 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.

* * * * *

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

Dated: May 28, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 23, 2009.

Kathleen Sebelius,

Secretary.

Note: The following Appendices will not appear in the Code of Federal Regulations.

BILLING CODE 4120–01–P

Table A: Universe of Codes used in the Analysis of Co-morbidities (Developed by KECC)
Cancer (excludes non-melanoma skin cancer includes some benign CNS neoplasms)
141 MAL NEOPLASM TONGUE
141.0 MAL NEO TONGUE BASE
141.1 MAL NEO DORSAL TONGUE
141.2 MAL NEO TIP/LAT TONGUE
141.3 MAL NEO VENTRAL TONGUE
141.4 MAL NEO ANT 2/3 TONGUE
141.5 MAL NEO TONGUE JUNCTION
141.6 MAL NEO LINGUAL TONSIL
141.8 MALIG NEO TONGUE NEC
141.9 MALIG NEO TONGUE NOS
142 Malignant neoplasm maj salivary/parotid
142.0 MALIG NEO PAROTID
142.1 MALIG NEO SUBMANDIBULAR
142.2 MALIG NEO SUBLINGUAL
142.8 MAL NEO MAJ SALIVARY NEC
142.9 MAL NEO SALIVARY NOS
143 malignant neoplasm gum
143.0 MALIG NEO UPPER GUM
143.1 MALIG NEO LOWER GUM
143.8 MALIG NEO GUM NEC
143.9 MALIG NEO GUM NOS
144 malignant neoplasm floor of mouth
144.0 MAL NEO ANT FLOOR MOUTH

144.1 MAL NEO LAT FLOOR MOUTH
144.8 MAL NEO MOUTH FLOOR NEC
144.9 MAL NEO MOUTH FLOOR NOS
145 malignant neo other/unspec mouth parts
145.0 MAL NEO CHEEK MUCOSA
145.1 MAL NEO MOUTH VESTIBULE
145.2 MALIG NEO HARD PALATE
145.3 MALIG NEO SOFT PALATE
145.4 MALIGNANT NEOPLASM UVULA
145.5 MALIGNANT NEO PALATE NOS
145.6 MALIG NEO RETROMOLAR
145.8 MALIG NEOPLASM MOUTH NEC
145.9 MALIG NEOPLASM MOUTH NOS
146 malignant neoplasm oropharynx
146.0 MALIGNANT NEOPL TONSIL
146.1 MAL NEO TONSILLAR FOSSA
146.2 MAL NEO TONSIL PILLARS
146.3 MALIGN NEOPL VALLECULA
146.4 MAL NEO ANT EPIGLOTTIS
146.5 MAL NEO EPIGLOTTIS JUNCT
146.6 MAL NEO LAT OROPHARYNX
146.7 MAL NEO POST OROPHARYNX
146.8 MAL NEO OROPHARYNX NEC
146.9 MALIG NEO OROPHARYNX NOS
147 malignant neoplasm nasopharynx

147.0 MAL NEO SUPER NASOPHARYN
147.1 MAL NEO POST NASOPHARYNX
147.2 MAL NEO LAT NASOPHARYNX
147.3 MAL NEO ANT NASOPHARYNX
147.8 MAL NEO NASOPHARYNX NEC
147.9 MAL NEO NASOPHARYNX NOS
148 malignant neoplasm hypopharynx
148.0 MAL NEO POSTCRICOID
148.1 MAL NEO PYRIFORM SINUS
148.2 MAL NEO ARYEPIGLOTT FOLD
148.3 MAL NEO POST HYPOPHARYNX
148.8 MAL NEO HYPOPHARYNX NEC
148.9 MAL NEO HYPOPHARYNX NOS
149 mal neo other/ill-defined lip/oral cavity/pharynx
149.0 MAL NEO PHARYNX NOS
149.1 MAL NEO WALDEYER'S RING
149.8 MAL NEO ORAL/PHARYNX NEC
149.9 MAL NEO OROPHRYN ILL-DEF
150 malignant neoplasm esophagus
150.0 MAL NEO CERVICAL ESOPHAG
150.1 MAL NEO THORACIC ESOPHAG
150.2 MAL NEO ABDOMIN ESOPHAG
150.3 MAL NEO UPPER 3RD ESOPH
150.4 MAL NEO MIDDLE 3RD ESOPH
150.5 MAL NEO LOWER 3RD ESOPH

150.8 MAL NEO ESOPHAGUS NEC
150.9 MAL NEO ESOPHAGUS NOS
151 malignant neoplasm stomach
151.0 MAL NEO STOMACH CARDIA
151.1 MALIGNANT NEO PYLORUS
151.2 MAL NEO PYLORIC ANTRUM
151.3 MAL NEO STOMACH FUNDUS
151.4 MAL NEO STOMACH BODY
151.5 MAL NEO STOM LESSER CURV
151.6 MAL NEO STOM GREAT CURV
151.8 MALIG NEOPL STOMACH NEC
151.9 MALIG NEOPL STOMACH NOS
152 malignant neo sm intestine/duodenum
152.0 MALIGNANT NEOPL DUODENUM
152.1 MALIGNANT NEOPL JEJUNUM
152.2 MALIGNANT NEOPLASM ILEUM
152.3 MAL NEO MECKEL'S DIVERT
152.8 MAL NEO SMALL BOWEL NEC
152.9 MAL NEO SMALL BOWEL NOS
153 malignat neoplasm colon
153.0 MAL NEO HEPATIC FLEXURE
153.1 MAL NEO TRANSVERSE COLON
153.2 MAL NEO DESCEND COLON
153.3 MAL NEO SIGMOID COLON
153.4 MALIGNANT NEOPLASM CECUM

153.5 MALIGNANT NEO APPENDIX
153.6 MALIG NEO ASCEND COLON
153.7 MAL NEO SPLENIC FLEXURE
153.8 MALIGNANT NEO COLON NEC
153.9 MALIGNANT NEO COLON NOS
154 malig neo rectum/rectosigmoid junct/anus
154.0 MAL NEO RECTOSIGMOID JCT
154.1 MALIGNANT NEOPL RECTUM
154.2 MALIG NEOPL ANAL CANAL
154.3 MALIGNANT NEO ANUS NOS
154.8 MAL NEO RECTUM/ANUS NEC
155 mal neo liver/intrahepatic bile ducts
155.0 MAL NEO LIVER, PRIMARY
155.1 MAL NEO INTRAHEPAT DUCTS
155.2 MALIGNANT NEO LIVER NOS
156 mal neo gall bladder/Xhepatic bile ducts
156.0 MALIG NEO GALLBLADDER
156.1 MAL NEO EXTRAHEPAT DUCTS
156.2 MAL NEO AMPULLA OF VATER
156.8 MALIG NEO BILIARY NEC
156.9 MALIG NEO BILIARY NOS
157 malig neo pancreas
157.0 MAL NEO PANCREAS HEAD
157.1 MAL NEO PANCREAS BODY
157.2 MAL NEO PANCREAS TAIL

157.3 MAL NEO PANCREATIC DUCT
157.4 MAL NEO ISLET LANGERHANS
157.8 MALIG NEO PANCREAS NEC
157.9 MALIG NEO PANCREAS NOS
158 mal neo retroperitoneum/peritoneum
158.0 MAL NEO RETROPERITONEUM
158.8 MAL NEO PERITONEUM NEC
158.9 MAL NEO PERITONEUM NOS
159 mal neo other/ill-defined digest org/peritone
159.0 MALIG NEO INTESTINE NOS
159.1 MALIGNANT NEO SPLEEN NEC
159.8 MAL NEO GI/INTRA-ABD NEC
159.9 MAL NEO GI TRACT ILL-DEF
160 mal neo nas cavities/mid ear/access sinuses
160.0 MAL NEO NASAL CAVITIES
160.1 MALIG NEO MIDDLE EAR
160.2 MAL NEO MAXILLARY SINUS
160.3 MAL NEO ETHMOIDAL SINUS
160.4 MALIG NEO FRONTAL SINUS
160.5 MAL NEO SPHENOID SINUS
160.8 MAL NEO ACCESS SINUS NEC
160.9 MAL NEO ACCESS SINUS NOS
161 malignant neo larynx
161.0 MALIGNANT NEO GLOTTIS
161.1 MALIG NEO SUPRAGLOTTIS

161.2 MALIG NEO SUBGLOTTIS
161.3 MAL NEO CARTILAGE LARYNX
161.8 MALIGNANT NEO LARYNX NEC
161.9 MALIGNANT NEO LARYNX NOS
162 mal neo trachea/bronchus/lung
162.0 MALIGNANT NEO TRACHEA
162.2 MALIG NEO MAIN BRONCHUS
162.3 MAL NEO UPPER LOBE LUNG
162.4 MAL NEO MIDDLE LOBE LUNG
162.5 MAL NEO LOWER LOBE LUNG
162.8 MAL NEO BRONCH/LUNG NEC
162.9 MAL NEO BRONCH/LUNG NOS
163 malignant neo pleura
163.0 MAL NEO PARIETAL PLEURA
163.1 MAL NEO VISCERAL PLEURA
163.8 MALIG NEOPL PLEURA NEC
163.9 MALIG NEOPL PLEURA NOS
164 mal neo thymus/heart/mediastinum
164.0 MALIGNANT NEOPL THYMUS
164.1 MALIGNANT NEOPL HEART
164.2 MAL NEO ANT MEDIASTINUM
164.3 MAL NEO POST MEDIASTINUM
164.8 MAL NEO MEDIASTINUM NEC
164.9 MAL NEO MEDIASTINUM NOS
165 mal neo othr/ill-defined resp syst/intrathoracic

165.0 MAL NEO UPPER RESP NOS
165.8 MAL NEO THORAX/RESP NEC
165.9 MAL NEO RESP SYSTEM NOS
170 mal neo bone/articular cartilage
170.0 MAL NEO SKULL/FACE BONE
170.1 MALIGNANT NEO MANDIBLE
170.2 MALIG NEO VERTEBRAE
170.3 MAL NEO RIBS/STERN/CLAV
170.4 MAL NEO LONG BONES ARM
170.5 MAL NEO BONES WRIST/HAND
170.6 MAL NEO PELVIC GIRDLE
170.7 MAL NEO LONG BONES LEG
170.8 MAL NEO BONES ANKLE/FOOT
170.9 MALIG NEOPL BONE NOS
171 mal neo connective/other soft tissue
171.0 MAL NEO SOFT TISSUE HEAD
171.2 MAL NEO SOFT TISSUE ARM
171.3 MAL NEO SOFT TISSUE LEG
171.4 MAL NEO SOFT TIS THORAX
171.5 MAL NEO SOFT TIS ABDOMEN
171.6 MAL NEO SOFT TIS PELVIS
171.7 MAL NEOPL TRUNK NOS
171.8 MAL NEO SOFT TISSUE NEC
171.9 MAL NEO SOFT TISSUE NOS
172 mal melanoma skin

172.0 MALIG MELANOMA LIP
172.1 MALIG MELANOMA EYELID
172.2 MALIG MELANOMA EAR
172.3 MAL MELANOM FACE NEC/NOS
172.4 MAL MELANOMA SCALP/NECK
172.5 MALIG MELANOMA TRUNK
172.6 MALIG MELANOMA ARM
172.7 MALIG MELANOMA LEG
172.8 MALIG MELANOMA SKIN NEC
172.9 MALIG MELANOMA SKIN NOS
174 malignant neoplasm female breast
174.0 MALIG NEO NIPPLE
174.1 MAL NEO BREAST-CENTRAL
174.2 MAL NEO BREAST UP-INNER
174.3 MAL NEO BREAST LOW-INNER
174.4 MAL NEO BREAST UP-OUTER
174.5 MAL NEO BREAST LOW-OUTER
174.6 MAL NEO BREAST-AXILLARY
174.8 MALIGN NEOPL BREAST NEC
174.9 MALIGN NEOPL BREAST NOS
175 malignant neoplasm male breast
175.0 MAL NEO MALE NIPPLE
175.9 MAL NEO MALE BREAST NEC
176 Kaposi's sarcoma
176.0 SKIN - KAPOSI'S SARCOMA

176.1 SFT TISUE - KPSI'S SRCMA
176.2 PALATE - KPSI'S SARCOMA
176.3 GI SITES - KPSI'S SRCOMA
176.4 LUNG - KAPOSI'S SARCOMA
176.5 LYM NDS - KPSI'S SARCOMA
176.8 SPF STS - KPSI'S SARCOMA
176.9 KAPOSI'S SARCOMA NOS
179 MALIG NEOPL UTERUS NOS
180 malignant neoplasm cervix uteri
180.0 MALIG NEO ENDOCERVIX
180.1 MALIG NEO EXOCERVIX
180.8 MALIG NEO CERVIX NEC
180.9 MAL NEO CERVIX UTERI NOS
181 MALIGNANT NEOPL PLACENTA
182 malignant neoplasm uterine body
182.0 MALIG NEO CORPUS UTERI
182.1 MAL NEO UTERINE ISTHMUS
182.8 MAL NEO BODY UTERUS NEC
183 malignant neo ovary/other uterine adnexa
183.0 MALIGN NEOPL OVARY
183.2 MAL NEO FALLOPIAN TUBE
183.3 MAL NEO BROAD LIGAMENT
183.4 MALIG NEO PARAMETRIUM
183.5 MAL NEO ROUND LIGAMENT
183.8 MAL NEO ADNEXA NEC

183.9 MAL NEO ADNEXA NOS
184 malignant neo other/unspec female genitals
184.0 MALIGN NEOPL VAGINA
184.1 MAL NEO LABIA MAJORA
184.2 MAL NEO LABIA MINORA
184.3 MALIGN NEOPL CLITORIS
184.4 MALIGN NEOPL VULVA NOS
184.8 MAL NEO FEMALE GENIT NEC
184.9 MAL NEO FEMALE GENIT NOS
185 MALIGN NEOPL PROSTATE
186 malignant neoplasm testis
186.0 MAL NEO UNDESCEND TESTIS
186.9 MALIG NEO TESTIS NEC
187 malignant neo penis/other male genitals
187.1 MALIGN NEOPL PREPUCE
187.2 MALIG NEO GLANS PENIS
187.3 MALIG NEO PENIS BODY
187.4 MALIG NEO PENIS NOS
187.5 MALIG NEO EPIDIDYMIS
187.6 MAL NEO SPERMATIC CORD
187.7 MALIGN NEOPL SCROTUM
187.8 MAL NEO MALE GENITAL NEC
187.9 MAL NEO MALE GENITAL NOS
188 malignant neoplasm bladder
188.0 MAL NEO BLADDER-TRIGONE

188.1 MAL NEO BLADDER-DOME
188.2 MAL NEO BLADDER-LATERAL
188.3 MAL NEO BLADDER-ANTERIOR
188.4 MAL NEO BLADDER-POST
188.5 MAL NEO BLADDER NECK
188.6 MAL NEO URETERIC ORIFICE
188.7 MALIG NEO URACHUS
188.8 MALIG NEO BLADDER NEC
188.9 MALIG NEO BLADDER NOS
189 mal neo kidney/other/unspec urinary organs
189.0 MALIG NEOPL KIDNEY
189.1 MALIG NEO RENAL PELVIS
189.2 MALIGN NEOPL URETER
189.3 MALIGN NEOPL URETHRA
189.4 MAL NEO PARAURETHRAL
189.8 MAL NEO URINARY NEC
189.9 MAL NEO URINARY NOS
190 malignant neoplasm eye
190.0 MALIGN NEOPL EYEBALL
190.1 MALIGN NEOPL ORBIT
190.2 MAL NEO LACRIMAL GLAND
190.3 MAL NEO CONJUNCTIVA
190.4 MALIGN NEOPL CORNEA
190.5 MALIGN NEOPL RETINA
190.6 MALIGN NEOPL CHOROID

190.7 MAL NEO LACRIMAL DUCT
190.8 MALIGN NEOPL EYE NEC
190.9 MALIGN NEOPL EYE NOS
191 malignant neoplasm brain
191.0 MALIGN NEOPL CEREBRUM
191.1 MALIG NEO FRONTAL LOBE
191.2 MAL NEO TEMPORAL LOBE
191.3 MAL NEO PARIETAL LOBE
191.4 MAL NEO OCCIPITAL LOBE
191.5 MAL NEO CEREB VENTRICLE
191.6 MAL NEO CEREBELLUM NOS
191.7 MAL NEO BRAIN STEM
191.8 MALIG NEO BRAIN NEC
191.9 MALIG NEO BRAIN NOS
192 mal neo other/unspec nervous system
192.0 MAL NEO CRANIAL NERVES
192.1 MAL NEO CEREBRAL MENING
192.2 MAL NEO SPINAL CORD
192.3 MAL NEO SPINAL MENINGES
192.8 MAL NEO NERVOUS SYST NEC
192.9 MAL NEO NERVOUS SYST NOS
193 MALIGN NEOPL THYROID
194 mal neo other endocrine/related structures
194.0 MALIGN NEOPL ADRENAL
194.1 MALIG NEO PARATHYROID

194.3 MALIG NEO PITUITARY
194.4 MALIGN NEO PINEAL GLAND
194.5 MAL NEO CAROTID BODY
194.6 MAL NEO PARAGANGLIA NEC
194.8 MAL NEO ENDOCRINE NEC
194.9 MAL NEO ENDOCRINE NOS
195 mal neo other/ill-defined sites
195.0 MAL NEO HEAD/FACE/NECK
195.1 MALIGN NEOPL THORAX
195.2 MALIG NEO ABDOMEN
195.3 MALIGN NEOPL PELVIS
195.4 MALIGN NEOPL ARM
195.5 MALIGN NEOPL LEG
195.8 MALIG NEO SITE NEC
196 secondry/unspec mal neo lymph nodes
196.0 MAL NEO LYMPH-HEAD/NECK
196.1 MAL NEO LYMPH-INTRATHOR
196.2 MAL NEO LYMPH INTRA-ABD
196.3 MAL NEO LYMPH-AXILLA/ARM
196.5 MAL NEO LYMPH-INGUIN/LEG
196.6 MAL NEO LYMPH-INTRAPELV
196.8 MAL NEO LYMPH NODE-MULT
196.9 MAL NEO LYMPH NODE NOS
197 secondary mal neo resp/digestive systems
197.0 SECONDARY MALIG NEO LUNG

197.1 SEC MAL NEO MEDIASTINUM
197.2 SECOND MALIG NEO PLEURA
197.3 SEC MALIG NEO RESP NEC
197.4 SEC MALIG NEO SM BOWEL
197.5 SEC MALIG NEO LG BOWEL
197.6 SEC MAL NEO PERITONEUM
197.7 SECOND MALIG NEO LIVER
197.8 SEC MAL NEO GI NEC
198 secondary mal neo other spec sites
198.0 SECOND MALIG NEO KIDNEY
198.1 SEC MALIG NEO URIN NEC
198.2 SECONDARY MALIG NEO SKIN
198.3 SEC MAL NEO BRAIN/SPINE
198.4 SEC MALIG NEO NERVE NEC
198.5 SECONDARY MALIG NEO BONE
198.6 SECOND MALIG NEO OVARY
198.7 SECOND MALIG NEO ADRENAL
198.81 SECOND MALIG NEO BREAST
198.82 SECOND MALIG NEO GENITAL
198.89 SECONDARY MALIG NEO NEC
199 mal neo w/o site specification
199.0 MALIG NEO DISSEMINATED
199.1 MALIGNANT NEOPLASM NOS
199.2 MAL NEO ASSOC W/ TRANSPLANT ORG
200 lymphosarcoma & reticulosarcoma

200.00 RETCLSRC UNSP XTRNDL ORG
200.01 RETICULOSARCOMA HEAD
200.02 RETICULOSARCOMA THORAX
200.03 RETICULOSARCOMA ABDOM
200.04 RETICULOSARCOMA AXILLA
200.05 RETICULOSARCOMA INGUIN
200.06 RETICULOSARCOMA PELVIC
200.07 RETICULOSARCOMA SPLEEN
200.08 RETICULOSARCOMA MULT
200.1 lymphosarcoma/reticulosarcoma/lymphosarc
200.10 LYMPHSRC UNSP XTRNDL ORG
200.11 LYMPHOSARCOMA HEAD
200.12 LYMPHOSARCOMA THORAX
200.13 LYMPHOSARCOMA ABDOM
200.14 LYMPHOSARCOMA AXILLA
200.15 LYMPHOSARCOMA INGUIN
200.16 LYMPHOSARCOMA PELVIC
200.17 LYMPHOSARCOMA SPLEEN
200.18 LYMPHOSARCOMA MULT
200.2 lymphosarc/reticulosarc, Brkt tmr/lymphoma
200.20 BRKT TMR UNSP XTRNDL ORG
200.21 BURKITT'S TUMOR HEAD
200.22 BURKITT'S TUMOR THORAX
200.23 BURKITT'S TUMOR ABDOM
200.24 BURKITT'S TUMOR AXILLA

200.25 BURKITT'S TUMOR INGUIN
200.26 BURKITT'S TUMOR PELVIC
200.27 BURKITT'S TUMOR SPLEEN
200.28 BURKITT'S TUMOR MULT
200.8 lymphosarcoma/reticulsarcoma other variants
200.80 OTH VARN UNSP XTRNDL ORG
200.81 MIXED LYMPHOSARC HEAD
200.82 MIXED LYMPHOSARC THORAX
200.83 MIXED LYMPHOSARC ABDOM
200.84 MIXED LYMPHOSARC AXILLA
200.85 MIXED LYMPHOSARC INGUIN
200.86 MIXED LYMPHOSARC PELVIC
200.87 MIXED LYMPHOSARC SPLEEN
200.88 MIXED LYMPHOSARC MULT
201 Hodgkin's disease
201.0 Hodgkin's disease Hodgkin's paragranuloma
201.00 HDGK PRG UNSP XTRNDL ORG
201.01 HODGKINS PARAGRAN HEAD
201.02 HODGKINS PARAGRAN THORAX
201.03 HODGKINS PARAGRAN ABDOM
201.04 HODGKINS PARAGRAN AXILLA
201.05 HODGKINS PARAGRAN INGUIN
201.06 HODGKINS PARAGRAN PELVIC
201.07 HODGKINS PARAGRAN SPLEEN
201.08 HODGKINS PARAGRAN MULT

201.1 Hodgkin's disease Hodgkin's granuloma
201.11 HODGKINS GRANULOM HEAD
201.10 H's dis H's granuloma unspec/Xnodal/sol org
201.12 HODGKINS GRANULOM THORAX
201.13 HODGKINS GRANULOM ABDOM
201.14 HODGKINS GRANULOM AXILLA
201.15 HODGKINS GRANULOM INGUIN
201.16 HODGKINS GRANULOM PELVIC
201.17 HODGKINS GRANULOM SPLEEN
201.18 HODGKINS GRANULOM MULT
201.2 Hodgkin's disease Hodgkin's sarcoma
201.20 HDGK SRC UNSP XTRNDL ORG
201.21 HODGKINS SARCOMA HEAD
201.22 HODGKINS SARCOMA THORAX
201.23 HODGKINS SARCOMA ABDOM
201.24 HODGKINS SARCOMA AXILLA
201.25 HODGKINS SARCOMA INGUIN
201.26 HODGKINS SARCOMA PELVIC
201.27 HODGKINS SARCOMA SPLEEN
201.28 HODGKINS SARCOMA MULT
201.4 Hodgkin's disease lymphocystic-histiocytic
201.40 LYM-HST UNSP XTRNDL ORGN
201.41 HODG LYMPH-HISTIO HEAD
201.42 HODG LYMPH-HISTIO THORAX
201.43 HODG LYMPH-HISTIO ABDOM

201.44 HODG LYMPH-HISTIO AXILLA
201.45 HODG LYMPH-HISTIO INGUIN
201.46 HODG LYMPH-HISTIO PELVIC
201.47 HODG LYMPH-HISTIO SPLEEN
201.48 HODG LYMPH-HISTIO MULT
201.5 Hodgkin's disease nodular sclerosis
201.50 NDR SCLR UNSP XTRNDL ORG
201.51 HODG NODUL SCLERO HEAD
201.52 HODG NODUL SCLERO THORAX
201.53 HODG NODUL SCLERO ABDOM
201.54 HODG NODUL SCLERO AXILLA
20155 HODG NODUL SCLERO INGUIN
201.56 HODG NODUL SCLERO PELVIC
201.57 HODG NODUL SCLERO SPLEEN
201.58 HODG NODUL SCLERO MULT
201.6 Hodgkin's disease mixed cellularity
201.60 MXD CELR UNSP XTRNDL ORG
201.61 HODGKINS MIX CELL HEAD
201.62 HODGKINS MIX CELL THORAX
201.63 HODGKINS MIX CELL ABDOM
201.64 HODGKINS MIX CELL AXILLA
201.66 HODGKINS MIX CELL PELVIC
201.67 HODGKINS MIX CELL SPLEEN
201.68 HODGKINS MIX CELL MULT
201.7 Hodgkin's disease lymphocytic depletion

201.70 LYM DPLT UNSP XTRNDL ORG
201.71 HODG LYMPH DEPLET HEAD
201.72 HODG LYMPH DEPLET THORAX
201.73 HODG LYMPH DEPLET ABDOM
201.74 HODG LYMPH DEPLET AXILLA
201.75 HODG LYMPH DEPLET INGUIN
201.76 HODG LYMPH DEPLET PELVIC
201.77 HODG LYMPH DEPLET SPLEEN
201.78 HODG LYMPH DEPLET MULT
201.9 Hodgkin's disease unspec
201.90 HDGK DIS UNSP XTRNDL ORG
201.91 HODGKINS DIS NOS HEAD
201.92 HODGKINS DIS NOS THORAX
201.93 HODGKINS DIS NOS ABDOM
201.94 HODGKINS DIS NOS AXILLA
201.95 HODGKINS DIS NOS INGUIN
201.96 HODGKINS DIS NOS PELVIC
201.97 HODGKINS DIS NOS SPLEEN
201.98 HODGKINS DIS NOS MULT
202 other mal neo lymphoid/histiocytic tissue
202.0 nodular lymphoma
202.00 NDLR LYM UNSP XTRNDL ORG
202.01 NODULAR LYMPHOMA HEAD
202.02 NODULAR LYMPHOMA THORAX
202.03 NODULAR LYMPHOMA ABDOM

202.04 NODULAR LYMPHOMA AXILLA
202.05 NODULAR LYMPHOMA INGUIN
202.06 NODULAR LYMPHOMA PELVIC
202.07 NODULAR LYMPHOMA SPLEEN
202.08 NODULAR LYMPHOMA MULT
202.1 other mal neo lymphoid/histiocytic tissue; mycosis fungoides
202.10 MYCS FNG UNSP XTRNDL ORG
202.11 MYCOSIS FUNGOIDES HEAD
202.12 MYCOSIS FUNGOIDES THORAX
202.13 MYCOSIS FUNGOIDES ABDOM
202.14 MYCOSIS FUNGOIDES AXILLA
202.15 MYCOSIS FUNGOIDES INGUIN
202.16 MYCOSIS FUNGOIDES PELVIC
202.17 MYCOSIS FUNGOIDES SPLEEN
202.18 MYCOSIS FUNGOIDES MULT
202.2 other mal neo lymphoid/histiocytic tissue; SZRY's disease
202.20 SZRY DIS UNSP XTRNDL ORG
202.21 SEZARY'S DISEASE HEAD
202.22 SEZARY'S DISEASE THORAX
202.23 SEZARY'S DISEASE ABDOM
202.24 SEZARY'S DISEASE AXILLA
202.25 SEZARY'S DISEASE INGUIN
202.26 SEZARY'S DISEASE PELVIC
202.27 SEZARY'S DISEASE SPLEEN
202.28 SEZARY'S DISEASE MULT

202.3 other mal neo lymphoid/histiocytic tissue; mal histiocytosis
202.30 MLG HIST UNSP XTRNDL ORG
202.31 MAL HISTIOCYTOSIS HEAD
202.32 MAL HISTIOCYTOSIS THORAX
202.33 MAL HISTIOCYTOSIS ABDOM
202.34 MAL HISTIOCYTOSIS AXILLA
202.35 MAL HISTIOCYTOSIS INGUIN
202.36 MAL HISTIOCYTOSIS PELVIC
202.37 MAL HISTIOCYTOSIS SPLEEN
202.38 MAL HISTIOCYTOSIS MULT
202.4 other mal neo lymphoid/histiocytic tis, leukemic reticuloendotheliosis
202.40 LK RTCTL UNSP XTRNDL ORG
202.41 HAIRY-CELL LEUKEM HEAD
202.42 HAIRY-CELL LEUKEM THORAX
202.43 HAIRY-CELL LEUKEM ABDOM
202.44 HAIRY-CELL LEUKEM AXILLA
202.45 HAIRY-CELL LEUKEM INGUIN
202.46 HAIRY-CELL LEUKEM PELVIC
202.47 HAIRY-CELL LEUKEM SPLEEN
202.48 HAIRY-CELL LEUKEM MULT
202.5 other mal neo lymphoid/histiocytic tis, LTR-SIWE dis
202.50 LTR-SIWE UNSP XTRNDL ORG
202.51 LETTERER-SIWE DIS HEAD
202.52 LETTERER-SIWE DIS THORAX
202.53 LETTERER-SIWE DIS ABDOM

202.54 LETTERER-SIWE DIS AXILLA
202.55 LETTERER-SIWE DIS INGUIN
202.56 LETTERER-SIWE DIS PELVIC
202.57 LETTERER-SIWE DIS SPLEEN
202.58 LETTERER-SIWE DIS MULT
202.6 other mal neo lymphoid/histiocytic tis, mal mast cell tumors
202.60 MLG MAST UNSP XTRNDL ORG
202.61 MAL MASTOCYTOSIS HEAD
202.62 MAL MASTOCYTOSIS THORAX
202.63 MAL MASTOCYTOSIS ABDOM
202.64 MAL MASTOCYTOSIS AXILLA
202.65 MAL MASTOCYTOSIS INGUIN
202.66 MAL MASTOCYTOSIS PELVIC
202.67 MAL MASTOCYTOSIS SPLEEN
202.68 MAL MASTOCYTOSIS MULT
202.8 other lymphomas
202.80 OTH LYMP UNSP XTRNDL ORG
202.81 LYMPHOMAS NEC HEAD
202.82 LYMPHOMAS NEC THORAX
202.83 LYMPHOMAS NEC ABDOM
202.84 LYMPHOMAS NEC AXILLA
202.85 LYMPHOMAS NEC INGUIN
202.86 LYMPHOMAS NEC PELVIC
202.87 LYMPHOMAS NEC SPLEEN
202.88 LYMPHOMAS NEC MULT

202.9 othr mal neo lymphoid/histiocytic tis, othr/unspec
202.90 UNSP LYM UNSP XTRNDL ORG
202.91 LYMPHOID MAL NEC HEAD
202.92 LYMPHOID MAL NEC THORAX
202.93 LYMPHOID MAL NEC ABDOM
202.94 LYMPHOID MAL NEC AXILLA
202.95 LYMPHOID MAL NEC INGUIN
202.96 LYMPHOID MAL NEC PELVIC
202.97 LYMPHOID MAL NEC SPLEEN
202.98 LYMPHOID MAL NEC MULT
203 mult myeloma/immunoproliferative neoplasms
203.0 multiple myeloma
203.00 MULT MYELM W/O REMISSION
203.01 MULT MYELM W REMISSION
203.1 plasma cell leukemia
203.10 PLSM CELL LEUK W/O RMSON
203.11 PLSM CELL LEUK W RMSON
203.8 other immunoproliferative neoplasms
203.80 OTH IMNPRFL NPL W/O RMSN
203.81 OTH IMNPRFL NPL W RMSN
204 lymphoid leukemia
204.0 acute lymphoid leukemia
204.00 ACT LYM LEUK W/O RMSION
204.01 ACT LYM LEUK W RMSION
204.02 AC LYMPHOID LEUKEMIA, IN RELAPSE

204.1 chronic lymphoid leukemia
204.10 CHR LYM LEUK W/O RMSION
204.11 CHR LYM LEUK W RMSION
204.12 CHR LYM LEUK, IN RELAPSE
204.2 subacute lymphoid leukemia
204.20 SBAC LYM LEUK W/O RMSION
204.21 SBAC LYM LEUK W RMSION
204.8 lymphoid leukemia other
204.80 OTH LYM LEUK W/O RMSION
204.81 OTH LYM LEUK W RMSION
204.9 lymphoid leukemia unspec
204.90 UNS LYM LEUK W/O RMSION
204.91 UNS LYM LEUK W RMSION
205 myeloid leukemia
205.0 acute myeloid leukemia
205.00 ACT MYL LEUK W/O RMSION
205.01 ACT MYL LEUK W RMSION
205.1 chronic myeloid leukemia
205.10 CHR MYL LEUK W/O RMSION
205.11 CHR MYL LEUK W RMSION
205.2 subacute myeloid leukemia
205.20 SBAC MYL LEUK W/O RMSION
205.21 SBAC MYL LEUK W RMSION
205.22 SBAC MYL LEUK, IN RELAPSE
205.3 myeloid leukemia, myeloid sarcoma

205.30 MYL SRCOMA W/O RMSION
205.31 MYL SRCOMA W RMSION
205.8 myeloid leukemia other
205.80 OTH MYL LEUK W/O RMSION
205.81 OTH MYL LEUK W RMSION
205.9 myeloid leukemia unspec
205.90 UNS MYL LEUK W/O RMSION
205.91 UNS MYL LEUK W RMSION
206 monocytic leukemia
206.0 acute monocytic leukemia
206.00 ACT MONO LEUK W/O RMSION
206.01 ACT MONO LEUK W RMSION
206.1 chronic monocytic leukemia
206.10 CHR MONO LEUK W/O RMSION
206.11 CHR MONO LEUK W RMSION
206.2 subacute monocytic leukemia
206.20 SBAC MONO LEUK W/O RMSON
206.21 SBAC MONO LEUK W RMSION
206.8 monocytic leukemia other
206.80 OTH MONO LEUK W/O RMSION
206.81 OTH MONO LEUK W RMSION
206.9 monocytic leukemia unspec
206.90 UNS MONO LEUK W/O RMSION
206.91 UNS MONO LEUK W RMSION
207 other spec leukemia

207.0 other specif leukemia, ac erythremia/erythroleukemia
207.00 ACT ERTH/ERYLK W/O RMSON
207.01 ACT ERTH/ERYLK W RMSON
207.1 other specif leukemia, chronic erythremia
207.10 CHR ERYTHRM W/O REMISION
207.11 CHR ERYTHRM W REMISION
207.2 other specif leukemia, megakaryocytic leuk
207.20 MGKRYCYT LEUK W/O RMSION
207.21 MGKRYCYT LEUK W RMSION
207.8 other specif leukemia other
207.80 OTH SPF LEUK W/O REMSION
207.81 OTH SPF LEUK W REMSION
208 leukemia unspecified cell type
208.0 acute leukemia unspecified cell type
208.00 ACT LEUK UNS CL W/O RMSN
208.01 ACT LEUK UNS CL W RMSON
208.1 chronic leukemia unspec cell type
208.10 CHR LEUK UNS CL W/O RMSN
208.11 CHR LEUK UNS CL W RMSON
208.2 subacute leukemia unspec cell type
208.20 SBAC LEUK UNS CL W/O RMS
208.21 SBAC LEUK UNS CL W RMSON
208.8 leukemia unspecified cell type other
208.80 OTH LEUK UNS CL W/O RMSN
208.81 OTH LEUK UNS CL W RMSON

208.9 leukemia unspec cell type unspec
208.90 LEUKEMIA NOS W/O REMSION
208.91 LEUKEMIA NOS W REMISSION
209.00 Mal carcinoid tmr sm intest, unspec portion
209.01 Malignant carcinoid tumor of the duodenum
209.02 Malignant carcinoid tumor of the jejunum
209.03 Malignant carcinoid tumor of the ileum
209.10 Mal carcinoid tmr lge intest, unspec portion
209.11 Malignant carcinoid tumor of the appendix
209.12 Malignant carcinoid tumor of the cecum
209.13 Malig carcinoid tumor of the ascend colon
209.14 Mal carcinoid tumor of the transverse colon
209.15 Mal carcinoid tumor of the descending colon
209.16 Mal carcinoid tumor of the sigmoid colon
209.17 Malignant carcinoid tumor of the rectum
209.20 Mal carcinoid tumor of unknown primary site
209.21 Mal carcinoid tumor of the bronchus and lung
209.22 Malignant carcinoid tumor of the thymus
209.23 Malignant carcinoid tumor of the stomach
209.24 Malignant carcinoid tumor of the kidney
209.25 Mal carcinoid tumor of foregut, NOS
209.26 Malignant carcinoid tumor of midgut, NOS
209.27 Malignant carcinoid tumor of hindgut, NOS
209.29 Malignant carcinoid tumor of other sites
209.30 Mal poorly differentiat neuroendo Ca, any site

209.40 Ben carcinoid tmr sm intest, unspec portion
209.41 Benign carcinoid tumor of the duodenum
209.42 Benign carcinoid tumor of the jejunum
209.43 Benign carcinoid tumor of the ileum
209.50 Ben carcinoid tmr lge intest, unspec portion
209.51 Benign carcinoid tumor of the appendix
209.52 Benign carcinoid tumor of the cecum
209.53 Benign carcinoid tumor ascend colon
209.54 Ben carcinoid tumor of the transverse colon
209.55 Benign carcinoid tumor descend colon
209.56 Benign carcinoid tumor of the sigmoid colon
209.57 Benign carcinoid tumor of the rectum
209.60 Benign carcinoid tumor unknown primary site
209.61 Benign carcinoid tumor bronchus/lung
209.62 Benign carcinoid tumor thymus
209.63 Benign carcinoid tumor of the stomach
209.64 Benign carcinoid tumor of the kidney
209.65 Benign carcinoid tumor of foregut, NOS
209.66 Benign carcinoid tumor of midgut, NOS
209.67 Benign carcinoid tumor of hindgut, NOS
209.69 Benign carcinoid tumor of other sites
22.5 benign neo brain/other nervous system parts
225.0 BENIGN NEOPLASM BRAIN
225.1 BENIGN NEO CRANIAL NERVE
225.2 BEN NEO CEREBR MENINGES

225.3 BENIGN NEO SPINAL CORD
225.4 BEN NEO SPINAL MENINGES
225.8 BENIGN NEO NERV SYS NEC
225.9 BENIGN NEO NERV SYS NOS
226 BENIGN NEOPLASM THYROID
227.3 BENIGN NEO PITUITARY
227.4 BEN NEOPL PINEAL GLAND
228.02 HEMANGIOMA INTRACRANIAL
237.0 UNC BEHAV NEO PITUITARY
237.1 UNC BEHAV NEO PINEAL
237.3 UNC BEHAV NEO PARAGANG
237.5 UNC BEH NEO BRAIN/SPINAL
237.6 UNC BEHAV NEO MENINGES
237.7 neurofibromatosis
237.70 NEUROFIBROMATOSIS NOS
237.71 NEUROFIBROMATOSIS TYPE I
237.72 NEUROFIBROMATOSIS TYP II
237.9 UNC BEH NEO NERV SYS NEC
239.6 BRAIN NEOPLASM NOS
259.2 other endocr disorders, carcinoid syndrome
Drug and/or Alcohol Induced Mental Disorders
291 Alcoholic psychosis
291.0 DELIRIUM TREMENS
291.1 Alcohol psychosis, alcoh amnestic syndrome

291.2 Alcoholic psychosis, other alcohol dementia
291.3 Alcoh psychosis, alc withdrawal hallucinosis
291.4 Alcoh psycho, idiosyncratic alcoh intoxicat
291.5 Alcoholic psychoses, alcohol jealousy
291.8 Alcoh psychoses, other spec alcoh psycho
291.81 Alc psych othr spec alco psych/alc wthdrwl
291.89 Alco psych, other spec alco psycho, other
291.9 Alcoholic psychoses/unspec alcoh psycho
292 Drug psychoses
292.0 DRUG WITHDRAWAL
292.1 Paranoid/hallucinatory induced by drugs
292.11 Paranoid/hallucinatory drgs induced, drg-induced organic delusion syndrome
292.12 DRUG PSY DIS W HALLUCIN
292.2 PATHOLOGIC DRUG INTOX
292.8 other spec drug-induced mental disorders
292.81 othr spec drg-induced ment disorders, drg-induced delirium
292.82 other specified drug-induced mental disorders, drug-induced dementia
292.84 other specified drug-induced mental disorders, drug-induced organic affective syndrome
292.89 othr spec drg-induced ment disorders, othr
292.9 unspecified drug-induced mental disorders
303 alcohol dependence syndrome
303.0 alco depend syndrome, ac alcoho intox
303.00 AC ALCOHOL INTOX-UNSPEC
303.01 alco depend syndr, ac alcoho intox, contin
303.02 alc depend syndr, ac alco intox, episodic

303.03 alc depend syndr, ac alc intox, in remission
303.9 alc depend syndr, othr & unspec alc depend
303.90 alco depend syndr, othr & unspec alc depend unspec
303.91 alcohol dependence syndrome, other & unspecified alcohol dependence, continuous
303.92 alcohol dependence syndrome, other & unspecified alcohol dependence, episodic
303.93 alcohol dependence syndrome, other & unspecified alcohol dependence, in remission
304 drug dependence
304.0 drug dependence, opioid
304.00 drug dependence, opioid, unspecified
304.01 drug dependence, opioid, continuous
304.02 drug dependence, opioid, episodic
304.03 drug dependence, opioid, in remission
304.1 drg depend barbit/similarly acting sdtv/hypnotic depend
304.10 drug dependence barbiturate/similarly acting sedative/hypnotic dependence unspec
304.11 drug dependence barbiturate/similarly acting sedative/hypnotic dependence continuous
304.12 drug dependence barbiturate/similarly acting sedative/hypnotic dependence episodic
304.13 drug dependence barbiturate/similarly acting sedative/hypnotic dependence in remission
304.2 drug dependence, cocaine
304.20 drug dependence, cocaine unspecified
304.21 drug dependence, cocaine continuous
304.22 drug dependence, cocaine episodic
304.23 drug dependence, cocaine in remission
304.3 drug dependence, cannabis
304.30 drug dependence, cannabis unspecified
304.31 drug dependence, cannibis continuous

304.32 drug dependence, cannabis episodic
304.33 drug dependence, cannabis in remission
304.4 drg depend, amphetamine/othr psychostim
304.40 drg depend amphetamine/othr psychostim unspec
304.41 drg depend amphetamine/othr psychostim contin
304.42 drug dependence, amphetamine/other psychostimulant episodic
304.43 drug dependence, amphetamine/other psychostimulant episodic in remission
304.5 drug dependence hallucinogen
304.50 drug dependence hallucinogen unspec
304.51 drug dependence hallucinogen continuous
304.52 drug dependence hallucinogen episodic
304.53 drug depend hallucinogen in remission
304.6 other specified drug dependence
304.60 other specified drug dependence unspec
304.61 other specified drug dependence continuous
304.62 other specified drug dependence episodic
304.63 other spec drug dependence in remission
304.7 drug dependence opioid type w/other drug
304.70 drug depend opioid type w/other drug unspec
304.71 drug depend opioid type w/other drug contin
304.72 drug depend opioid type w/other drug episod
304.73 drg depend opioid w/othr drg in remission
304.8 drug depend combination w/o opioid
304.80 drug depend comb w/o opioid type unspec
304.81 drug depend comb w/o opioid type contin

304.82 drug depend comb w/o opioid type episodic
304.83 drug depend comb w/o opioid type episodic
304.9 drug dependence unspec dependence
304.90 drug dependence unspec depend unspec
304.91 drug depend unspec depend continuous
304.92 drug depend unspec dependence episodic
304.93 drug depend unspec depend in remission
305.0 nondependence drug abuse alcohol
305.00 nondependence drug abuse alcohol unspec
305.01 nondependence drug abuse alcohol contin
305.02 nondependence drug abuse alcohol episodic
305.03 nondepend drug abuse alcohol in remission
571.0 Alcoholic fatty liver
571.1 Acute alcoholic hepatitis
571.2 Alcoholic cirrhosis of liver
571.3 Alcoholic liver damage unspecified
V11.3 personal mental disorder history alcoholism
Cardiac Conditions
425.5 Alcoholic cardiomyeopathy
427.5 cardiac arrest
Pericarditis
420 acute pericarditis
420.0 ac pericarditis in dis classified elsewhere

420.9 other/unspec pericarditis
420.90 other/unspec pericard, ac pericard unspec
420.91 other/unspec pericard, ac idiopathic pericard
420.99 other/unspec pericarditis other
HIV/AIDS
042 HIV w/spec cond includes AIDS
V08 asymptotic HIV infection status
079.53 HIV-2 INFECTION OTH DIS
Hepatitis B
070.2 viral hepatitis B w/hepatic coma
070.20 viral hep B w/hep coma ac or unspec w/o hep delta
070.21 viral hepatitis B w/hepatic coma acute or unspec w/ hepatitis delta
070.22 viral hepatitis B w/hepatic coma chronic w/o hepatitis delta
070.23 viral hepatitis B w/hepatic coma chronic w/hepatitis delta
070.3 viral hepatitis B w/o hepatic coma
070.30 viral hepatitis B w/o hepatic coma acute or unspec w/o hepatitis delta
070.31 viral hepatitis B w/o hepatic coma acute or unspec w/ hepatitis delta
070.32 viral hepatitis B w/o hepatic coma chronic w/o hepatitis delta
070.33 viral hepatitis B w/ohepatic coma chronic w/ hepatitis delta
Septicemia and Shock
020.2 SEPTICEMIC PLAGUE
020.3 PRIMARY PNEUMONIC PLAGUE

031 diseases due to other mycobacteria
036.2 meningococcemia
038 septicemia
038.0 septicemia, streptococcal
038.1 septicemia, staphylococcal
038.10 septicemia, staphylococcal unspec
038.11 septicemia, staphylococcal staph aureus
038.19 septicemia, staphylococcal other
038.2 septicemia pneumococcal septicemia
038.3 septicemia due to anaerobes
038.4 septicemia due to other gram neg organisms
038.41 septicemia d/t othr gram neg hemophilus influenza
038.42 septicemia d/t othr gram neg org E coli
038.43 septice d/t othr gram neg org pseudomonas
038.44 septicemia d/t othr gram neg org serratia
038.49 septicemia d/t othr gram neg organism othr
038.8 septicemia other specified
038.9 septicemia other unspecified
040.82 toxic shock syndrome
054.5 herpetic septicemia
771.81 newborn septicemia
785.59 othr shock: endotox, gram neg hypovolem
Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias
003.22 salmonella pneumonia

006.4 amebic lung abcess
007.4 cryptosporidosis
020.3 primary pneumonia
020.4 SECONDARY PNEUMON PLAGUE
020.5 pneumonic unspecified
021.2 PULMONARY TULAREMIA
022.1 PULMONARY ANTHRAX
031.2 disseminated mycobacteria
039.1 PULMONARY ACTINOMYCOSIS
078.5 CYTOMEGALOVIRAL DISEASE
112.4 candidiasis lung
112.5 candidiasis disseminated
112.84 candidal esophagitis
114.0 primary coccidioidomycosis pulmonary
114.4 chronic pulmonary coccidioidomycosis
114.5 primary coccidioidomycosis unspecified
115.05 histoplasma capsulatum pneumonia
115.15 histoplasma duboisii pneumonia
115.95 histoplasmosis unspecified pneumonia
117.3 aspergillosis
117.5 cryptococcosis
117.7 zygomycosis (phycomycosis/mucomycosis)
121.2 paragonimiais
122.1 echinoccus granulosis lung
130.0 toxoplasmosis meningoencephalitis

130.4 toxoplasmosis pneumonitis (strep pneumoniae pneumonia)
130.8 multisystemic disseminated toxoplasmosis
136.3 pneumocytosis
321.0 cryptococcal meningitis
481 pneumococcal pneumonia (streptococcus pneumoniae pneumonia)
482 other bacterial pneumonias
482.0 pneumonia due to Klebsiella pneumoniae
482.1 pneumonia due to pseudomonas
482.2 hemophilus influenzae pneumonia
482.3 streptococcus pneumonia
482.30 streptococcus pneumonia unspecified
482.31 streptococcus Group A pneumonia
482.32 streptococcus Group B pneumonia
482.39 streptococcus other strep pneumonia
482.4 pneumonia due to staphlococcus
482.40 pneumonia due to staphlococcus unspec
482.41 pneumonia due to staphlococcus aureus
482.49 pneumonia due to other staph pneumonia
482.8 pneumonia due to other specified bacteria
482.81 pneumonia due to anaerobes
482.82 pneumonia due to E. coli
482.83 pneumonia due to other gram neg bacteria
482.84 Legionnaires' disease
482.89 pneumonia due to other specified bacteria
484.1 cytomegalic inclusion disease pneumonia

484.6 aspergillosis pneumonia
484.7 other systemic mycoses pneumonia
507 pneumonitis due to solids & liquids
507.0 pneumonia due to inhalation of food/vomitus
507.1 pneumonia due to inhalation of oils/essences
507.8 pneumonitis due to other solids & liquids
510 empyema
510.0 empyema with fistula
510.9 empyema without fistula
513 lung/mediastinum abscess
513.0 lung abscess
513.1 mediastinal abscess
Gastrointestinal Tract Bleeding
530.21 esophageal ulcer w/bleeding
531.0 acute gastric ulcer w/hemorrhage
531.00 acute gastric ulcer w/hemorrhage w/o obst
531.01 acute gastric ulcer w/hemorrhage w/obstruct
531.2 acute gastric ulcer w/hemorrhage/perforation
531.20 ac gastric ulcer w/hemorrhage/perf w/obst
531.21 ac gastric ulcer w/hemorrhage/perf w/o obst
531.4 chronic/unspec gastric ulcer w/hemorrhage
531.40 chr/unspec gastric ulcer w/hemorrhage w/o obst
531.41 chr/unspec gastric ulcer w/hemorrhage w/obst
531.6 chr/unspec gastric ulcer w/hemorrhage/perf

531.60 chronic/unspec gastric ulcer w/hemorrhage/perforation w/o obstruct
531.61 chronic/unspec gastric ulcer w/hemorrhage/perforation w/obstruct
532.0 acute duodenal ulcer w/hemorrhage
532.00 acute duodenal ulcer w/hemorrhage w/o obst
532.01 acute duodenal ulcer w/hemorrhage w/obst
532.2 ac duodenal ulcer w/hemorrhage/perforation
532.20 ac duodenal ulcer w/hemorrhage/perforation w/obstruction
532.21 ac duodenal ulcer w/hemorrhage/perforation w/o obstruction
532.4 chr/unspec duodenal ulcer w/hemmorhage
532.40 chr/unspec duodenal ulcer w/hemmorhage w/o obstruction
532.41 chr/unspec duodenal ulcer w/hemmorhage w/obstruction
532.6 chr/unspec duodenal ulcer w/hemmorhage/perforation
532.60 chr/unspec duodenal ulcer w/hemmorhage/perforation w/o obstruction
532.61 chr/unspec duodenal ulcer w/hemmorhage/perforation w/obstruction
533.0 acute peptic ulcer w/hemorrhage
533.00 acute peptic ulcer w/hemorrhage w/o obst
533.01 acute peptic ulcer w/hemorrhage w/obstruct
533.2 acute peptic ulcer w/hemorrhage/perforation
533.20 ac peptic ulcer w/hemorrhage/perf w/obstr
533.21 ac peptic ulcer w/hemorrhage/perf w/obst
533.4 chronic/unspec peptic ulcer w/hemorrhage
533.40 chr/unspec pep ulc w/hemorrhage w/o obst
533.41 chr/unspec pep ulcer w/hemorrhage w/obst
533.6 chronic/unspec peptic ulcer w/hemorrhage/perforation
533.60 chr/unspec pep ulc w/hemorr/perf w/o obs

533.61 chr/unspec pep ulc w/hemorr/perf w/obs
534.0 acute gastrojejunal ulcer w/hemorrhage
534.00 ac gastrojejunal ulcer w/hemorrhage w/o obs
534.01 ac gastrojejunal ulcer w/hemorrhage w/obst
534.2 ac gastrojejunal ulcer w/hemorrhage/perf
534.20 ac gastrojejunal ulcr w/hemorr/perf w/obst
534.21 ac gastrojejunal ulc w/hemorr/perf w/o obst
534.4 chr/unspec gastrojejunal ulcer w/hemorrhage
534.40 chr/unspec gastrojejunal ulc w/hemo w/o obs
534.41 chr/unspec gastrojejunal ulc w/hemorr w/obs
534.6 chronic/unspec gastrojejunal ulcer w/hemorrhage/perforation
534.60 chr/unspec gastrojejunal ulcer w/hemorrhage/perf w/o obst
534.61 chr/unspec gastrojejunal ulcer w/hemorrhage/perf w/obst
537.83 angiodysplagia stomach/duod w/hemorrhage
562.02 diverticulosis small intest w/hemorrhage
562.03 diverticulitis small intest w/hemorrhage
562.12 diverticulosis colon w/hemorrhage
562.13 diverticulitis colon w/hemorrhage
569.85 angiodysplagia intestine w/hemorrhage
Hereditary hemollytic anemias/sickle cell anemias
282 hereditary hemolytic anemias
282.0 hereditary spherocytosis
282.1 hereditary elliptocytosis
282.2 anemias d/to glutathione metabolism disorder

282.3 othr hemolytic anemias d/t enzyme def
282.4 Thalassemias
282.41 sickle cell thalassemia w/o crisis
282.42 sickle cell thalassemia w/crisis
282.49 other thalassemia
282.5 sickle-cell trait
282.6 sickle-cell disease
282.61 sickle-cell dis Hb-SS disease w/o crisis
282.62 sickle-cell dis Hb-SS disease w/crisis
282.63 sickle-cell dis sickle-cell Hb-C dis w/o crisis
282.64 sickle-cell dis sickle-cell Hb-C dis w/crisis
282.68 sickle-cell dis other sickle-cell dis w/o crisis
282.69 sickle-cell dis other sickle-cell dis w/crisis
282.7 other hemoglobinopathies
282.8 other spec hereditary hemolytic anemias
282.9 hereditary hemolytic anemia unspec
Myelodysplastic Syndrome
238.7 neoplasm other lymphatic/hematopoietic tissues (includes myelodysplastic syndrome)
Monoclonial Gammopathy
273.1 monoclonial paraproteinemia (includes monoclonial gammopathy)

Table B: ICD-9 Codes eligible for a Co-Morbidity Payment Adjustment
Cancer (excludes non-melanoma skin cancer)
141.0 malignant neoplasm tongue base
141.1 malignant neoplasm dorsal tongue
141.2 malignant neoplasm tip/lateral tongue
141.3 malignant neoplasm ventral tongue
141.4 malignant neoplasm anterior 2/3 tongue
141.5 malignant neoplasm tongue junction
141.6 malignant neoplasm lingual tonsil
141.8 malignant neoplasm tongue nec
142.0 malignant neoplasm parotid
142.1 malignant neoplasm submandibular
142.2 malignant neoplasm sublingual gland
143.0 malignant neoplasm upper gum
143.1 malignant neoplasm lower gum
144.0 malignant neoplasm anterior floor mouth
144. malignant neoplasm lateral floor mouth
144.8 malignant neoplasm mouth floor nec
145.0 malignant neoplasm cheek mucosa
145.1 malignant neoplasm vestibule
145.2 malignant neoplasm hard palate

145.3 malignant neoplasm soft palate
145.4 malignant neoplasm uvula
145.6 malignant neoplasm retromolar
145.8 malignant neoplasm mouth nec
146.0 malignant neoplasm tonsil
146.1 malignant neoplasm tonsillar fossa
146.2 malignant neoplasm tonsil pillars
146.3 malignant neoplasm vallecula
146.4 malignant neoplasm anterior epiglottis
146.5 malignant neoplasm epiglottis junction
146.6 malignant neoplasm lateral oropharynx
146.7 malignant neoplasm posterior oropharynx
146.8 malignant neoplasm oropharynx nec
147.0 malignant neoplasm superior nasopharyn
147.1 malignant neoplasm posterior nasopharynx
147.2 malignant neoplasm lateral nasopharynx
147.3 malignant neoplasm anterior nasopharynx
148.0 malignant neoplasm postcricoid
148.1 malignant neoplasm pyriform sinus
148.2 malignant neoplasm aryepiglottic fold
148.3 malignant neoplasm posterior hypopharynx
148.8 malignant neoplasm hypopharynx nec

149.1 malignant neoplasm waldeyer's ring
149.8 malignant neoplasm oral/pharynx nec
149.9 malignant neoplasm orophryn ill-defined
150.0 malignant neoplasm cervical esophagus
150.1 malignant neoplasm thoracic esophagus
150.2 malignant neoplasm abdomin esophagus
150.3 malignant neoplasm upper 3rd esoph
150.4 malignant neoplasm middle 3rd esoph
150.5 malignant neoplasm lower 3rd esoph
151.0 malignant neoplasm stomach cardia
151.1 malignant neoplasm pylorus
151.2 malignant neoplasm pyloric antrum
151.3 malignant neoplasm stomach fundus
151.4 malignant neoplasm stomach body
151.5 malignant neoplasm stomach lesser curvature
151.6 malignant neoplasm stomach greater curvature
152.0 malignant neoplasm duodenum
152.1 malignant neoplasm jejunum
152.2 malignant neoplasm ileum
152.3 malignant neoplasm meckel's diverticulum
152.8 malignant neoplasm small bowel nec
153.0 malignant neoplasm hepatic flexure

153.1 malignant neoplasm transverse colon
153.2 malignant neoplasm descending colon
153.3 malignant neoplasm sigmoid colon
153.4 malignant neoplasm cecum
153.5 malignant neoplasm appendix
153.6 malignant neoplasm ascending colon
153.7 malignant neoplasm splenic flexure
154.0 malignant neoplasm rectosigmoid junction
154.1 malignant neoplasm rectum
154.2 malignant neoplasm anal canal
155.0 malignant neoplasm liver, primary
155.1 malignant neoplasm intrahepat ducts
156.0 malignant neoplasm gallbladder
156.1 malignant neoplasm extrahepatic ducts
156.2 malignant neoplasm ampulla of vater
156.8 malignant neoplasm biliary nec
157.0 malignant neoplasm pancreas head
157.1 malignant neoplasm pancreas body
157.2 malignant neoplasm pancreas tail
157.3 malignant neoplasm pancreatic duct
157.4 malignant neoplasm islet langerhans
157.8 malignant neoplasm pancreas nec

158.0 malignant neoplasm retroperitoneum
158.8 malignant neoplasm peritoneum nec
160.0 malignant neoplasm nasal cavities
160.1 malignant neoplasm middle ear
160.2 malignant neoplasm maxillary sinus
160.3 malignant neoplasm ethmoidal sinus
160.4 malignant neoplasm frontal sinus
160.5 malignant neoplasm sphenoid sinus
160.8 malignant neoplasm access sinus nec
161.0 malignant neoplasm glottis
161.1 malignant neoplasm supraglottis
161.2 malignant neoplasm subglottis
161.3 malignant neoplasm cartilage larynx
161.8 malignant neoplasm larynx nec
162.0 malignant neoplasm trachea
162.2 malignant neoplasm main bronchus
162.3 malignant neoplasm upper lobe lung
162.4 malignant neoplasm middle lobe lung
162.5 malignant neoplasm lower lobe lung
163.0 malignant neoplasm parietal pleura
163.1 malignant neoplasm visceral pleura
164.0 malignant neoplasm thymus

164.1 malignant neoplasm heart
164.2 malignant neoplasm anterior mediastinum
164.3 malignant neoplasm posterior mediastinum
165.8 malignant neoplasm thorax/resp nec
170.0 malignant neoplasm skull/face bone
170.1 malignant neoplasm mandible
170.2 malignant neoplasm vertebrae
170.3 malignant neoplasm ribs/sternum/clavicle
170.4 malignant neoplasm long bones arm
170.5 malignant neoplasm bones wrist/hand
170.6 malignant neoplasm pelvic girdle
170.7 malignant neoplasm long bones leg
170.8 malignant neoplasm bones ankle/foot
171.0 malignant neoplasm soft tissue head
171.2 malignant neoplasm soft tissue arm
171.3 malignant neoplasm soft tissue leg
171.4 malignant neoplasm soft tissue thorax
171.5 malignant neoplasm soft tis abdomen
171.6 malignant neoplasm soft tissue pelvis
172.0 malignant melanoma lip
172.1 malignant melanoma eyelid
172.2 malignant melanoma ear

172.4 malignant melanoma scalp/neck
172.5 malignant melanoma trunk
172.6 malignant melanoma arm
172.7 malignant melanoma leg
174.0 malignant neoplasm nipple
174.1 malignant neoplasm breast-central
174.2 malignant neoplasm breast upper-inner
174.3 malignant neoplasm breast lower-inner
174.4 malignant neoplasm breast upper-outer
174.5 malignant neoplasm breast lower-outer
174.6 malignant neoplasm breast-axillary
175.0 malignant neoplasm male nipple
176.0 skin - kaposi's sarcoma
176.1 sft tisue - kaposi's sarcoma
176.2 palate - kaposi's sarcoma
176.3 gi sites - kaposi's sarcoma
176.4 lung - kaposi's sarcoma
176.5 lymph nodes - kaposi's sarcoma
176.8 specified sites - kaposi's sarcoma
180.0 malignant neoplasm endocervix
180.1 malignant neoplasm exocervix
180.8 malignant neoplasm cervix nec

182.0 malignant neoplasm corpus uteri
182.1 malignant neoplasm uterine isthmus
182.8 malignant neoplasm body uterus nec
183.0 malignant neoplasm ovary
183.2 malignant neoplasm fallopian tube
183.3 malignant neoplasm broad ligament
183.4 malignant neoplasm parametrium
183.5 malignant neoplasm round ligament
184.0 malignant neoplasm vagina
184.1 malignant neoplasm labia majora
184. 2 malignant neoplasm labia minora
184.3 malignant neoplasm clitoris
186.0 malignant neoplasm undescend testis
186.9 malignant neoplasm testis nec
187.1 malignant neoplasm prepuce
187.2 malignant neoplasm glans penis
187.3 malignant neoplasm penis body
187.5 malignant neoplasm epididymis
187.6 malignant neoplasm spermatic cord
187.7 malignant neoplasm scrotum
188.0 malignant neoplasm bladder-trigone
188.1 malignant neoplasm bladder-dome

188.2 malignant neoplasm bladder-lateral
188.3 malignant neoplasm bladder-anterior
188.4 malignant neoplasm bladder-post
188.5 malignant neoplasm bladder neck
188.6 malignant neoplasm ureteric orifice
188.7 malignant neoplasm urachus
189.0 malignant neoplasm kidney
189.1 malignant neoplasm renal pelvis
189.2 malignant neoplasm ureter
189.3 malignant neoplasm urethra
189.4 malignant neoplasm paraurethral
190.0 malignant neoplasm eyeball
190.1 malignant neoplasm orbit
190.2 malignant neoplasm lacrimal gland
190.3 malignant neoplasm conjunctiva
190.4 malignant neoplasm cornea
190.5 malignant neoplasm retina
190.6 malignant neoplasm choroid
190.7 malignant neoplasm lacrimal duct
190.8 malignant neoplasm eye nec
191.0 malign neopl cerebrum
191.1 malignant neoplasm frontal lobe

191.2 malignant neoplasm temporal lobe
191.3 malignant neoplasm parietal lobe
191.4 malignant neoplasm occipital lobe
191.5 malignant neoplasm cereb ventricle
191.7 malignant neoplasm brain stem
192.0 malignant neoplasm cranial nerves
192.1 malignant neoplasm cerebral meninges
192.2 malignant neoplasm spinal cord
192.3 malignant neoplasm spinal meninges
194.0 malignant neoplasm adrenal
194.1 malignant neoplasm parathyroid
194.3 malignant neoplasm pituitary
194.4 malignant neoplasm pineal gland
194.5 malignant neoplasm carotid body
194.6 malignant neoplasm paraganglia nec
195.0 malignant neoplasm head/face/neck
195.1 malignant neoplasm thorax
195.2 malignant neoplasm abdomen
195.3 malignant neoplasm pelvis
195.4 malignant neoplasm arm
195.5 malignant neoplasm leg
196.0 malignant neoplasm lymph-head/neck

196.1 malignant neoplasm lymph-intrathoracic
196.2 malignant neoplasm lymph intra-abdoman
196.3 malignant neoplasm lymph-axilla/arm
196.5 malignant neoplasm lymph-inguin/leg
196.6 malignant neoplasm lymph-intrapelvic
196.8 malignant neoplasm lymph node-multiple
197.0 secondary malignant neoplasm lung
197.1 secondary malignant neoplasm mediastinum
197.2 secondary malignant neoplasm pleura
197.4 secondary malignant neoplasm small bowel
197.5 secondary malignant neoplasm large bowel
197.6 secondary malignant neoplasm peritoneum
197.7 secondary malignant neoplasm liver
198.0 secondary malignant neoplasm kidney
198.1 secondary malignant neoplasm urinary nec
198.2 secondary malignant neoplasm skin
198.3 secondary malignant neoplasm brain/spine
198.4 secondary malignant neoplasm nerve nec
198.5 secondary malignant neoplasm bone
198.6 secondary malignant neoplasm ovary
198.7 secondary malignant neoplasm adrenal
198.81 secondary malignant neoplasm breast

199.0 malignant neoplasm disseminated
199.2 malignant neoplasm associated with transplant
200.00 reticulosarcoma unsppecified extrandodal
200.01 reticulosarcoma head
200.02 reticulosarcoma thorax
200.03 reticulosarcoma abdoman
200.04 reticulosarcoma axilla
200.05 reticulosarcoma inguinal
200.06 reticulosarcoma pelvic
200.07 reticulosarcoma spleen
200.08 reticulosarcoma multiple
200.10 lymphosarcoma unspecified xtranodal
200.11 lymphosarcoma head
200.12 lymphosarcoma thorax
200.13 lymphosarcoma abdoman
200.14 lymphosarcoma axilla
200.15 lymphosarcoma inguinal
200.16 lymphosarcoma pelvic
200.17 lymphosarcoma spleen
200.18 lymphosarcoma multiple
200.20 burkitt's tumor unspecified xtranodal
200.21 burkitt's tumor head

200.22 burkitt's tumor thorax
200.23 burkitt's tumor abdom
200.24 burkitt's tumor axilla
200.25 burkitt's tumor inguin
200.26 burkitt's tumor pelvic
200.27 burkitt's tumor spleen
200.28 burkitt's tumor multiple
200.81 mixed lymphosarcoma head
200.82 mixed lymphosarcoma thorax
200.83 mixed lymphosarc abdoman
200.84 mixed lymphosarcoma axilla
200.85 mixed lymphosarcoma inguinal
200.86 mixed lymphosarcoma pelvic
200.87 mixed lymphosarcoma spleen
200.88 mixed lymphosarcoma multiple
201.00 hodgkins paragran unspecified extranodal origin
201.01 hodgkins paragran head
201.02 hodgkins paragran thorax
201.03 hodgkins paragran abdom
201.04 hodgkins paragran axilla
201.05 hodgkins paragran inguinal
201.06 hodgkins paragran pelvic

201.07 hodgkins paragran spleen
201.08 hodgkins paragran multiple
201.11 hodgkins granuloma head
201.10 hodgkins granuloma unspecified/extranodal/solitary organ
201.12 hodgkins granuloma thorax
201.13 hodgkins granuloma abdom
201.14 hodgkins granuloma axilla
201.15 hodgkins granuloma inguin
201.16 hodgkins granuloma pelvic
201.17 hodgkins granuloma spleen
201.18 hodgkins granuloma mult
201.20 hodgkins sarcoma unspecified/extranodal
201.21 hodgkins sarcoma head
201.22 hodgkins sarcoma thorax
201.23 hodgkins sarcoma abdom
201.24 hodgkins sarcoma axilla
201.25 hodgkins sarcoma inguinal
201.26 hodgkins sarcoma pelvic
201.27 hodgkins sarcoma spleen
201.28 hodgkins sarcoma multiple
201.40 lymphocytic-histiocytic unspecified extranodal
201.41 hodgkins lymphocytic-histiocytic head

201.42 hodgkins lymphocytic-histiocytic thorax
201.43 hodgkins lymphocytic-histiocytic abdoman
201.44 hodgkins lymphocytic-histiocytic axilla
201.45 hodgkins lymphocytic-histiocytic inguinal
201.46 hodgkins lymphocytic-histiocytic pelvic
201.47 hodgkins lymphocytic-histiocytic spleen
201.48 hodgkins lymphocytic-histiocytic multiple
201.50 nodular sclerosis unspecified extranodal
201.51 hodgkins nodular sclerosis head
201.52 hodgkins nodular sclerosis thorax
201.53 hodgkins nodular sclerosis abdoman
201.54 hodgkins nodular sclerosis axilla
201.55 hodgkins nodular sclerosis inguinal
201.56 hodgkins nodular sclerosis pelvic
201.57 hodgkins nodular sclerosis spleen
201.58 hodgkins nodular sclerosis multiple
201.60 mixed cellular unspecified extranodal
201.61 hodgkins mixed cell head
201.62 hodgkins mixed cell thorax
201.63 hodgkins mixed cell abdom
201.64 hodgkins mixed cell axilla
201.66 hodgkins mixed cell pelvic

201.67 hodgkins mixed cell spleen
201.68 hodgkins mixed cell multiple
201.70 lymphocytic depletion unspecified extranodal origin
201.71 hodgkins lymphocytic depletion head
201.72 hodgkins lymphocytic depletion thorax
201.73 hodgkins lymphocytic depletion abdoman
201.74 hodgkins lymphocytic depletion axilla
201.75 hodgkins lymphocytic depletion inguinal
201.76 hodgkins lymphocytic depletion pelvic
201.77 hodgkins lymphocytic depletion spleen
201.78 hodgkins lymphocytic depletion multiple
201.90 hodgkins disease unspecified extrananodal origin
201.91 hodgkins disease nos head
201.92 hodgkins disease nos thorax
201.93 hodgkins disease nos abdom
201.94 hodgkins disease nos axilla
201.95 hodgkins disease nos inguin
201.96 hodgkins disease nos pelvic
201.97 hodgkins disease nos spleen
201.98 hodgkins disease nos multiple
202.00 nodular lymphoma unspecified extrananodal origin
202.01 nodular lymphoma head

202.02 nodular lymphoma thorax
202.03 nodular lymphoma abdoman
202.04 nodular lymphoma axilla
202.05 nodular lymphoma inguinal
202.06 nodular lymphoma pelvic
202.07 nodular lymphoma spleen
202.08 nodular lymphoma multiple
202.10 mycosis fungoides unspecified extrananodal origin
202.11 mycosis fungoides head
202.12 mycosis fungoides thorax
202.13 mycosis fungoides abdom
202.14 mycosis fungoides axilla
202.15 mycosis fungoides inguinal
202.16 mycosis fungoides pelvic
202.17 mycosis fungoides spleen
202.18 mycosis fungoides multiple
202.20 sezary's disease unspecified extrananodal origin
202.21 sezary's disease head
202.22 sezary's disease thorax
202.23 sezary's disease abdom
202.24 sezary's disease axilla
202.25 sezary's disease inguinal

202.26 sezary's disease pelvic
202.27 sezary's disease spleen
202.28 sezary's disease multiple
202.30 malignant histiocytosis unspecified extrananodal origin
202.31 malignant histiocytosis head
202.32 malignant histiocytosis thorax
202.33 malignant histiocytosis abdoman
202.34 malignant histiocytosis axilla
202.35 malignant histiocytosis inguinal
202.36 malignant histiocytosis pelvic
202.37 malignant histiocytosis spleen
202.38 malignant histiocytosis multiple
202.40 leukemic reticuloendotheleosis unspecified extrananodal origin
202.41 hairy-cell leukemia head
202.42 hairy-cell leukemia thorax
202.43 hairy-cell leukemia abdoman
202.44 hairy-cell leukemia axilla
202.45 hairy-cell leukemia inguinal
202.46 hairy-cell leukemia pelvic
202.47 hairy-cell leukemia spleen
202.48 hairy-cell leukemia multiple
202.50 letterer-siwe unspecified extrananodal origin

202.51 letterer-siwe dis head
202.52 letterer-siwe dis thorax
202.53 letterer-siwe dis abdoman
202.54 letterer-siwe dis axilla
202.55 letterer-siwe dis inguinal
202.56 letterer-siwe dis pelvic
202.57 letterer-siwe dis spleen
202.58 letterer-siwe dis multiple
202.60 malignant mast unspecified extrananodal origin
202.61 malignant mastocytosis head
202.62 malignant mastocytosis thorax
202.63 malignant mastocytosis abdoman
202.64 malignant mastocytosis axilla
202.65 malignant mastocytosis inguinal
202.66 malignant mastocytosis pelvic
202.67 malignant mastocytosis spleen
202.68 malignant mastocytosis multiplr
202.80 other lymphomas unspecified extrananodal origin
202.81 lymphomas nec head
202.82 lymphomas nec thorax
202.83 lymphomas nec abdom
202.84 lymphomas nec axilla

202.85 lymphomas nec inguin
202.86 lymphomas nec pelvic
202.87 lymphomas nec spleen
202.88 lymphomas nec multiple
202.90 unspecified lymphoma unspecified extrananodal origin
202.91 lymphoid malignancy nec head
202.92 lymphoid malignancy nec thorax
202.93 lymphoid malignancy nec abdoman
202.94 lymphoid malignancy nec axilla
202.95 lymphoid malignancy nec inguinal
202.96 lymphoid malignancy nec pelvic
202.97 lymphoid malignancy nec spleen
202.98 lymphoid malignancy nec multiple
203.00 multiple myeloma w/o remission
203.01 multiple myeloma w remission
203.10 plasma cell leukemia without remission
203.11 plasma cell leukemia with remission
203.80 other immunoproliferative neoplasm without remission
203.81 other immunoproliferative neoplasm with remission
204.00 acute lymphoid leukemia without remission
204.01 acute lymphoid leukemia with remission
204.02 acute lymphoid leukemia, in relapse

204.10 chronic lymphoid leukemia without remission
204.11 chronic lymphoid leukemia with remission
204.12 chronic lymphoid leukemia, in relapse
204.20 subacute lymphoid leukemia without remission
204.21 subacute lymphoid leukemia with remission
204.80 other lymphoid leukemia without remission
204.81 other lymphoid leukemia with remission
204.90 unspecified lymphoid leukemia without remission
204.91 unspecified lymphoid leukemia with remission
205.00 acute myeloid leukemia without remission
205.01 acute myeloid leukemia with remission
205.10 chronic myeloid leukemia without remission
205.11 chronic myeloid leukemia with remission
205.20 subacute myeloid leukemia without remission
205.21 subacute myeloid leukemia with remission
205.22 subacute myeloid leukemia, in relapse
205.30 myeloid sarcoma without remission
205.31 myeloid sarcoma with remission
205.80 other myeloid sarcoma without remission
205.81 other myeloid sarcoma with remission
205.90 unspecified myeloid sarcoma without remission
205.91 unspecified myeloid sarcoma with remission

206.00 acute monocytic leukemia without remission
206.01 acute monocytic leukemia with remission
206.10 chronic monocytic leukemia without remission
206.11 chronic monocytic leukemia with remission
206.20 subacute monocytic leukemia without remission
206.21 subacute monocytic leukemia with remission
206.80 other monocytic leukemia without remission
206.81 other monocytic leukemia with remission
206.90 unspecified monocytic leukemia without remission
206.91 unspecified monocytic leukemia with remission
207.00 acute erythremia/erythroleukemia without remission
207.01 acute erythremia/erythroleukemia with remission
207.10 chronic erythremia/erythroleukemia without remission
207.11 chronic erythremia/erythroleukemia with remission
207.20 megakaryocytic leukemia without remission
207.21 megakaryocytic leukemia with remission
207.80 other specified leukemia without remission
207.81 other specified leukemia without remission
208.00 acute leukemia unspecified cell without remission
208.01 acute leukemia unspecified cell remission
208.10 chronic leukemia unspecified cell without remission
208.11 chronic leukemia unspecified cell with remission

209.01 malignant carcinoid tumor of the duodenum
209.02 malignant carcinoid tumor of the jejunum
209.03 malignant carcinoid tumor of the ileum
209.11 malignant carcinoid tumor of the apendix
209.12 malignant carcinoid tumor of the cecum
209.13 malignant carcinoid tumor of the ascending colon
209.14 malignant carcinoid tumor of the transverse colon
209.15 malignant carcinoid tumor of the descending colon
209.16 malignant carcinoid tumor of the sigmoid colon
209.17 malignant carcinoid tumor of the rectum
209.21 malignant carcinoid tumor of the bronchus and lung
209.22 malignant carcinoid tumor of the thymus
209.23 malignant carcinoid tumor of the stomach
209.24 malignant carcinoid tumor of the kidney
228.02 hemangioma intracranial
237.0 uncharacteristic behavior neoplasm of the pituitary
237.1 uncharacteristic behavior neoplasm of the pineal
237.3 uncharacteristic behavior neoplasm of the paragang
237.5 uncharacteristic behavior neoplasm of the brain/spinal
237.6 uncharacteristic behavior neoplasm of the meninges
237.71 neurofibromatosis type i
237.72 neurofibromatosis type ii

Drug and/or Alcohol Induced Mental Disorders
303.02 alcoholic dependence syndrome, acute alcoholic intoxication, episodic
303. alcoholic dependence syndrome, acute alcoholic intoxication, episodic, in remission
303.91 alcoholic dependence syndrome, acute alcoholic intoxication, episodic, continuous
303.92 alcohol dependence syndrome, other & unspecified alcohol dependence, episodic
303.93 alcohol dependence syndrome, other & unspecified alcohol dependence, in remission
304.01 drug dependence, opioid, continuous
304.02 drug dependence, opioid, episodic
304.03 drug dependence, opioid, in remission
304.11 drug dependence barbiturate/similarly acting sedative/hypnotic dependence continuous
304.12 drug dependence barbiturate/similarly acting sedative/hypnotic dependence episodic
304.13 drug dependence barbiturate/similarly acting sedative/hypnotic dependence in remission
304.21 drug dependence, cocaine continuous
304.22 drug dependence, cocaine episodic
304.23 drug dependence, cocaine in remission
304.31 drug dependence, cannibis continuous
304.32 drug dependence, cannabis episodic
304.33 drug dependence, cannabis in remission
304.41 drug depend amphetamine/othr psychostim contin
304.42 drug dependence, amphetamine/other psychostimulant episodic
304.43 drug dependence, amphetamine/other psychostimulant episodic in remission

304.51 drug dependence hallucinogen continuous
304.52 drug dependence hallucinogen episodic
304.53 drug depend hallucinogen in remission
304.61 other specified drug dependence continuous
304.62 other specified drug dependence episodic
304.63 other spec drug dependence in remission
304.71 drug dependence opioid type with other drug continuous
304.72 drug dependence opioid type with other drug episod
304.73 drug dependence opioid with othr drug in remission
304.81 drug dependence comb without opioid type continuous
304.82 drug dependence comb without opioid type episodic
304.83 drug dependence comb without opioid type episodic
304.91 drug dependence unspecified dependence continuous
304.92 drug dependence unspecified dependence episodic
304.93 drug dependence unspecified depend in remission
305.01 nondependence drug abuse alcohol continuous
305.02 nondependence drug abuse alcohol episodic
305.03 nondepend drug abuse alcohol in remission
571.0 alcoholic fatty liver
571.1 acute alcoholic hepatitis
571.2 alcoholic cirrhosis of liver

Cardiac Conditions
425.5 alcoholic cardiomyeopathy
427.5 cardiac arrest
Pericarditis
420.90 other/unspecified pericarditis, acute pericarditis unspecified
420.91 other/unspecified pericarditis, acute idiopathic pericarditis
HIV/AIDS
042 hiv w/spec cond includes aids
v08 asymptotic hiv infection status
Hepatitis B
070.30 viral hepatitis b without hepatic coma acute or unspecified without hepatitis delta
070.31 viral hepatitis b without hepatic coma acute or unspecified w/ hepatitis delta
070.32 viral hepatitis b without hepatic coma chronic without hepatitis delta
070.33 viral hepatitis b without hepatic coma chronic w/ hepatitis delta
Septicemia and Shock
038.0 septicemia, streptococcal
038.11 septicemia, staphylococcal staphlococcus aureus
038.2 septicemia pneumococcal septicemia

038.3 septicemia due to anaerobes
038.41 septicemia due to other gram negative hemophilus influenza
038.42 septicemia due to other gram negative organism e coli
038.43 septice due to other gram negative organism pseudomonas
038.44 septicemia due to other gram negative organism serratia
038.49 septicemia due to othr gram negative organism other
038.8 septicemia other specified
Bacterial Pneumonias/Opportunistic Infections/Pneumococcal Pneumonias
020.3 primary pneumonia
020.5 pneumonic unspecified
112.84 candidal esophagitis
114.5 primary coccidioidomycosis unspecified
321.0 cryptococcal meningitis
481 pneumococcal pneumonia (streptococcus pneumoniae pneumonia)
482.0 pneumonia due to klebsiella pneumoniae
482.1 pneumonia due to pseudomonas
482.2 hemophilus influenzae pneumonia
482.31 streptococcus group a pneumonia
482.32 streptococcus group b pneumonia
482.41 pneumonia due to staphlococcus aureus
482.81 pneumonia due to anaerobes

482.82 pneumonia due to e. coli
482.84 legionnaires' disease
484.1 cytomegalic inclusion disease pneumonia
484.6 aspergillosis pneumonia
507.0 pneumonia due to inhalation of food/vomitus
507.1 pneumonia due to inhalation of oils/essences
507.8 pneumonitis due to other solids & liquids
510.0 empyema with fistula
510.9 empyema without fistula
513.0 lung abscess
513.1 mediastinal abscess
Gastrointestinal Tract Bleeding
530.21 esophageal ulcer with bleeding
531.00 acute gastric ulcer with hemorrhage without obstruction
531.01 acute gastric ulcer with hemorrhage with obstructtion
531.20 acute gastric ulcer with hemorrhage/perf with obst
531.21 acute gastric ulcer with hemorrhage/perf without obst
532.00 acute duodenal ulcer with hemorrhage without obst
532.01 acute duodenal ulcer with hemorrhage with obst
532.20 acute duodenal ulcer with hemorrhage/perforation with obstruction
532.21 acute duodenal ulcer with hemorrhage/perforation without obstruction

533.00 acute peptic ulcer with hemorrhage without obstruction
533.01 acute peptic ulcer with hemorrhage with obstruction
533.20 acute peptic ulcer with hemorrhage/perforation with obstruction
533.21 acute peptic ulcer with hemorrhage/perforation with obstruction
534.00 acute gastrojejunal ulcer with hemorrhage without obstruction
534.01 acute gastrojejunal ulcer with hemorrhage with obstruction
534.20 acute gastrojejunal ulcer with hemorrhage/perforation with obstruction
534.21 acute gastrojejunal ulcer with hemorrhage/perforation without obstruction
537.83 angiodysplagia stomach/duod with hemorrhage
562.02 diverticulosis small intestine with hemorrhage
562.03 diverticulitis small intestine with hemorrhage
562.12 diverticulosis colon with hemorrhage
562.13 diverticulitis colon with hemorrhage
569.85 angiodysplagia intestine with hemorrhage
Hereditary Hemollytic Anemias/Sickle Cell Anemias
282.0 hereditary spherocytosis
282.1 hereditary elliptocytosis
282.2 anemias due to glutathione metabolism disorder
282.3 other hemolytic anemias due to enzyme deficiency
282.41 sickle cell thalassemia without crisis
282.42 sickle cell thalassemia with crisis

282.49 other thalassemia
282.5 sickle-cell trait
282.61 sickle-cell disease hb-ss disease without crisis
282.62 sickle-cell disease hb-ss disease with crisis
282.63 sickle-cell disease sickle-cell hb-c disease without crisis
282.64 sickle-cell disease sickle-cell hb-c disease with crisis
282.68 sickle-cell disease other sickle-cell disease without crisis
282.7 other hemoglobinopathies
282.8 other spec hereditary hemolytic anemias
Monoclonial Gammopathy
273.1 monoclonial paraproteinemia (includes monoclonial gammopathy)

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
Drug Class: Vitamin D Analogs			
Ingredient Name	**NDC**	**Strength**	**Trade Name**
Calcitriol	260530051	.25 MCG	Calcitriol Capsules
	540007	.25 MCG	Calcitriol Capsules
	930657	.25MCG	Calcitriol Capsules
	930658	0.5MCG	Calcitriol Capsules
	1791578	0.25MG	Calcitriol Capsules

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
	1791603	0.5MCG	Calcitriol Capsules
	4800657	0.25 MCG	Calcitriol Capsules
	4800658	0.5 MCG	Calcitriol Capsules
	110140011	0.25 MCG	Calcitriol Capsules
	142880007	.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
	543120	1 MCG/ML	Calcitriol Oral Solution
	682589030	0.5 MCG	Calcitriol Capsules
	548683461	.25 MCG	Rocaltrol Capsules
	604910562	0.5 MCG	Rocaltrol Capsules
	49115	1 MCG/ML	Rocaltrol Oral Solution
Paricalcitol	744314	2 MCG	Zemplar Capsules
	744315	4 MCG	
	744317	1 MCG	
	110140056	2 MCG	
	110140057	4 MCG	
	242360664	1 MCG	
	511294272	1 MCG	
	551540001	1 MCG	
	551546971	1 MCG	

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
Doxercalciferol	110140017	0.5 MCG	Hectorol Capsules
	110140018	2.5 MCG	
	511293550	2.5 MCG	
	584680120	0.5 MCG	
	584680122		
	584680121	2.5 MCG	
Drug Class: Calcimimetic			
Ingredient Name	**NDC**	**Strength**	**Trade Name**
Cinacalcet Hydrochloride	682589225	30 MG	Cinacalcet HCL Tablet
	632850074	66 MG	Sensipak Tablets
	1791845	30 MG	Sensipar Tablets
	548685616	30 MG	Sensipar Tablets
	555130073	33 MG	Sensipar Tablets
	555130074	66 MG	Sensipar Tablets
	555130075	99 MG	Sensipar Tablets
	632850073	30 MG	Sensipar Tablets
	632850075	K99 MG	Sensipar Tablets
Drug Class: Oral Phosphate Binder			
Ingredient Name	**NDC**	**Strength**	**Trade Name**
Lanthanum Carbonate	540920252	500 MG	Fosrenol Chewable Tablets
	540920253	750 MG	
	540920254	1000 MG	
	635520250	750 MG	
	635520251	1000 MG	

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
	635520252	500 MG	
Calcium Acetate	540026	667 MG	Calcium Acetate Capsules
	142880954	667 MG	Calcium Acetate Capsules
	597306402	667 MG	PhosLo Gelcaps
	1791371	667 MG	PhosLo Tablets
	1791934		PhosLo Tablets
	522680200	667 MG	PhosLo Tablets
	548683460	667 MG	PhosLo Tablets
	548685691		PhosLo Tablets
	647250260	667 MG	PhosLo Tablets
Sevelamer Hydrochloride	178560020	400 MG	Crenagel Tablets
	260530308	800 MG	Renagel Tablet
	260530394	400 MG	Renagel Tablet
	6155613	800 MG	Renagel Tablets
	178560021	800 MG	Renagel Tablets
	242360660	400 MG	Renagel Tablets
	511293461	800 MG	Renagel Tablets
	548685615	800 MG	Renagel Tablets
	551549726	400 MG	Renagel Tablets
	551549727	800 MG	Renagel Tablets
	580160778	800 MG	Renagel Tablets
	584680020	400 MG	Renagel Tablets
	584680021	800 MG	Renagel Tablets
	613920721	400 MG	Renagel Tablets

Table C			
List of National Drug Codes Used to Identify Part D Drugs for the Expanded ESRD PPS			
	647250284	400 MG	Renagel Tablets
	647250285	800 MG	Renagel Tablets
	654970020	400 MG	Renagel Tablets
	654970021	800 MG	Renagel Tablets
	675440656	800 MG	Renagel Tablets
	682990002	400 MG	Renagel Tablets
	682990021	800 MG	Renagel Tablets
	584680130	800 MG	Renvela Tablets
	711144207	403 MG	Sevelamer Hydrochloride Capsules
	68258-9013	800 MG	Sevelamer Hydrochloride Tablets
	68258-9070	400 MG	Sevelamer Hydrochloride Tablets
Sevelamer Carbonate	68299-0130	800 MG	Renvela Tablets

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