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ANALYSES TO INFORM THE DESIGN AND IMPLEMENTATION OF THE END-STAGE RENAL DISEASE PROSPECTIVE PAYMENT SYSTEM

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I. INTRODUCTION

A. OBJECTIVES AND ORGANIZATION OF THIS REPORT

The primary objective of this technical report is to provide an overview of the analytic work done by the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to support the Centers for Medicare & Medicaid Services (CMS) in the development of the End- Stage Renal Disease (ESRD) Prospective Payment System (PPS) implemented on January 1, 2011. The organization of this report follows the key decisions that were made in the design of the ESRD PPS and focuses on analytic work that occurred between the issuance of the 2008 CMS Report to Congress on the bundled payment system and the final payment rule issued in late 2010. Those decisions include the structure of the statistical model used to assess the impact of case-mix on the costs covered by the ESRD PPS , the composition of the bundle of services included in the ESRD PPS , the specification and selection of payment adjustment factors at both the patient and facility levels, the outlier payment mechanism to protect facilities from the costs of unusually expensive cases, the standardization of the base payment rate per dialysis treatment for these payment adjusters. In addition, analyses to support CMS decisions regarding payment for two specific types of dialysis services, those provided to pediatric patients and those provided to patients undergoing training for home dialysis, are described.

Much information on the development of the payment system and the analytic techniques used is already in the public domain. This report is intended to supplement, rather than to replicate, that information. Key reports that may be of interest to the reader include:

- 2005 BCMA report: Methodology for Developing a Basic Case-mix Adjustment for the Medicare ESRD Prospective Payment System: http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/Basic_Case_Mix_Methods_appendices%204_01_05.pdf
- 2008 KECC Report to CMS: End Stage Renal Disease Payment System: Results of Research on Case-mix Adjustment for an Expanded Bundle: http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/UM_KECC_ESRD_Bundle_Report.pdf
- 2008 Report to Congress: https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/downloads/ESRDReportToCongress.pdf
- 2009 Proposed Rule for 2011: https://www.gpo.gov/fdsys/pkg/FR-2009-09-29/pdf/E9-22486.pdf

- 2010 Final Rule for 2011: https://www.gpo.gov/fdsys/pkg/FR-2010-08-12/pdf/2010-18466.pdf

The analyses described in this report were developed iteratively over a period of several years. Therefore, the tables that are included were output at different times over the years. For example, some tables from earlier in the development process may reflect data from 2004-2006, while others reflect the 2006-2008 data that subsequently became available for use in finalizing the payment rule. Similarly, some models in this report will reflect case-mix adjusters that were not ultimately selected to be payment adjusters in the Final Rule for the 2011 ESRD PPS. Finally, although this report is intended primarily as a technical report and some of the presentation assumes a basic understanding of statistics and regression modeling, it can also be of use to a wider audience. In particular, each section opens with Background/Rationale, discussing the section's focus and motivation in non-technical terms. Likewise, each section's Conclusion briefly summarizes the section's analyses and related decisions about the structure of the 2011 Final Rule.

B. Legislative History of Payment for Renal Dialysis under the Medicare Program

This section summarizes key legislation establishing and revising the Medicare program's entitlement to coverage for end-stage renal disease (ESRD) patients and the methods for paying the institutional providers of dialysis-related services.

Section 299I of the Social Security Amendments of 1972, Public Law 92-603, established the ESRD program under Medicare. That law extended Medicare coverage to individuals regardless of age who have permanent kidney failure, requiring either dialysis or kidney transplantation to maintain life, and meet certain other eligibility criteria. 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 rise in expenditures for the ESRD program, Congress enacted legislation in 1978 (Public Law 95-292, ESRD Program Amendments of 1978), which amended title XVIII of the Social Security Act (hereafter, the Act), add section 1881, which governs Medicare payment for ESRD benefits. In particular, section 1881(b)(2)(B) of the Act directed CMS 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 CMS 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 of the U.S. Department of Health and Human Services (hereafter, 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 individuals who do dialysis treatments 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 a 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, CMS 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), which is adjusted for geographic differences in area wage levels for the treatment furnished in the facility or at home. The methodology for payment of outpatient maintenance dialysis services on a per-treatment basis is commonly referred to as the composite rate payment system. Final regulations implementing the composite rate 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 per treatment for hospital-based facilities. The composite rate 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.

CMS established separate rates for hospital-based and independent dialysis facilities, and provided a process by 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.)

The composite rate payment system implemented in 1983 was relatively comprehensive with respect to the renal dialysis services included as part of the composite rate payment bundle. However, a substantial portion of expenditures for renal dialysis services (some of which were developed after the implementation of the composite rate system) were excluded (or not added to) the composite rate payment system and were instead reimbursed in accordance with the respective fee schedules or other payment methodologies. For example, payments for erythropoiesis stimulating agents (ESAs) such as epoetin alfa (EPO) (for example, Epogen and darbepoetin alfa (Aranesp) used to treat anemia), and vitamin D analogs (paracalcitol, doxercalciferol, calcitriol), were made outside of the composite rate payment system as separately billable services. These separately billable services eventually comprised nearly 40 percent of total spending for outpatient maintenance dialysis. Subsequent inflation adjustments to the composite rate payment system were 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 2000s, policymakers and other interested parties, including the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO), 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 (http://www.medpac.gov/documents/reports/Mar01_Entire_report.pdf?sfvrsn=0), March 2005 (http://www.medpac.gov/documents/reports/Mar05_EntireReport.pdf?sfvrsn=0), and March 2007 (http://www.medpac.gov/documents/reports/Mar07_EntireReport.pdf?sfvrsn=0), 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 (http://www.gao.gov/assets/260/253347.pdf). Beginning in 2000, CMS studied the feasibility of an expanded payment bundle under a series of contracts to the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC). That work has continued through the implementation and refinement of the ESRD PPS.

CMS took the approach that a fully bundled PPS should combine composite rate dialysis services with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix per facility. 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, CMS believed 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, it could also increase desirable clinical outcomes, resulting in an enhanced quality of care.

C. STATUTORY AUTHORITY FOR A BUNDLED ESRD PPS

1. Benefits Improvement and Protection Act of 2000

Congress required studies on the bundling of additional services into the composite rate 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, Congress required the Secretary to issue a report on a bundled payment system that would include separately billable drugs and clinical laboratory services routinely used in furnishing dialysis. The Secretary submitted the report, Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System, to Congress in May 2003. This 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 that CMS had initiated on its own prior to the enactment of the law. In September 2000, UM–KECC was awarded a multi-phased research contract. That research led to the UM–KECC 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. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108-173, also required the Secretary to submit to 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.". Section 623(f)(1) also required that the report describe the methodology to be used to establish payment rates, provide details about the design of an appropriate bundled payment system, and be submitted to 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 rate payment system. Specifically, section 623 of the MMA required the following:

- 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.
- 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 rate 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 (also known as 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 that used in the previous payment system).
- Reinstatement of the composite rate exceptions process, which was 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, CMS 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 rate payment system effective January 1, 2005, as set forth in section 623 of the MMA. The modified composite rate payment system is commonly referred to as the "basic case-mix adjusted (BCMA) composite rate 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 rate payment rate, yielded the basic case-mix adjustment required by the MMA. The basic case-mix adjusted composite rate payment system became effective April 1, 2005, and was derived from UM–KECC research summarized in the 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 CMS's implementation of the MMA requirements discussed above, UM–KECC continued its research to inform development of 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. The report is available on the Internet at: http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/UM_KECC_ESRD_Bundle_Report.pdf. UM–KECC's final report formed the basis for the Secretary's February 2008 Report to Congress, A Design for a Bundled End Stage Renal Disease Prospective Payment System, mandated under section 623(f)(1) of the MMA (https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/Downloads/ESRDReportToCongress.pdf). The aspects of the basic case-mix adjusted composite rate 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 rate 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, it costs more to deliver the same dose of dialysis to larger than to smaller patients. Also, severely debilitated patients may require more staff time than do 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 resource use over the entire patient population. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite rate 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 more resource-intensive 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.

In order to inform 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/comorbidity data from the CMS 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 frail, malnourished, or suffering from comorbidities 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 comorbidities 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 comorbidities to composite rate costs was not stable over time. In addition, establishment of the diagnostic criteria used in connection with specific comorbidities 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 years old) incurred greater composite rate costs as well, was unexpected. The latter finding might reflect other factors correlated with young age, such as propensity to skip treatments, which result in higher facility costs per treatment actually delivered.

The outcome of UM–KECC 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 based on analysis of a sample of Medicare cost reports, independent from the UM–KECC research methodology. 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:

CMS special adjuster for pediatric patients

Age group (years)	Composite rate multiplier
< 18	*1.62
18–44	1.223
45–59	1.055
60–69 (reference group)	1.000
70–79	1.094
80+	1.174
Body Surface Area (BSA): (per 0.1m² change in BSA from national average of 1.84)	1.037
Low Body Mass Index (BMI): (<18.5kg/m2)	1.112
*Developed by CMS. The age, BSA, and BMI multipliers do not apply under the basic case-mix adjustments for patients under age 18.	

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

Case-mix adjuster for a 47-year old ESRD patient who is underweight

Adjuster	Multiplier
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 × 1.060 ×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 rate payment. 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. Medicare Improvements for Patients and Providers Act of 2008

The implementation of the basic case-mix adjustments to the composite rate payment system effective April 1, 2005, and the Secretary's February 2008 Report to Congress, suggested that an expanded or bundled

ESRD PPS that 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.

Section 153(b) of Medicare Improvements for Patients and Providers Act of 2008 (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 had not been implemented. Such an 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 forego 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 rate payments 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, CMS published the Calendar Year (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. The CY 2010 1.0 percent increase to the composite rate was announced in the CY 2010 Physician Fee Schedule final rule.

D. OVERVIEW OF THE 2011 ESRD PPS

The CY 2011 ESRD PPS final rule implemented 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. The proposed ESRD PPS replaced the basic case-mix adjusted composite rate payment system and the fee-for-service methodologies with the reimbursement of separately billable outpatient ESRD services.

Specifically, the ESRD PPS combined payments for composite rate and separately billable services into an adjusted base rate of $229.63 developed from CY 2007 claims data. The base rate was subsequently adjusted using patient-specific case-mix adjustment factors developed from separate regression equations for composite rate and separately billable services. The patient-specific case-mix adjusters included variables for age, body surface area (BSA), low body mass index (BMI), six comorbidity categories, and the onset (first four months) of renal dialysis. These proposed adjustment factors were developed using standard multiple regression techniques to yield case-mix adjusted payments per treatment. The per treatment payment amounts were also adjusted to reflect differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSA) definitions. The proposed rule also provided that ESRD facilities treating patients with unusually high resource requirements as measured through their utilization of identified services beyond a specified threshold were entitled to outlier payments, that is, additional payments beyond the otherwise applicable case-mix adjusted bundled prospective payment amount.

The proposed ESRD PPS also provided for special adjustments for pediatric patients and for facilities treating a low volume of ESRD patients, as well as a four-year transition (phase-in) period under which facilities would receive a blend of payments under the prior case-mix adjusted composite rate payment system and the new ESRD PPS.

The payment model implemented on January 1, 2011, is presented in Table 1. The remainder of this report provides detailed technical information on UM-KECC research methods and approach to the development of the 2011 Final Rule payment model.

Table 1.1 Payment Multipliers for an Expanded Bundle of Services, ages 18 and older, 2006-2008 (Base Rate - $229.63)

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]
	Composite rate services[1]	Separately billable services[2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics			
Age (years)			
18-44	1.254	0.996	1.171
45-59	1.023	0.992	1.013
60-69	1.000	1.000	1.000
70-79	1.033	0.963	1.011
80+	1.063	0.915	1.016
Body surface area (per 0.1 m^2)	1.023	1.014	1.020
Underweight (BMI <18.5)	1.000^	1.078	1.025
Time since onset of renal dialysis < 4 months	1.539	1.450	1.510
Pericarditis (acute*)	1.000^	1.354	1.114
Bacterial pneumonia (acute*)	1.000^	1.422	1.135
Gastro-intestinal tract bleeding (acute*)	1.000^	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic*)	1.000^	1.225	1.072
Myelodysplastic syndrome (chronic*)	1.000^	1.309	1.099
Monoclonal gammopathy[5] (chronic*)	1.000^	1.074	1.024
Low volume facility adjustment			
Facility size < 4,000 treatments each year 2006-2008	1.347	0.975	1.189

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

[1]The CR payment multipliers ($PmtMult_{CR}$) are based on a facility level log-linear regression model of the average composite rate cost/session for 2006-08 (n=12,974 facility years). This model also include facility characteristics (an indicator of low volume facilities as a potential payment variable and control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate exception, % of patients in the facility with URR<65%, and % of home dialysis training treatments in the facility) and the percent of pediatric patients as additional covariates (R^2=41.0%).

[2]Based on a patient-month level log-linear regression model of separately billable Medicare Allowable Payments/session for 2006-08 (n=8,603,325 patient months) that includes facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates. An R^2 value of 5.1% was calculated at the patient level based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain the variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R^2 value for the patient-month level log-linear SB model was 3.3%.

[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable MAP. Based on total estimated costs of $177.72 per session for composite rate services, $83.97 per session for separately billable services, and $261.69 per session for composite rate and separately billable services ($177.72+$83.97), the relative weights are $Weight_{CR}$=0.6791 for composite rate services ($177.72/$261.69) and $Weight_{SB}$=0.3209 for separately billable services ($83.97/$261.69). The combined low volume multiplier was calculated relative to all other facilities.

[4]To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression model (which correspond to the CR and SB multipliers of 1.347 and 0.975, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.189. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

[5]Excludes multiple myeloma.

*Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

II. STRUCTURE OF THE PROSPECTIVE PAYMENT SYSTEM PAYMENT MODEL

A. BACKGROUND/RATIONALE

Cost information for services included in the dialysis composite rate payment system are only available at the facility level from Medicare cost reports. Payments or changes at the patient level for composite rate services were generally uniform within a facility, so they do not provide information on the variation of costs across patients within a facility. Therefore, the basic case-mix adjustment (BCMA) to the composite rate was developed using a facility-level regression model relating average cost across all treatments delivered by the facility to case-mix measures aggregated to the facility level (e.g., percent of patients in each of several age groups, average body surface area (BSA), percent of patients with low body mass index (BMI)). Because cost reports remain the only national source of data on the costs associated with composite rate services, the Calendar Year (CY) 2011 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CY 2011 Final Rule) relied on a similar, facility-level modeling approach for composite rate costs. However, patient-level variation in utilization of the separately billable services being added to the payment bundle in 2011 are available from Medicare claims (payment under the separately billable system was per unit of drug or per laboratory test performed). This creates a choice between estimating a single equation case-mix adjustment model by aggregating separately billable costs per treatment to the facility level and adding them to facility-level composite rate costs per treatment, versus a two-equation approach that maintains the facility-level composite rate model but estimates a separately billable case-mix adjustment model at the patient level. A two-equation approach requires a method of combining the results into a single payment model.

This section describes the pros and cons of the one-equation and two-equation approaches; presents evidence on the accuracy, precision, and stability of estimates using these alternative approaches; describes the method of combining the results from the two-equation model; and considers other issues relevant to model structure such as functional form (linear vs. logarithmic) and the inclusion of facility fixed effects to control for time invariant differences across facilities.

B. BUILDING THE PAYMENT MODEL

The structure of the ESRD PPS model reflects costs estimated using data from the Centers for Medicare & Medicaid Services (CMS) claims files for Medicare dialysis patients and the Medicare Cost Reports for dialysis facilities. In the analyses reported in the February 2008 KECC report to CMS, resource utilization for most separately billable services (injectable medications, laboratory tests, blood products, and a few miscellaneous supplies) was based on patient-level Medicare outpatient claims for the years 2002-2004. The claims data was

subsequently updated to claims from 2006-2008 for the underlying analyses supporting the CY 2011 Final Rule. Since composite rate cost information is available only at the facility level, resource utilization for composite rate services was and is measured using the Independent Renal Dialysis Facility Cost Reports and Hospital Cost Reports. For the 2008 report, the most current annual cost report data were available through 2004. Models for the CY 2011 Final Rule used cost report data for the years 2006-2008, which was the best available data at the time.

Several other data sources were used to measure patient and facility characteristics. These data sources include the Medicare Enrollment Database and the CMS Medical Evidence Form (CMS Form 2728), which is completed at onset of dialysis. Patient body size measures were initially derived for modeling purposes from the height and weight values reported on CMS Form 2728. Since the implementation of the basic case-mix adjustment for composite rate services in April 2005, height and weight values have been available directly from the Medicare claims. Therefore, these values now reflect the patient's size at the time of the claim rather than at onset of dialysis. Patient comorbidities were measured using a combination of CMS Form 2728 and diagnoses reported on Medicare claims. The claims diagnoses were used both to identify comorbidities that were not available on CMS Form 2728 and to capture changes in patient condition since the start of dialysis. Because comorbidities were rarely reported on dialysis claims prior to 2011, the vast majority of comorbidities were derived from other claim types (e.g., inpatient, physician/supplier). With the implementation of provisions included in the CY 2011 Final Rule, patient characteristics for those comorbidities in the payment model have been reported on the dialysis claims. Dialysis facility characteristics were measured using a combination of the ESRD Standard Information Management System (ownership type, hospital affiliation for satellite units and geographic location), the Medicare Cost Reports (facility size), the Online Survey and Certification and Reporting System (hospital affiliation for satellite units), and other information obtained from CMS (composite rate payment exceptions).

Given the available patient-level data on resource use for separately billable services and facility-level data on resource use for composite rate services, a cost modeling approach could be based on one of two estimating approaches:

- One-equation approach: facility-level combined model for composite rate and separately billable services
- Two-equation approach: facility-level model for composite rate services and single patient-level model for separately billable services (including Part B separately billable services)

Whatever the approach for cost modeling, it is possible to create a single equation payment model; that is, a patient-level model for separately billable services can be combined with a facility-level model for composite

rate services by calculating a weighted average of the multipliers from each equation to yield a single payment model for an expanded bundle.

The relative strengths and limitations of one- and two-equation cost modeling approaches are discussed below. We first present analyses comparing one-equation models with multiple equation models in general. These analyses led to a decision to implement a two-equation cost model in 2011.

1. Accuracy, precision and stability of estimates

The major difference between the two primary modeling approaches (a single facility-level cost model and a multiple-cost equation approach) is that a multiple-cost equation approach uses the most disaggregated data available for each equation (that is, a facility-level model for composite rate services and a patient-level model for separately billable services), whereas a single equation model requires aggregation to the largest unit at which any of the outcomes is observed (that is, to estimate a single equation model, patient-level data on separately billable services must be summarized to the facility level in order to be combined with facility-level cost report data as a single, global measure of cost per treatment). The multi-equation approach therefore has the advantage of utilizing the patient-level variation that is available from the Medicare claims. Under this approach, individual resource use per treatment can be modeled as a function of individual characteristics. The second approach has the relative simplicity of deriving the case-mix adjustment based on a single statistical model that is estimated at the facility level using a relatively small database, but essentially disregards available information on variation in separately billable services across patients within a facility. Under this approach, facility average resource per treatment is modeled as a function of facility average case-mix (e.g., percentage of a facility's treatments delivered to patients with a certain comorbid condition or in a certain age group). The main similarity between the two modeling approaches is that the form of the resulting payment model is the same and will not depend on the form of the estimation model (one or two-equation). That is, a multi-equation estimation model can be converted into a one-equation payment model.

To understand the differences between these two modeling approaches in practice, we evaluated patient-level and facility-level models that were limited to separately billable services. By using the same patient-level data in both models, we isolate the effect of aggregating the patient-level data to the facility level. These analyses were then used to compare patient-level models and facility-level models for separately billable services (Table 2.1).

Based on both models in Table 1, predictors of higher separately billable Medicare allowable payment (SB MAP) per session include younger age, female sex, BSA, and most comorbidities. Despite using the same data and same set of predictors, large differences emerge in the estimated coefficients for several case-mix factors, especially rare conditions having large effects on SB MAP. For example, the coefficient estimate for other

cancers based on the facility-level data is $27.49, while the estimate based on the patient-level data is $5.39. Both coefficients are statistically significant, and were estimated with sufficient precision that their 95 percent confidence intervals are non-overlapping. Therefore, it must be determined which of these coefficients represents an unbiased estimate of the true, underlying relationship between other cancers and dialysis costs.

One theoretical source of bias in the coefficient estimates arises if a correlation exists between case-mix measures and unobserved facility characteristics. The nature of this bias is explained intuitively here. Unobserved facility characteristics can be considered a latent variable. The biasing effects of this latent variable can be minimized in a patient-level analysis by estimating a model that uses the difference between patient-level cost and facility mean cost as a dependent variable, and uses the difference between the patients' characteristics and the mean value of the characteristics at the facility level as predictor variables. This patient-level model will be unbiased by unobserved facility characteristics. The facility-level model will be biased unless the latent variable is uncorrelated with case-mix. Estimating these two models yields quite different coefficients for a number of case-mix variables, confirming the presence of bias in the facility-level model.

Theoretically, the bias is greatest when the correlation between the case-mix measure and the latent variable is high, the effect of the latent variable on cost is large, the standard deviation of the latent variable is large, and the standard deviation of the case-mix measure is small. Empirically, because the latent variable cannot be observed, the first three factors cannot be directly estimated. However, the standard deviation of the case-mix measure across facilities can be measured. For rare conditions, this standard deviation is low, which helps explain why the bias is often large in the case of rare conditions (e.g., gastrointestinal bleeding, pericarditis, and esophageal varices).

Table 2.1 Comparison of patient-level and facility-level models of separately billable services (2002-2004)

Case Mix Factor	Linear models of SB MAP per session			
	Facility-level model n=12,142 R^2=0.1511		Patient-level model n=848,331 R^2=0.0882	
	Parameter Estimate	p-value	Parameter Estimate	p-value
Age (years)				
<18	-$42.31	0.0014	-$15.40	<.0001
18-44	$1.31	0.729	$5.50	<.0001
45-59	$8.71	0.0183	$2.36	<.0001
60-69	$0.00	ref	$0.00	ref
70-79	-$14.58	<.0001	-$4.30	<.0001
80+	-$15.09	<.0001	-$7.59	<.0001
Female	$18.40	<.0001	$10.74	<.0001
Body surface area (per 0.1 m^2)	$6.34	<.0001	$3.25	<.0001
Underweight (BMI <18.5)	$29.07	<.0001	$3.45	<.0001
Less than 4 previous months of RRT	$14.62	0.0365	$24.05	<.0001
Alcohol/drug dependence: claims since 1999 or 2728 (any)	$7.59	0.0002	$6.41	<.0001
Cardiac arrest: claims since 1999 or 2728 (any)	$8.95	0.2316	$7.94	<.0001
Pericarditis within one year	$105.30	<.0001	$21.32	<.0001
HIV/AIDS: claims since 1999 or 2728 (any)	$13.46	<.0001	$9.78	<.0001
Hepatitis B since 1999	$1.03	0.4571	$2.27	<.0001
Specified infection (includes 4 categories) within 1 month	$88.36	<.0001	$84.03	<.0001
Gastro-intestinal tract bleeding within 1 month	$406.51	<.0001	$109.37	<.0001
Esophageal varices within 6 months	$13.12	0.7704	$58.91	<.0001
Acquired hemolytic anemias within one year	-$5.94	0.0359	$9.80	<.0001
Hereditary hemolytic or sickle cell anemias since 1999	$17.55	0.0006	$14.68	<.0001
Specified cancer (includes 6 categories) since 1999	$19.51	<.0001	$9.21	<.0001
Other cancers since 1999	$27.49	<.0001	$5.39	<.0001
Myelodysplastic syndrome since 1999	$27.77	0.0153	$25.73	<.0001
Monoclonal gammopathy since 1999	$45.95	<.0001	$7.64	<.0001

Note: Includes adjustments for facility characteristics. Models are weighted by the number of hemodialysis-equivalent dialysis sessions. MAP=Medicare Allowable Payments from Medicare claims.

Table 2.2 provides information about the precision and stability of the parameter estimates from both facility-level and patient-level models. Coefficients from the patient-level model are more precisely estimated and more stable over time. Precision is demonstrated using the 95 percent confidence intervals reported for the pooled 3-year models. As an illustrative example, we use hereditary hemolytic or sickle cell anemias, which has relatively similar point estimates from the patient-level and facility-level models, but has much wider confidence intervals based on the facility-level model. Regarding stability, coefficient estimates for each individual year from 2002-2004 are reported for both patient and facility models. As an illustrative example, myelodysplastic syndrome is statistically significant and has a similar coefficient based on patient-level and facility-level models using pooled 2002-2004 data, but is highly unstable from year to year in the facility-level model. Cardiac arrest provides another example where the two pooled models yield similar point estimates, but the facility-level model demonstrates greater instability in the estimates over time. The generally higher level of precision in coefficient estimation using patient-level data motivated increased consideration of a two-equation cost estimation approach.

Table 2.2 Confidence intervals and yearly estimates for case-mix coefficients, facility-level versus patient-level linear models of MAP/session for separately billable services, 2002-2004

Variable	Facility-level						Patient-level					
	2002-2004 (n=12,142)			2002	2003	2004	2002-2004 (n=848,331)			2002	2003	2004
	Confidence intervals		Est. coeffi-cient	n= 3,840	n= 4,066	n= 4,236	Confidence intervals		Est. coeffi-cient	n= 266,700	n= 285,032	n= 296,599
	95% Low	95% High					95% Low	95% High				
Age (years)												
<18	$68.31	$16.32	-$42.31	-$46.59	-$56.40	-$34.54	-$18.88	-$11.93	-$15.40	-$12.31	-$13.86	-$18.68
18-44	-$6.08	$8.69	$1.31	$4.38	-$1.24	$1.36	$5.13	$5.88	$5.50	$5.16	$5.82	$5.55
45-59	$1.47	$15.94	$8.71	$1.02	$1.30	$22.75	$2.03	$2.68	$2.36	$1.95	$2.57	$2.53
70-79	-$21.51	-$7.65	-$14.58	-$11.52	-$18.90	-$12.91	-$4.62	-$3.97	-$4.30	-$3.58	-$4.70	-$4.58
80+	-$22.42	-$7.77	-$15.09	-$11.43	-$21.93	-$12.03	-$7.99	-$7.19	-$7.59	-$6.61	-$8.05	-$7.98
Female	$13.89	$22.91	$18.40	$18.70	$19.10	$17.96	$10.50	$10.98	$10.74	$10.67	$10.42	$11.07
Body surface area (per 0.1 m^2)	$5.67	$7.02	$6.34	$5.48	$5.56	$7.77	$3.20	$3.30	$3.25	$3.05	$3.14	$3.50
Underweight (BMI <18.5)	$16.20	$41.95	$29.07	$9.65	$17.99	$60.54	$2.86	$4.05	$3.45	$3.35	$3.06	$3.93
<4 previous months of RRT	$0.92	$28.33	$14.62	$4.95	$10.65	$29.65	$23.39	$24.72	$24.05	$19.58	$25.80	$26.53
Alcohol/drug dependence: claims since 1999 or 2728 (any)	$3.55	$11.62	$7.59	$9.01	$6.35	$7.03	$6.05	$6.77	$6.41	$5.51	$6.02	$7.45
Cardiac arrest: claims since 1999 or 2728 (any)	-$5.72	$23.63	$8.95	$24.41	$10.41	-$6.51	$7.28	$8.61	$7.94	$6.74	$7.81	$9.05
Pericarditis within one year	$80.36	$130.23	$105.30	$77.16	$97.21	$141.14	$20.14	$22.50	$21.32	$17.17	$21.85	$24.90
HIV/AIDS: claims since 1999 or 2728 (any)	$9.43	$17.48	$13.46	$21.07	$10.08	$11.40	$9.20	$10.35	$9.78	$10.11	$9.40	$9.90
Hepatitis B since 1999	-$1.69	$3.76	$1.03	-$0.91	$3.20	$0.39	$1.82	$2.71	$2.27	$1.66	$2.96	$1.97
Specified infection (includes 4 types) within 1 month	$74.03	$102.69	$88.36	$74.15	$104.10	$90.12	$82.87	$85.20	$84.03	$72.94	$84.55	$93.77
Gastrointestinal tract bleeding within 1 month	$322.49	$490.53	$406.51	$380.97	$371.85	$452.42	$106.03	$112.71	$109.37	$95.85	$108.50	$121.17
Esophageal varices within 6 months	-$74.98	$101.22	$13.12	$60.89	-$51.87	$56.38	$55.30	$62.51	$58.91	$53.96	$58.64	$63.40
Acquired hemolytic anemias within 1 year	-$11.49	-$0.39	-$5.94	-$8.17	-$0.10	$0.50	$8.78	$10.81	$9.80	$5.08	$14.53	$14.32
Hereditary hemolytic or sickle cell anemias since 1999	$7.48	$27.61	$17.55	$20.98	$16.50	$15.86	$13.95	$15.40	$14.68	$13.86	$14.80	$15.26
Specified cancer (includes 6 categories) since 1999	$11.71	$27.31	$19.51	$21.68	$19.47	$14.17	$8.76	$9.65	$9.21	$8.63	$9.10	$9.82
Other cancers since 1999	$21.12	$33.87	$27.49	$19.70	$23.50	$39.42	$5.02	$5.76	$5.39	$4.73	$5.01	$6.44
Myelodysplastic syndrome since 1999	$5.32	$50.23	$27.77	-$16.35	$48.07	$40.66	$24.64	$26.82	$25.73	$23.53	$26.99	$26.30
Monoclonal gammopathy since 1999	$26.36	$65.55	$45.95	$37.95	$28.97	$67.18	$6.67	$8.60	$7.64	$7.35	$6.65	$8.78

Includes adjustments for facility characteristics. Models weighted by # hemodialysis-equivalent dialysis sessions. MAP=Medicare Allowable Payments from Medicare claims.

2. Potential refinement for the two-equation approach

To determine the relationship between case-mix and resource use for separately billable services, a patient-level model relies on a combination of the variation occurring among individual patients within the same facility and the variation occurring among patients in different facilities. Since the number of facility-year observations (~12,000) is small relative to the number of patient observations (~800,000), the impact of unobserved facility characteristics in a patient-level model will be limited relative to a facility-level model (i.e., as with the single equation approach). However, the case-mix coefficients may still be influenced by unobserved facility characteristics.

As an alternative modeling approach for separately billable services that fully controls for time invariant unobserved facility characteristics, we tested individual facility effects in a patient-level model. This approach includes individual facility intercepts, or essentially a separate indicator variable for each of the approximately 4,000 facilities. This analysis includes one observation per patient per facility, for each year from 2002-2004.

The inclusion of individual facility fixed effects (versus including several measurable facility characteristics in the model) increased the explanatory power of the model from 8.4 percent to 18.3 percent (Table 2.3). This increase in explanatory power reflects the addition of approximately 4,000 individual facility indicator variables. The case-mix multipliers estimated by the two models, however, are generally very similar, varying within one percentage point for most factors. Those factors that had somewhat larger differences tended to represent relatively small numbers of patients (e.g., pediatric, pericarditis, HIV/AIDS). The difference in multipliers was largest for the pediatric variable, and may reflect the concentration of many pediatric patients in facilities that specialize in treating these patients. The ability to distinguish the effect of being a pediatric patient and the effect of being a patient in a largely pediatric facility is limited by the relatively small number of pediatric patients treated in other facilities. For pediatric facilities, the individual facility effects may be at least partly capturing the effect of what is inherently a patient characteristic (pediatric), and thereby removing it from the payment adjustment for pediatric patients. This is a possible disadvantage of controlling for individual facility effects. Since the adjustment for individual facility effects had a limited effect on most multipliers, it was not explored further as part of a patient-level separately billable equation.

Table 2.3 Impact of adjusting patient-level analyses of separately billable services for individual facility effects, 2002-2004

Variable	Model 1: Includes facility characteristics R^2: 0.0841		Model 2: Includes individual facility intercepts R^2: 0.1834	
	Estimated Multiplier	P-value	Estimated Multiplier	P-value
Age (years)				
<18	0.64	<.0001	0.80	<.0001
18-44	1.01	0.0005	1.01	<.0001
45-59	0.99	<.0001	0.99	<.0001
60-69	1.00	ref	1.00	ref
70-79	0.96	<.0001	0.97	<.0001
80+	0.93	<.0001	0.94	<.0001
Female	1.16	<.0001	1.15	<.0001
Body surface area (per 0.1 m^2)	1.04	<.0001	1.04	<.0001
Underweight (BMI <18.5)	1.04	<.0001	1.03	<.0001
Duration of RRT <4 months	1.41	<.0001	1.42	<.0001
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.08	<.0001	1.07	<.0001
Cardiac arrest: claims since 1999 or 2728 (any)	1.09	<.0001	1.09	<.0001
Pericarditis from same month to 3 months ago	1.62	<.0001	1.55	<.0001
HIV/AIDS: claims since 1999 or 2728 (any)	1.13	<.0001	1.10	<.0001
Hepatitis B since 1999	1.03	<.0001	1.03	<.0001
Specified infection (4 categories) from same month to 3 months ago	1.64	<.0001	1.65	<.0001
GI tract bleeding from same month to 3 months ago	1.83	<.0001	1.78	<.0001
Hereditary hemolytic or sickle cell anemias since 1999	1.16	<.0001	1.15	<.0001
Specified cancer (includes 6 categories) since 1999	1.10	<.0001	1.09	<.0001
Other cancers since 1999	1.07	<.0001	1.06	<.0001
Myelodysplastic syndrome	1.29	<.0001	1.29	<.0001
Monoclonal gammopathy since 1999	1.09	<.0001	1.08	<.0001

n=1,112,456 patient-facility-year observations. Models of the average separately billable Medicare Allowable Payment per session from the Medicare claims were weighted by the number of hemodialysis-equivalent dialysis sessions.

The two primary modeling approaches that were possible given the available resource use data differ with regard to whether a facility-level model or a patient-level model was used to explain variation in separately billable services. By utilizing patient-to-patient variation in both case-mix and resource use, a patient-level model has the advantage of reducing potential bias related to unobserved facility characteristics, producing more precise coefficient estimates and yielding greater stability in coefficient estimates over time. Further, a patient-level model for separately billable services can be combined with a facility-level model for composite rate services to yield a single payment model for an expanded bundle. A two-equation modeling approach was

therefore used as the basis for developing the payment model promulgated in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and implemented on January 1, 2011.

3. Linear versus logarithmic models

Models of resource use for composite rate services and separately billable services could be estimated using alternative function forms, such logarithmic models or linear models. Logarithmic models are often useful with skewed data. Typically, health care cost data feature a skewed distribution in which a relatively small fraction of individuals account for a disproportionate fraction of costs. The cost distribution for both composite rate and separately billable services exhibits this type of skewness.

However, since the skewness in costs for outpatient dialysis related costs is not nearly as pronounced as with other cost data (e.g., inpatient spending), we examined both logarithmic and linear forms of the case-mix models. For these analyses, the dependent variable was the average cost per session in the linear models and the log of the average cost per session in the logarithmic models, while the independent variables were the same in all models. For both composite rate and separately billable services, the explanatory power of the logarithmic models was either similar to or slightly lower than that of the linear models (Table 2.4).

The explanatory power of the logarithmic models was assessed using two separate R^2 values. The R^2 statistic from the logarithmic model, which is labeled as R^2 (log dollars) in Table 7-4, measures the ability of the model to explain variation in resource use in terms of log dollars rather than in dollars. However, the extent to which a model explains variation in resource use measured in dollars will be more relevant to providers, since they are reimbursed in dollars. A separate R^2 value, R^2 (dollars), is based on a linear model in which the average cost per session (in dollars) is the dependent variable and the predicted cost per session from the log-linear model (i.e., retransformed to dollars) is used as the only independent variable. When evaluated in terms of dollars, the explanatory power is not affected by which functional form is used for composite rate services (39.8%) and remains slightly lower with the logarithmic form for separately billable services (9.1% vs. 10.3%).

Based on the factors that have a statistically significant association with costs, the list of potential case-mix adjusters implied by the two functional forms is very similar, although the magnitude of the payment adjustments varies for individual factors. A secondary analysis of residuals shows that the logarithmic form of the separately billable model had a modest advantage in better satisfying the assumptions of the model (e.g., normality and homoskedasticity of residuals). By reducing the influence of individual observations that reflect unusually high levels of resource use, logarithmic models yield more stable estimates.

Table 2.4 Explanatory power of linear and log-linear models of resource utilization, 2002-2004

Measure of resource utilization	n	Functional form		
		Linear	Log-linear	
		R^2	R^2 (log dollars)*	R^2 (dollars)**
Composite rate cost per session	11,174	39.8%	38.7%	39.8%
Separately billable MAC per session	809,208	10.3%	8.8%	9.1%

* R^2 (log dollars) is the R^2 statistic from the log-linear model, and measures the ability of the case-mix model to explain variation in log dollars.
** R^2 (dollars) is a measure of the ability of the log-linear model to explain variation in dollars. This statistic is the R^2 value from a linear model in which the average cost/session is the dependent variable and the predicted cost/session from the log-linear model (i.e., retransformed to dollars) is used as the independent variable.

In addition to the skewness in the cost data, there may be other factors to consider when choosing between logarithmic and linear models. A log transformation was applied to the resource utilization measure that was used to develop the BCMA for the composite rate system. The log-transformed dependent variable allows the case-mix adjustments to be applied multiplicatively to the wage adjustment, which reflects a multiplier in the composite rate system (i.e., results in a larger case-mix adjustment for facilities in higher wage areas). Hence, a logarithmic form is consistent with prior methods employed by CMS to adjust payment for dialysis services.

One potential disadvantage of a logarithmic model is a by-product of the multiplicative nature of the case-mix adjustments. A given upward payment adjustment based on BSA will be larger for dialysis patients who also have a costly comorbidity. An example from the composite rate BCMA shows that larger patients who are younger (18-44 years) receive a greater incremental payment for their large size than do large patients in the middle age category (60-69 years). This is not necessarily inappropriate, but it does represent a different policy choice than using an additive adjustment that would pay the same number of extra dollars for each characteristic regardless of which other characteristics are present.

Logarithmic models have both advantages and disadvantages relative to linear models. Separate analyses of composite rate and separately billable services suggest that the choice of functional form does not substantially affect overall model performance. Based on the somewhat skewed cost data for composite rate and separately billable services, and based on prior methods used to adjust payment for dialysis services in a multiplicative fashion, we applied a log transformation to both measures of resource use for the estimation of the cost models used in developing the payment model implemented in the CY 2011 Final Rule.

4. Combining two cost models to create a single payment model

The CY 2011 Final Rule, which implemented the MIPPA provisions, was based on a re-estimated two-equation cost model using Medicare claims data and cost reports for the years 2006-2008. Table 2.5 presents the estimated cost models for composite rate (CR) services and separately billable (SB) services, plus the modeled case-mix adjustment payment multipliers that are reflected in the payment system implemented in the CY 2011 Final Rule.

Footnote 3 provides a detailed explanation of the manner in which the estimates from the separate cost models were combined to create a single equation payment model. Essentially, the payment multipliers for a particular patient or facility characteristic were calculated as the weighted average of the coefficients in the two cost models, where the weights (0.673 for CR and 0.327 for SB) reflect the relative estimated costs for CR and SB services from 2006 to 2008.

Table 2.5. Payment multipliers for an expanded bundle of services, ages 18 and older, 2006-2008 (Base Rate - $229.63)

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]
	Composite rate services[1]	Separately billable services[2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics			
Age (years)			
18-44	1.254	0.996	1.171
45-59	1.023	0.992	1.013
60-69	1.000	1.000	1.000
70-79	1.033	0.963	1.011
80+	1.063	0.915	1.016
Body surface area (per 0.1 m^2)	1.023	1.014	1.020
Underweight (BMI <18.5)	1.000^	1.078	1.025
Time since onset of renal dialysis < 4 months	1.539	1.450	1.510
Pericarditis (acute*)	1.000^	1.354	1.114
Bacterial pneumonia (acute*)	1.000^	1.422	1.135
Gastro-intestinal tract bleeding (acute*)	1.000^	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic*)	1.000^	1.225	1.072
Myelodysplastic syndrome (chronic*)	1.000^	1.309	1.099
Monoclonal gammopathy[5] (chronic*)	1.000^	1.074	1.024
Low volume facility adjustment			
Facility size < 4,000 treatments during each year from 2006-2008	1.347	0.975	1.189

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

[1]The CR payment multipliers ($PmtMult_{CR}$) are based on a facility-level log-linear regression model of the average composite rate cost/session for 2006-08 (n=12,974 facility years). This model also include facility characteristics (an indicator of low volume facilities as a potential payment variable and control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate exception, % of patients in the facility with URR<65%, and % of home dialysis training treatments in the facility) and the percent of pediatric patients as additional covariates (R^2=41.0%).

[2]Based on a patient-month level log-linear regression model of separately billable Medicare Allowable Payments/session for 2006-08 (n=8,603,325 patient months) that includes facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates. An R^2 value of 5.1% was calculated at the patient level based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain the variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R^2 value for the patient-month level log-linear SB model was 3.3%.

[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility-level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient-level model of separately billable MAP. Based on total estimated costs of $177.72 per session for composite rate services, $83.97 per session for separately billable services, and $261.69 per session for composite rate and separately billable services ($177.72+$83.97), the relative weights are $Weight_{CR}$=0.6791 for composite rate services ($177.72/$261.69) and $Weight_{SB}$=0.3209 for separately billable services ($83.97/$261.69). The combined low volume multiplier was calculated relative to all other facilities.

[4]To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression model (which correspond to the CR and SB multipliers of 1.347 and 0.975, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.189. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

[5]Excludes multiple myeloma.

*Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

Conclusion

The CY 2011 Final Rule built upon the existing BCMA system for composite rate services in several important ways. First, the basic structure of the BCMA was maintained (facility-level, logarithmic model for composite rate costs), but the model was re-estimated using more recent data (2006-2008). Based on concerns about reduced accuracy (bias), reduced precision, and lower stability across years raised by analyses comparing separately billable models estimated at the facility level compared to those estimated at the patient level, CMS decided to use a two-equation approach. The two-equation approach avoids disregarding information on variation in resource use and case-mix characteristics across individual patients, but requires a method to combine the results of the two equations into a single equation payment model. That combination was achieved by creating a weighted average of the payment multipliers from the two equations, using the share of total cost per treatment accounted for by composite rate and separately billable services, respectively, as the weights.

A logarithmic functional form was selected over the linear functional form due to the skewness present in the cost data, and to maintain consistency with the multiplicative adjustment for the wage index in the payment system. Finally, the use of facility fixed effects was explored in the separately billable model. Because adding fixed effects had trivial impacts on the magnitudes and significance of the adjusters ultimately selected for the payment model, the simpler specification without fixed effects was selected.

III. BUNDLE COMPONENTS

A. BACKGROUND/RATIONALE

Any bundled payment system must consider the issue of delineating the set of services for which providers will be paid prospectively. In addition to the services already bundled under the composite rate payment system (the dialysis treatment itself and specified drugs and laboratory tests directly related to the treatment), the expanded bundle could, in principle, include any number of services related to dialysis or the care of common conditions associated with dialysis. Such services potentially include injectable and oral medications used to treat conditions commonly associated with end-stage renal disease (ESRD), an expanded set of laboratory tests, supplies and equipment not included in the composite rate, blood products, and vascular access-related services.

This section reviews previous work by the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) work informing decisions about each key component of the dialysis bundle, focusing on work performed following the UM-KECC 2008 report to the Centers for Medicare & Medicaid Services (CMS) entitled "End-Stage Renal Disease: Results of Research on Case-Mix Adjustment for an Expanded Bundle" (UM-KECC Bundling Report of 2008). When applicable, UM-KECC analyses of changes made after the implementation of the bundle are also discussed.

B. LABORATORY TESTS

UM-KECC's original work using 2003 Medicare claims determined that most labs performed on chronic dialysis patients were ordered by a Monthly Capitation Payment provider (MCP); that is, a physician who submitted a bill for the monthly payment for supervision of outpatient dialysis and related services. In addition, over 90 percent of the laboratory tests performed on chronic dialysis patients were related to ESRD and chronic conditions associated with chronic kidney failure and related diseases. This information is contained in the UM-KECC Bundling Report of 2008. In 2009, UM-KECC performed repeat analysis of laboratory test frequencies using 2007 Medicare Claims. The results of these analyses were similar to the original studies.

At the time of the Notice of Proposed Rulemaking (NPRM) for payment year 2011, published in 2009, there was renewed interest in defining a specific list of laboratories for inclusion in the expanded PPS, rather than including all laboratory tests ordered by MCP physicians during the treatment of these beneficiaries. Kidney Care Partners (KCP) and one UM-KECC clinician independently developed lists of ESRD laboratory tests for consideration. In addition, these lists were compared to the ESRD Network's list of ESRD-related

laboratory tests. Of note, most, but not all of the laboratory tests performed most frequently in chronic dialysis patients were included on the lists from these sources, and is detailed in Table 3.1.

Table 3.1 Carrier Claim Lab Codes Ranked by Total Payment (2007)

HCPCS	Frequency	Clinical Indication	KCP includes	ESRD network includes	KECC includes	Title	Approximate cumulative % of payments
83970	1878099	bone disease	Y	Y	Y	Parathormone (parathyroid hormone)	37.62%
82728	1530742	anemia	Y	Y	Y	Ferritin	47.70%
83550	1784929	anemia	Y	Y	Y	Iron binding capacity	55.11%
87340	1481001	Hep B infection	Y	Y	Y	Infectious agent antigen detection by enzyme immunoassay	62.43%
83540	2205027	anemia	Y	Y	Y	Iron	69.34%
82108	442269	dialysis water quality	Y	N	Y	Aluminum	74.77%
84466	438771	anemia	Y	Y	Y	Transferrin	77.44%
86706	401690	Hep B infection	Y	Y	Y	Hepatitis B surface antibody (HBsAb)	79.50%
83036	424835	diabetes mellitus	N	Y	N	Hemoglobin; glycated	81.48%
86803	245918	Hep C infection	Y	Y	Y	Hepatitis C antibody;	83.15%
82310	1082505	bone disease	Y	Y	Y	Calcium; total	84.57%
83718	333514	vascular disease	Y	N	Y	Lipoprotein, direct measurement; high density cholesterol (HDL)	85.89%
85045	667580	anemia	N	Y	Y	Blood count; reticulocyte, automated	87.18%
84100	1048094	bone disease	Y	Y	Y	Phosphorus inorganic (phosphate);	88.41%
83735	303929	ESRD	N	Y	Y	Magnesium	89.39%
84132	545686	ESRD	Y	Y	Y	Potassium; serum	90.31%
84443	101097	thyroid disease	Y	N	N	Thyroid stimulating hormone (TSH)	91.12%
87040	192241	infection	N	Y	Y	Culture, bacterial; blood, aerobic, with isolation and presumptive	91.88%
82607	78282	anemia	N	N	Y	Cyanocobalamin (Vitamin B-12);	92.44%
84134	79196	nutrition	N	N	Y	Prealbumin	92.98%
82746	63186	anemia	N	N	Y	Folic acid; serum	93.43%
82330	66707	bone disease	Y	N	Y	Calcium; ionized	93.87%
80162	47359	cardiac	N	N	N	Digoxin	94.17%
80202	46623	drug monitoring	N	N	Y	Vancomycin	94.44%
85046	99360	anemia	N	Y	Y	Blood count; reticulocytes, automated, including one or more	94.70%
85025	69123	anemia	?	Y	Y	Blood count; complete	94.96%
87186	50913	infection	N	N	N	Susceptibility studies, antimicrobial agent; microdilution or agar	95.16%
84540	83557	ESRD	?	?	Y	Urea nitrogen, urine	95.35%
86704	31423	Hep B infection	N	N	Y	Hepatitis B core antibody (HBcAb); total	95.54%
82570	72789	ESRD	?	?	Y	Creatinine; other source	95.72%
87077	44746	infection	N	Y	N	Culture, bacterial; aerobic isolate, additional methods required	95.88%
88305	14110	misc	N	N	N	Level IV: Surgical pathology, gross and microscopic examination	96.05%
87070	36669	infection	N	N	N	Culture, bacterial; any source no turine, blood or stool,	96.19%
80185	22236	drug monitoring	N	N	N	Phenytoin; total	96.34%
82306	9595	misc	N	N	N	Calcifediol (25-OH Vitamin D-3)	96.47%
83090	16152	vascular disease	N	Y	?	Homocystine	96.61%
86140	48357	misc	N	N	N	C-reactive protein;	96.73%
85027	31205	anemia	?	Y	Y	Blood count; complete	96.82%
85610	49304	drug monitoring	N	N	N	Prothrombin time;	96.92%
84520	108168	ESRD	?	Y	Y	Urea nitrogen; quantitative	97.00%
87517	4548	Hep B infection	N	N	Y	Infectious agent detection by nucleic acid hepatitis B	97.09%
83721	19125	vascular disease	?	?	?	Lipoprotein, direct measurement	97.18%
84439	18837	thyroid disease	N	N	N	Thyroxine; free	97.26%
82040	101676	ESRD	?	Y	Y	Albumin; serum	97.34%

Table 3.1 Carrier Claim Lab Codes Ranked by Total Payment (2007)

HCPCS	Frequency	Clinical Indication	KCP includes	ESRD network includes	KECC includes	Title	Approximate cumulative % of payments
88346	4986	misc	?	?	?	Immunofluorescent study, each antibody; direct method	97.41%
80061	14385	vascular disease	?	N	?	Lipid panel	97.48%
85041	47615	anemia	?	Y	Y	Blood count; red blood cell (RBC), automated	97.55%
HCPCS	**Frequency**	**Clinical Indication**	**KCP includes**	**ESRD network includes**	**KECC includes**	**Title**	**Approximate cumulative % of payments**
84153	8262	misc	N	N	n	Prostate specific antigen (PSA); total	97.62%
82947	86631	diabetes mellitus	Y	Y	N	Glucose; quantitative, blood (except reagent strip)	97.68%
84630	11610					Zinc	97.75%

Of the 15 most common laboratory tests performed in Medicare chronic dialysis patients, UM-KECC and Kidney Care Partners (KCP) agreed on the appropriateness of inclusion on the ESRD laboratory list for over two-thirds of laboratory tests. This information was provided to CMS for consideration in their development of the 2011 ESRD PPS Final Rule, published in August 2010.

In addition, UM-KECC performed analyses that informed the CMS decision regarding the laboratory test "50/50 rule" by identifying claims frequency and payments for laboratory claims with modifiers that identified them as being influenced by the 50/50 rule. Under that rule, if more than half of the tests performed using an Automated Multi-Channel Chemistry (AMCC) equipment are covered under the Composite Rate (CR), the remaining tests cannot be separately billed. UM- KECC's final analysis was presented to CMS on 9/14/2009. Table 3.2 describes Medicare payment for laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients and billed on carrier claims in 2007. The focus of the analysis was on use of Automated Multi-Channel Chemistry AMCC tests submitted with the CD, CE or CF modifiers. Approximately 97 percent of the identified lab tests did not include a modifier. Of the remainder, 3.05 percent included the CE modifier (AMCC composite rate test that is beyond the normal frequency covered under the CR and is separately reimbursable based on medical necessity), 0.05 percent included the CD modifier (AMCC test that is covered under the composite rate and is not separately billable) and 0.14 percent included the CF modifier (AMCC test that is not covered under the composite rate and is separately billable).

Table 3.2 Medicare payments for laboratory tests included in the expanded ESRD PPS (2007)

Pricing by AMCC modifier code	Payments	Percent of total
No AMCC modifier code	$308,821,607	96.76%
CD: AMCC test that is covered under the composite rate and is not separately billable	$160,312	0.05%
CE: AMCC composite rate test that is beyond the normal frequency covered under the CR and is separately reimbursable based on medical necessity	$9,739,572	3.05%
CF: AMCC test that is not covered under the composite rate and is separately billable	$444,233	0.14%
Total	$319,165,723	100.00%

*Includes laboratory tests billed by dialysis facilities and ordered by physicians receiving monthly capitation payments for treating ESRD patients and billed on carrier claims in 2007.

C. Blood and Blood Products

In 2009, UM-KECC began developing analyses to inform CMS policy decisions regarding possible inclusion of blood transfusions in the list of bundled services. Our initial analyses that were shaped by input from the CMS Project Officer, explored payment for blood and other blood products (including plasma, platelet, and other blood product transfusions) from type 72x (dialysis) claims only. These analyses showed 2007 spending of about $1.4 million; sub-analyses broke this out into freestanding and hospital-based facilities and by Healthcare Common Procedure Coding System (HCPCS) code and reported that about half occurred in each setting. Given the small fraction of facilities that was hospital-based, hospital-based facilities clearly represented a disproportionate share of transfusions reported on dialysis claims. A subsequent set of analyses in the blood transfusion series also presented information regarding payment for blood and other blood products, but expanded the search for transfusion events to all outpatient provider claims, showing about $7 million in spending during 2007. Using HCPCS codes to identify transfusion events, a substantial majority of outpatient transfusion events were billed by non-dialysis facilities.

These analyses initiated discussions about characteristics associated with a transfusion. These characteristics might be attributed to ESRD anemia management versus an unrelated acute medical or surgical event. Subsequent analyses informed CMS about the relative frequency of blood transfusion payments from different outpatient provider types. Additionally, an analysis was performed to identify the magnitude of transfusion events that occurred in close temporal proximity to surgical events. For patients having a surgical claim (surgical HCPCS) within one week before or after the transfusion event, these transfusion events accounted for slightly less than half (~$3 million) of the payments for outpatient transfusions

In 2010, UM-KECC performed an additional blood transfusion related analysis for CMS. This analysis described the number and fraction of dialysis patient facility month claims as well as the frequency and percent of facilities that received payment for administration of blood products in 2008. The results of this analysis are as follows: 4,353 of 3,216,416 (0.14 percent total patient facility month claims and 528 of 5,187 facilities (10.18 percent received payment for blood or blood products in 2008. The analysis also showed the presence of payment variation across facility type (hospital-based versus freestanding) and across states. Nearly half of these facilities were hospital-based. A disproportionate number of these facilities are in Louisiana (13 percent). However, nearly every state has at least one facility with payments for these services. UM-KECC was subsequently informed by CMS that blood and blood product costs would not be included in the expanded bundle of ESRD-related services.

During the four year period from 2008-2011, transfusion rates varied between 4 percent and 4.5 percent of patients having at least one transfusion in a given month. To the extent transfusions rose in 2011, there is some indication that the increase was concentrated among patients who received multiple transfusions over the year. There was little change in the percentage of patients who had either zero or one transfusions during the year. Average hemoglobin levels also declined gradually prior to the implementation of the bundle, falling from 11.6 in 2008, to 11.5 in 2009, to 11.4 in 2010. A sharper decrease to 11.0 was observed in 2011. Characteristics that predicted a higher likelihood of transfusion included non-Black race, female gender, and co-morbidity count.

In addition to outpatient transfusions, many transfusions occur in the inpatient setting. These can most reliably be identified through revenue center codes on inpatient claims, but identification can be ambiguous. Inclusion of blood products in the bundle may be useful as transfusions sometimes are clinical substitutes for bundled injectable medications in the treatment of anemia. However, the fact that fewer transfusions are performed in the dialysis setting than in other outpatient or inpatient settings, and that identification of transfusions in claims in not always clear, bundling blood products could create operational challenges both for dialysis facilities (who would have to make payment arrangements with multiple providers) and for CMS (in determining the appropriate amount of money to be added to the bundled payment rate to cover expected costs of transfusions).

D. DURABLE MEDICAL EQUIPMENT AND SUPPLIES

A small component considered for inclusion in the bundle, was support services, durable medical equipment and supplies (DME). UM-KECC provided analysis of payments to CMS for these services. By 2008, such services made up a very small (well under 1 percent) share of per treatment spending. Table 3.3

Table 3.3 Average Medicare Allowable Payments for composite rate and separately billable services (2007-2009)*

	Time period				
	January to June 2007	**January to June 2008**	**January to June 2009**	**2007 (full year)**	**2008 (full year)**
Dialysis patients	289,088	293,338	291,814	328,246	332,505
Hemodialysis-equivalent dialysis treatments	18,106,908.07	18,508,630.93	18,527,730.57	36,659,266.43	37,531,292.14
Medicare Allowable Payments (MAP) per treatment for services in the expanded ESRD PPS					
Total	$245.18	$242.36	$242.50	$242.94	$242.63
Composite rate services	$155.92	$158.73	$158.66	$156.72	$158.99
Separately billable services					
Part B drugs	$78.02	$73.69	$74.28	$75.43	$73.91
Laboratory services	$9.50	$9.54	$9.18	$9.10	$9.25
Dialysis support services	$1.18	$0.02	$0.01	$1.23	$0.02
Dialysis equipment and supplies	$0.53	$0.20	$0.17	$0.50	$0.20
Other dialysis facility services	$1.18	$0.18	$0.21	$1.23	$0.26

*Data for 2009 are based on first 6 months of 2009. MAP for 2007 and 2008 were adjusted to reflect prices for 2009, using estimates of price inflation from Yaminee Thaker (1/12/10). The estimates exclude patient facility months with no hemodialysis-equivalent treatments. The monthly hemodialysis-equivalent treatments were capped at the number of days in the month (e.g., 31 for January). All analyses weighted by treatments. Payments for erythropoietin (EPO) and darbepoetin were capped to reflect the medically unbelievable edit threshold that applied at the time (500,000 and 400,000 units of EPO per month in 2007 and 2008-2009, respectively, and 1,500 and 1,200 mcg of darbepoetin per month in 2007 and 2008-2009, respectively).

The preliminary estimates in this table include payments for certain Part B drugs and other services billed separately by dialysis facilities that CMS plans to exclude from the expanded bundle, notably blood and blood products, immunosuppressive drugs, drugs that were covered under the composite rate system, and other less commonly used Part B drugs that will remain outside the payment bundle. Together, we expect the total MAP for these drugs and other services which will be excluded from the final calculations to account for well under $1.00 per treatment in each year from 2007 to 2009.
These are based on a treatment weighted approach, which involves calculating the average MAP per treatment among all patients, while weighting by the number of hemodialysis-equivalent treatments for each patient. These results are provided for comparison to the patient weighted approach.

When limiting comparisons to the first 6 months of the year, there is a slightly lower average MAP per treatment in January-June 2008 ($242.36) than in Jan-June 2009 ($242.50), while the highest average MAP per treatment again occurs in January-June 2007 ($245.18).
When comparing results for the first 6 months of 2009 with the full years for 2007 and 2008, the average MAP per treatment is within $0.50 for all 3 years, but again is lowest in 2009 as we found with the patient weighted approach.

E. PART B DRUGS

In July 2009, UM-KECC presented a summary analysis of Medicare Allowable Payments (MAP) for separately billable drugs for calendar year 2007 to CMS. Table 3.4 lists total MAP and average per session MAP for 17 drugs identified in Part B and Part D Medicare claims files, including erythropoiesis-stimulating agents (ESAs), oral and parenteral vitamin D analogs, parenteral iron, levocarnitine, alteplase, vancomycin, daptomycin, cinacalcet, and oral phosphorus binders. Total separately billable drug spending for these drugs was $3.15 billion. Of the total, $2.7 billion was accounted for from Part B injectable medications, with ESAs and vitamin D analogs accounting for the majority of Part B payments. Oral ESRD- related drugs (Part D) accounted for nearly $456 million in payments in 2007. Over two-thirds of that total was accounted for by payments for cinacalcet and sevelamer, two medications used in the treatment of ESRD related bone and mineral disease. In December 2009, UM-KECC provided CMS a list of SB medications and total MAP from type 72x claims for CY 2008. CMS decided to remove vaccines, immuno-suppressants, and miscellaneous procedure charges used to calculate the SB base rate.

Table 3.4 Medicare Allowable Payments (MAP) for separately billable drugs, 2007

Drugs and biologicals[3]	Total MAP for2007[1]			Average MAP/session for 2007[1,2]		
	Injectable medications (Part B)	Oral medications (PartD)	Total (Part B and Part D)	Injectable medications (Part B)	Oral medications (Part D)	Total (Part B and Part D)
ESAs						
Epogen[4]	$1,846,771,009	--	$1,846,771,009	$50.56	--	$50.56
Darbepoetin	$167,776,951	--	$167,776,951	$4.59	--	$4.59
VitaminD						
Calcitriol	$3,116,590	$2,487,301	$5,603,891	$0.09	$0.07	$0.15
Doxercalciferol	$76,770,839	$4,763,273	$81,534,112	$2.10	$0.13	$2.23
Paricalcitol	$322,559,988	$2,802,120	$325,362,108	$8.83	$0.08	$8.91
Iron						
Iron Sucrose	$165,992,904	--	$165,992,904	$4.54	--	$4.54
NA Ferric Gluconate	$68,038,379	--	$68,038,379	$1.86	--	$1.86
Levocarnitine	$5,025,914	--	$5,025,914	$0.14	--	$0.14
Alteplase	$26,682,197	--	$26,682,197	$0.73	--	$0.73
Vancomycin	$3,578,996	--	$3,578,996	$0.10	--	$0.10
Daptomycin	$1,234,405	--	$1,234,405	$0.03	--	$0.03
Calcimimetic						
Cinacalcet	--	$167,426,186	$167,426,186	--	$4.58	$4.58
Phosphorus Binders						
Calciumacetate	--	$29,018,258	$29,018,258	--	$0.79	$0.79
Lanthanumcarbonate	--	$36,174,822	$36,174,822	--	$0.99	$0.99
Sevelamer	--	$213,011,780	$213,011,780	--	$5.83	$5.83
Other	$7,467,546	--	$7,467,546	$0.20	--	$0.20
Total	$2,695,015,716	$455,683,740	$3,150,699,456	$73.79	$12.48	$86.26

[1] Facilities that were paid through the composite rate system but did not have a valid county code were excluded do to the unavailability of the relevant CBSA wage index, which was needed to calculate projected dialysis payments for 2011. Patients with an unknown birthdate which is needed to calculate the BCMA multiplier were also excluded.
[2] Calculated by dividing the total MAP for each drug category by the total number of Medicare hemodialysis-equivalent sessions (36,523,791).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 (12.5in2007).
[3] Billed by dialysis facilities under Part B or covered under Part D.
[4] Monthly payments for EPO were capped to reflect no more than 30,000 units per session.

In January 2010, UM-KECC provided CMS with an analysis of frequency and magnitude of payment for medically unbelievable threshold erythropoietin (EPO) payments (> 400,000 units/month). In 2008, 0.03 percent of patient facility month claims included payments for EPO that exceeded the medically unbelievable edit threshold of 400,000 units per month. We identified the total payments for EPO occurring above the threshold (i.e., as the MAP for EPO from all claims minus the MAP for 400,000 units of EPO). This yielded a total EPO MAP of approximately $1.92 million above the threshold. This represented the total dollar amount that would be excluded from the base-rate calculation for 2008 because EPO was capped at the threshold.

UM-KECC also presented CMS the 2008 data on dialysis facilities with hemodialysis-equivalent dialysis treatments that exceeded the number of days in the month, dialysis facilities with paid claims and no dialysis treatments, and data on facilities with negative payments by Part B category. Of the 2008 patient facility month claims that had negative payments, 0.08 percent had no dialysis treatments reported. On these claims, the payments to dialysis facilities were for services other than dialysis. In 87.9 percent of these cases, there was no other facility with payments for the same patient in the same month. In the vast majority of these cases, there was not another facility billing for dialysis (or other services and Medicare is not a secondary payer). For the remaining 12.1 percent of cases, there was at least one other facility providing services for the same patient in the same month. Over two-thirds of the payments on these claims were for "other Part B drugs" that were not among the top 11 injectable drugs billed by dialysis facilities. This amount may include services such as immunosuppressive drugs, which were excluded from the bundle definition. It was determined that up to $2.7 million in MAP for services in the expanded ESRD PPS would be excluded when limiting the base-rate calculation to patient facility month claims with dialysis treatments> 0. This amount may be lower depending on the magnitude of the payments for services excluded from the bundle definition.

As a result of the analyses presented above, in January 2010, CMS instructed UM-KECC to:

1. Cap EPO payments in the claims at 400,000 units per month and exclude claims for over that amount.
2. Cap the monthly dialysis treatments reported in the claims at the number of days in each month, and exclude those over that number in the base-rate calculation.
3. Exclude claims for months with no dialysis treatments.
4. Include negative payment amounts in the claims.

Appendix A, Table A.1 list all items billed under drug revenue center which may or may not be appropriately or correctly billed. In Appendix A, Table A.1, those items categorized as "unclassified" are considered "other drugs and services" and were not addressed for analysis by UM-KECC and include a variety of non-ESRD items billed on a type 72x claim under revenue center codes: 0250, 0251, 0252, 0254, 0255, 0258, 0259, 0260, 0261, 0269, 0630, 0634, 0635, 0636. Finally, we also explored the use of AY modifiers on Part B drug claims, indicating that the drug was given for a non-dialysis-related indication, for both facilities participating in the PPS transition as well as those opting out of the transition payment plan. These results may be found in Appendix A, Table A.2.

F. PART D DRUGS

The Medicare Improvements for Patients and Providers Act (MIPPA) called for ESRD-only oral drugs that were equivalent to parenteral drugs included in the expanded PPS to also be included in the bundle. UM-

KECC had been performing analyses on Medicare Part D data since 2009 to help inform CMS implementation decisions regarding this MIPPA requirement.

Initial discussions between UM-KECC clinicians and CMS to explore categories of oral drugs that might be suitable for inclusion in the expanded bundle occurred prior to publication of the 2011 NPRM. As a result of those initial discussions, UM-KECC was instructed to focus on the treatment categories of anemia management and bone and mineral disease, given the historical predominance of parenteral separately billed medication usage for these clinical indications (i.e., ESAs and parenteral vitamin D analogs) in chronic dialysis patients.

There are no prescription oral medication equivalents for ESAs or parenteral iron. Over-the-counter oral iron has been available for some time although its therapeutic equivalence to parenteral iron in this clinical setting has been questioned. As with any Over-the-counter medication, utilization and spending information is unavailable in the Medicare claims system, so it is not possible to determine spending levels. The possibility that oral androgens might be used to stimulate erythropoiesis as a partial replacement for ESAs was considered.

Several categories of oral prescription medication that could be used by providers in the treatment of bone/mineral disease in ESRD dialysis patients were identified, including oral vitamin D analogs, a calcimimetic (cinacalcet), and oral phosphorus binders (calcium carbonate, calcium acetate, lanthanum carbonate, sevelamer hydrochloride, and sevelamer carbonate). In 2009, UM-KECC performed analyses using 2007 Medicare Part D data to define the frequency of use and payment amounts for these drugs in ESRD dialysis patients subscribing to Medicare Part D prescription plans. These findings are summarized Figure 1 below.

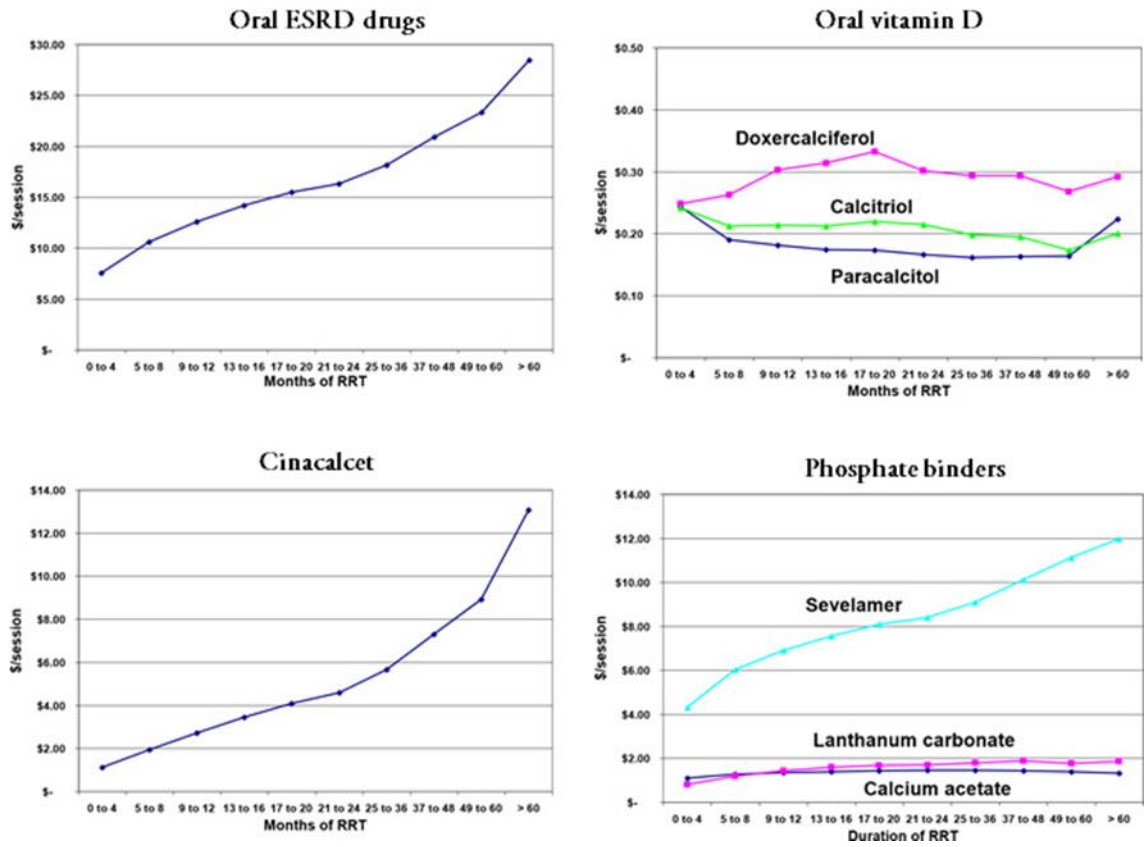
Total spending for all Part D drugs was $1.957 billion in 2007, with beneficiaries being responsible for 39.2 percent of the total cost. The total for drugs that would eventually be considered part of the bundle was $534 million, with beneficiaries being responsible for 38.5 percent. Sevelamer was the most expensive single agent. Therefore, bundling these drugs would reduce the patient's obligation (relative to historical Part D coverage norms) and might improve drug adherence. It should be noted that as the Part D "donut hole" is phased out, the extent of the difference between the percentage of cost for which the patient is responsible and the standard 20 percent Part B copay will diminish (Figure 3.1).

Note that Part D bundled drugs are counted if the patient was included in the model used to estimate the case-mix model adjustment multipliers at any point during 2007. To the extent that patients received bundled drugs in months when they were not in the case-mix model (e.g., 2007 incident patients who were already

Medicare eligible and incurring drug costs before they started dialysis, or post-transplant for patients transplanted during the year), the cost per facility/month or cost per session might be slightly different. Because prescriptions may span several months (e.g., 90 day fills), it is impossible to precisely track Part D bundled drugs relative to the time period on dialysis.

Additional analyses informing the cost per treatment that ESRD-related Part D drugs would contribute to the base rate were presented to CMS in January 2010. These analyses presented information about the costs of individual Part D medications, using several variations in methodology to define the cost contribution of Part D ESRD related medications. These analyses also provided updates for 2008 and 2009 (partial year data through November) Part D ESRD drug spending, to allow trend analysis for overall spending, as well as specific drug category spending from 2007 through 2009.

Figure 3.1 ESRD Part D spending by month of renal replacement therapy



- Time on dialysis is associated with a substantial increase in spending on oral ESRD drugs covered under Part D.
- This pattern largely reflects the increasing use of cinacalcet and sevelamer.
- This pattern is not observed with the oral vitamin D analogs.

G. MODELING PART D SPENDING

Initial options for developing a Part D Model and combining Part D costs in the expanded ESRD PPS models were presented to CMS in August 2009. Key issues considered in the analysis were the technical nature of the model (e.g., estimate a separate Part D equation versus combining Part B and D into a single equation) and how to handle non-Part D enrollees.

In September and October 2009, additional analyses, including predictive models of Part D costs were presented to CMS. Tables 3.5, 3.6, 3.7, and 3.8 describe patterns of Part D use across calendar quarters, the characteristics of Part D enrollees with and without the low income subsidy (LIS), and alternative models in terms of how LIS status is accounted for (models using all Part D enrollees, with and without a control variable indicating LIS status, and models that are estimated separately for LIS and non-LIS recipients). In

December 2009, CMS was provided with a preliminary three-equation model (composite rate, separately billable and Part D) predicting cost by utilizing the most current two-equation model available at that time and including a model of Part D costs based on one year of Part D data (2007).

The 2009 NPRM for the expanded PPS and the 2010 Final Rule describe results of this work and CMS' final decision regarding inclusion in the revised payment system. In 2011, oral equivalents of parenteral vitamin D medications were included in the expanded ESRD payment system. Other bone/mineral metabolism drugs (calcimimetics and oral phosphorus binders) were defined as ESRD drugs, but implementation was deferred until 2014 as described in the 2010 Final Rule. This information is detailed in Table 3.9 (Calculation of payment multipliers using a three-equation model, ages 18 and older). Further analyses for these drugs became moot as Congress passed the legislation, Protecting Access to Medicare Act of 2014 (H.R. 4302; Pub.L. 113–93) and delayed until 2024 implementation of inclusion of Part D oral medications.

Conclusion

A key decision in any bundled payment system is the scope of included services. As described in the 2011 Final Rule, in addition to the dialysis treatment itself, the expanded ESRD PPS included dialysis-related laboratory tests, a set of injectable medications (most prominently, ESAs, iron, and Vitamin D analogs) as well as a limited set of oral medications previously covered under Part D that were equivalents of bundled injectable medications. A limited set of supplies and durable medical equipment that had previously been billed separately from the dialysis treatment were also included, but spending for those supplies had already become negligible by 2008. CMS decided to exclude blood products from the bundle, and vascular access procedures (placements and revisions) were not extensively analyzed or considered for inclusion in the 2011 bundle definition. For both blood products and vascular access procedures, the number of providers outside the dialysis facilities and the number of settings (multiple outpatient and inpatient locations) where such services could be provided present both analytic and operational challenges. The ESRD PPS also included add-on payments for home dialysis training; these are described in detail in section VII. of this report.

Table 3.5 Patterns in Part D spending across patient quarters, ages 18+ (2007)*

Quarters with Part D costs >0	Patients	
	n	%
All 4 quarters	134,314	61.9
Early part of the year		
Q1 only	13,328	6.1
Q1,Q2	11,172	5.2
Q1, Q2,Q3	11,094	5.1
Subtotal	35,594	16.4
Middle quarters		
Q2 only	1,703	0.8
Q3 only	1,769	0.8
Q2, Q3only	1,688	0.8
Subtotal	5,160	2.4
Latter part of the year		
Q2, Q3,Q4	12,520	5.8
Q3,Q4	12,729	5.9
Q4 only	12,231	5.6
Subtotal	37,480	17.3
One or two "skipped" quarters indicating a gap in spending during the middle of the year		
Q1, Q3,Q4	1,645	0.8
Q1, Q2,Q4	1,630	0.8
Q1,Q4	437	0.2
Q1,Q3	389	0.2
Q2,Q4	379	0.2
Subtotal	4,480	2.1
Total	217,028	100.0

*Includes Medicare dialysis patients with annual Part D costs >0. Excludes patients with missing data for patient and facility variables used in models of Part D costs.
-In defining the patient sample for analysis of Part D costs, patient quarters with no spending on Part D drugs, which may indicate that patients were not enrolled in Part D, were excluded.
-Most patients had Part D spending in all 4 quarters (62%). The remaining 38% of patients had spending in 1 to 3 quarters. This includes 2 % who had a gap in spending during the middle of the year that lasted for at least one quarter.

Table 3.6 Patient and facility variables, ages 18+ (2007)*

Variable	Total	Low income subsidy(LIS)**	
		Yes	No
Patients(n)	217,028	166,384	50,644
Average Part D drug cost per session	$18.57	$20.78	$10.66
Facility characteristics			
Facility size***	0.7%	0.6%	0.9%
Low volume(<3,000 and not open or closed 2005-07)	1.9%	1.9%	2.0%
<3,000 not low volume	5.3%	5.0%	6.3%
3,000-4,999	24.1%	23.4%	26.6%
5,000-9,999	68.0%	69.1%	64.1%
10,000+			
Ownership	64.5%	64.6%	64.1%
Large dialysis	15.6%	15.6%	16.0%
Regional chain	19.0%	19.0%	18.8%
Independent Unknown	0.9%	0.9%	1.1%
Rural	18.1%	17.9%	19.0%
Hospital based	10.5%	10.1%	12.1%
Exception for composite rate	7.3%	7.3%	7.2%
URR <65%	7.9%	8.0%	7.7%
Patient characteristics Low income subsidy(LIS) Age (years)			
18-44	78.2%	100.0%	0.0%
45-59			
60-69	16.1%	19.5%	4.2%
70-79	29.4%	33.1%	16.2%
80+	23.8%	22.9%	26.8%
Female	20.4%	17.1%	32.0%
Race (Form 2728)	10.4%	7.5%	20.7%
American Indian / Alaskan Native	49.2%	51.1%	42.1%
Asian/Pacific Islander			
Black	1.5%	1.8%	0.6%
White	4.2%	4.6%	2.9%
Other	40.9%	45.7%	23.5%
Unknown	51.5%	45.8%	71.8%
	1.1%	1.2%	0.7%
Ethnicity	0.8%	0.9%	0.5%
Hispanic	15.4%	17.8%	6.6%
Not Hispanic	81.3%	78.5%	91.3%
Unknown	3.3%	3.7%	2.1%
Average body surface area(per0.1m2)	1.86	1.86	1.88
Underweight (BMI<18.5)	4.1%	4.2%	3.9%
Duration of RRT: <4months	4.4%	3.7%	7.0%
Alcohol/drug dependence(claims since2000 or 2728)	11.2%	12.4%	6.9%
Cardiac arrest (claims since 2000 or 2728)	3.7%	3.8%	3.3%
Pericarditis from same month to three months ago	0.4%	0.4%	0.3%
HIV/AIDS (claims since 2000 or 2728)	3.1%	3.6%	1.1%
Hepatitis B (claims since 2000Specified infection 0-3 months)	3.1%	3.5%	1.9%
Septicemia	10.6%	11.1%	8.5%
Bacterial pneumonia and other pneumonias/opportunistic	2.6%	2.6%	2.4%
infections	1.1%	1.1%	1.3%
Intestinal tract bleed (0-3 months)	2.4%	2.5%	2.0%
Hereditary hemolyticor sickle cell anemias (claims since2000)	19.9%	17.8%	27.2%
Cancer (claims since2000;excludes non-melanoma skin cancer)	1.1%	0.9%	1.9%
Myelodysplastic syndrome (claims since 2000)			
Monoclonal gammopathy (claims since2000)	1.5%	1.3%	2.5%

*Includes Medicare dialysis patients with annual Part D costs >0. Excludes patients with missing data for patient and facility variables used in models of Part D costs.
**Includes patients with the LIS at any time during the year.
***Based on data reported in SIMS.
- Among patients with at least one quarter of Part D spending, the average cost was $18.57 per dialysis session. Part D costs were nearly twice as high for those with the low income subsidy (LIS). Patients with the LIS were more likely to be younger, female, and a racial or ethnic minority.

Table 3.7 Patient-level models of Part D drug costs per session, ages 18+ (2007)

Variable	Model 1: No control for low income subsidy (LIS)	Model 2: Include control for LIS status	Model 3: Patients with LIS status	Model 4: Patients without LIS
	n=217,028R^2:5.4%	n=217,028 R^2:7.2%	n=166,384 R^2:5.0%	n=50,644R R^2:2.0%
Facility characteristics				
Facility size				
Low volume (<3,000 and neither opened nor closed during2005-07)	0.831 0.0263	0.916 0.2844	0.996 0.9623	0.694 0.0279
<3,000 and not low volume3,000-4,999	0.905 0.0436	0.918 0.0801	0.877 0.0148	1.061 0.6050
5,000-9,999	0.903 0.0005	0.955 0.1090	0.928 0.0214	0.996 0.9514
10,000+	0.887 <.0001	0.922 <.0001	0.908 <.0001	0.957 0.2088
Ownership	1.000 ref	1.000 ref	1.000 ref	1.000 ref
Large Dialysis Organization	1.290 <.0001	1.330 <.0001	1.291 <.0001	1.482 <.0001
Regional Chain	0.960 0.0614	0.985 0.4852	0.963 0.1109	1.067 0.1997
Independent	1.000 ref	1.000 ref	1.000 ref	1.000 ref
Rural	1.117 0.1359	1.184 0.0212	1.278 0.0032	0.969 0.8371
Unknown	0.832 <.0001	0.817 <.0001	0.812 <.0001	0.840 <.0001
Hospital Based	0.821 <.0001	0.866 <.0001	0.829 <.0001	0.983 0.7460
Exception for composite Rate	0.884 <.0001	0.901 <.0001	0.901 <.0001	0.905 0.0748
URR < 65%	1.003 0.7199	1.003 0.7551	0.997 0.7891	1.017 0.3747
Patient characteristics				
Low income subsidy	-- --	2.591 <.0001	-- --	-- --
Age (years)				
18-44	1.197 <.0001	1.130 <.0001	1.141 <.0001	0.657 <.0001
45-59	1.000 ref	1.000 ref	1.000 ref	1.000 ref
60-69	0.674 <.0001	0.764 <.0001	0.742 <.0001	0.989 0.8010
70-79	0.454 <.0001	0.565 <.0001	0.517 <.0001	0.827 <.0001
80+	0.275 <.0001	0.377 <.0001	0.311 <.0001	0.604 <.0001
Female	1.389 <.0001	1.285 <.0001	1.237 <.0001	1.547 <.0001
Average body surface area (per0.1m2)	1.055 <.0001	1.065 <.0001	1.065 <.0001	1.079 <.0001
Underweight (BMI<18.5)	0.737 <.0001	0.751 <.0001	0.726 <.0001	-- n.s.
Duration of RRT: <4months	0.212 <.0001	0.235 <.0001	0.168 <.0001	0.408 <.0001
Cardiac arrest (claims since 2000 or2728)	1.077 0.0178	-- n.s.	-- n.s.	-- n.s.
Pericarditis from same month to three months ago	1.375 0.0175	1.406 0.0103	1.417 0.0146	-- n.s.
Hepatitis B (claims since2000)	1.262 <.0001	1.205 <.0001	1.194 <.0001	1.268 0.0170
Septicemia from same month to three months ago	0.666 <.0001	0.617 <.0001	0.610 <.0001	0.684 <.0001
Bacterial pneumonia and other pneumonias/opportunistic				
infections from same month to three months ago	0.728 <.0001	0.703 <.0001	0.683 <.0001	-- n.s.
Cancer (claims since 2000; excludes non-melanoma skin				
cancer)	1.081 <.0001	1.123 <.0001	1.123 <.0001	1.095 0.0035
Myelodysplastic syndrome (claims since2000)	0.882 0.0234	-- n.s.	-- n.s.	-- n.s.
Alcohol/drug dependence (claims since 2000 or2728)	-- n.s.	0.931 0.0001	0.950 0.0090	0.771 <.0001
HIV/AIDS (claims since 2000 or2728)	-- n.s.	-- n.s.	0.932 0.0426	-- n.s.

*Includes Medicare dialysis patients with annual Part D costs>0.

-Model 1 explained 5.4% of the variation in costs for Part D drugs. Costs were higher for LDOs and lower for facilities that were hospital based or rural. Patient characteristics associated with higher Part D costs included younger age female, larger BSA, and several comorbidities. There were lower costs in the first 4 months of RRT and in patients who were underweight or with either of two major types of infections.
- Based on Model2, costs were more than twice as high for patients with the low income subsidy. When including an adjustment for LIS status, most patient multipliers changed by less than 5%.The main exceptions are the age multipliers, which moved closer to1.00 and included changes of approximately 10%.
-Separate models by LIS status indicate that the patient and facility variables explained more of the variation in cost among patients with the LIS (5% vs. 2%).There were larger cost differences by patient age and duration of RRT and smaller cost differences by gender among patients with the LIS.

Table 3.8 Sample size for composite rate and separately billable analyses, ages 18 and older, 2004-06

	Includes facilities with no URR values on Medicare outpatient dialysis claims	
	No[1]	**Yes[2]**
CR analyses		
Facilities		
Low-Volume	4,250	4,314
Other	89	100
Facility years	4,161	4,214
SB Analyses	890,776	894,041
Patient years Patients	452,850	454,200

[1]Corresponds to the analyses used for the Proposed Rule.

[2]For facilities with no URR value, the overall mean URR in that year was used. When including facilities with no URR values, there were 64 additional facilities included in the CR analyses, as the facility count increased from 4,250 to 4,314. This includes 11 additional low volume facilities and 53 other facilities.
-Several of the 25 facilities that were classified using SIMS data as low volume facilities during 2005-07 with a high concentration (>50%) of home dialysis patients continued to be excluded from the cost analyses, for a combination of reasons. These reasons include having extremely high CR costs for 1 or more year from 2004-06, having at least 3,000 treatments during 2004, or having at least 3,000 treatments in the cost reports for 2005 or 2006 (in contrast to the <3,000 treatments that was estimated using SIMS data for2005/2006).

Table 3.9 Calculation of payment multipliers using a three-equation model, ages 18 and older

	CR model ,200406 n=11,814 R^2:46.0%	SB model ,2004-06 n=890,776 R^2:8.7%	Part D model, 2007 n=217,028 R^2:6.7%	Modeled case-mixadjustment	
				3-equation model	2-equation model (Proposed Rule)
Variable	**$PmtMult_{CR}$**	**$PmtMult_{SB}$**	**$PmtMult_{D}$**	**$PmtMult_{EB}$**	**$PmtMult_{EB}$**
Adjustments for dialysis patient characteristics					
Age (years)					
18-44	1.280	1.018	1.159	1.192	1.194
45-59	1.000	1.000	1.000	1.000	1.000
60-69	1.014	1.006	0.699	0.990	1.012
70-79	1.105	0.960	0.483	1.018	1.057
80+	1.150	0.923	0.305	1.023	1.076
Female	1.124	1.149	1.404	1.151	1.132
Body surface area (per $0.1m^2$)	1.035	1.033	1.067	1.036	1.034
Underweight (BMI<18.5)	1.000	1.060	0.718	0.999	1.020
Time since onset of renal dialysis					
<4months	1.508	1.401	1.000	1.440	1.473
4-11months	1.000	1.000	1.000	1.000	1.000
1 to 2years	1.000	1.000	1.717	1.049	1.000
2 to 3years	1.000	1.000	1.969	1.066	1.000
3 to 4years	1.000	1.000	2.258	1.086	1.000
4 to 5years	1.000	1.000	2.857	1.127	1.000
5 or more years	1.000	1.000	3.271	1.156	1.000
Alcohol/drug dependence (claims since 2000 or2728)	1.155	1.139	0.945	1.136	1.150
Cardiac arrest (claims since 2000 or2728)	1.000	1.098	1.000	1.030	1.032
Pericarditis from same month to three month sago	1.000	1.595	1.375	1.207	1.195
HIV/AIDS (claims since 2000 or 2728)	1.363	1.220	1.000	1.294	1.316
Hepatitis B (claims since 2000)	1.115	1.035	1.167	1.094	1.089
Specified infection from same month to 3 months ago					
Septicemia	1.000	1.715	0.693	1.197	1.234
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	1.412	0.685	1.264	1.307
Gastro-intestinal tract bleeding from same month to 3months ago	1.000	1.965	1.000	1.294	1.316
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	1.179	1.000	1.210	1.226
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	1.097	1.000	1.119	1.128
Myelodysplastic syndrome (claims since 2000)	1.000	1.257	1.000	1.078	1.084
Monoclonal gammopathy (claims since 2000)	1.000	1.063	1.000	1.019	1.021
Low volume facility adjustment					
Facility size < 3,000 treatments during each year from 2004-06	1.383	0.940	0.735	1.171	1.202

^The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB}=Weight_{CR}\times PmtMult_{CR}+Weight_{SB}\times PmtMult_{SB}+Weight_{D}\times PmtMult_{D}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs, $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable costs, and $PmtMult_{D}$ is the estimated multiplier from a patient level model of Part D spending.

- The above table illustrates how the payment adjustments in an expanded PPS can be determined using a three-equation model for CR,SB, and Part D services. The estimates from the Part D model are based on n=217,028 patients enrolled in Part D. It should be noted that the PartD model is currently based on just one year of data (2007).

IV. PATIENT-LEVEL (CASE-MIX) ADJUSTMENTS

A. SUMMARY OF ANALYSES SUPPORTING THE 2008 REPORT TO CONGRESS

The Medicare Prescription Drug and Modernization Act of 2003 (MMA 2003) (1) required both the development and implementation of a basic case-mix adjustment for the composite rate payment system for outpatient dialysis and the design and demonstration of a fully case-mix adjusted bundled ESRD payment system. The Centers for Medicare & Medicaid Services (CMS) contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to examine potential case-mix adjustments for composite rate payments that consist of a "limited number of patient characteristics" in accordance with the MMA 2003. A methodology to apply a basic case-mix adjustment (BCMA) to composite rate payments was developed, and was implemented on April 1, 2005 (2). The BCMA includes adjustments for age (five age categories), body size, and patient frailty (as measured by low body mass index). The research supporting these adjustments is fully described in Reference 3 in the UM-KECC report *Understanding the Basic Case-Mix Adjustment for the Composite Rate* (Wheeler, 2006) and in the 2005 CMS Final Rule. This research is also reported and discussed in Hirth et al. (JASN 2005) and Wheeler et al. (AJKD 2006).

In addition to the short term basic case-mix adjustment to the existing bundle of composite rate services implemented in 2005, MMA 2003 required a Report to Congress that delineated the elements and features for the design and implementation of a fully bundled ESRD and case-mix adjusted prospective payment system (PPS). The Centers for Medicare & Medicaid Services February 2008 Report to Congress, based on research by UM-KECC, reviewed in detail the design and specifications for an expanded prospective payment system (PPS) for end-stage renal disease (ESRD).

In considering an expanded set of patient characteristics for risk adjustment, UM-KECC held the view that good payment systems will have concordance between the cost of efficiently providing care and the reimbursement given for that care, for various types of patients. For example, a payment that is too low for a particular type of patient introduces a disincentive to provide appropriate care to that type of patient. Even when the average payment is set correctly for a broad class of patients, heterogeneity within that group introduces risk to providers who might face different mixes of patients within that broad subgroup. Since case-mix adjustment is one tool that can reduce the financial risk to providers of medical care, we use the terms risk-adjustment and case-mix adjustment interchangeably.

Two major approaches have been used to account for the financial risk assumed by health care providers who must provide care to a variety of types of patients in a prospective payment system: case-mix adjustment and

provision for outliers: (1) Case-mix adjustment accounts for predictable differences in the average cost of providing care to various types of patients, and (2) Special reimbursement for outlier, or exceptional, costs that are not predictable on the basis of patient characteristics are used to account for unpredictable variation in the cost of providing appropriate care to members of a heterogeneous patient population.

A case-mix adjustment for ESRD costs can be based on identification of subgroups of patients who, on average, require different levels of expenditures in order to provide appropriate care. The definition of these patient subgroups should be based on objective, consistently measured, and universally reported characteristics. The characteristics used for case-mix adjustment should allow prospective classification of high- and low-cost patient groups. Therefore, current measures of resource use are typically not used as case-mix adjusters since they do not identify high-cost patients until after the costs have been incurred. In contrast, actual levels of resource use are typically used to identify outliers. The identification of patient subgroups with different costs can be based upon several types of patient characteristics.

- Patient characteristics that do not change or which are entirely predictable, such as gender and age
- Medical condition, as indicated by diagnosis codes (e.g. diabetes) which can change over time
- Functional status, which can change over time
- Historical levels of resource utilization levels of pharmaceuticals required to achieve targeted outcome goals (e.g, erythropoietin (EPO) resistance based upon prior treatment experience).
- Use of specific resources (e.g., recent hospitalization intensity) or drugs indicative of special needs (insulin, cancer drugs, or cardiac drugs).

The literature on patient severity or risk-adjustment methodology, as applied to health care generally, is extensive. Risk adjustment has been used to account for differences in patient outcomes and differences in costs for different patient groups. Many of the methods used to develop risk adjustors for outcomes and costs are similar. However, it is important to recognize that the factors used to adjust patient outcomes are likely to differ from those used to adjust costs. Here, we focus on risk adjustors for costs. The risk adjustment literature has been developed to serve several purposes, including the conduct of health services research, the development of appropriate health care policy, and the support of efficient health care management.

In both health services research and policy development, risk adjusters are used in comparative analyses of the production costs of different health care provider organizations to answer the question "How different would the costs have been, if patient mix had been the same for the various providers?" For example, most comparisons of the cost and utilization associated with managed care and fee-for-service systems require that some measure of patient severity be accounted for so as to eliminate the possibility that differences in patient

condition account for differences in observed utilization patterns. Such comparative analyses are characterized as being "adjusted," or "controlled" for patient mix.

A closely related use of patient severity measures is in the conduct of research on the determinants of health care use and costs. Failure to account for patient severity might lead to incorrect conclusions regarding the influence of factors such as price or income on health care use.

Researchers, policy makers, and managers who wish to determine fair compensation for health plans and managed care organizations employ measures of the relative health care expenditure risks presented by people who join specific health plans, compared to those who join other plans. A related concern is that failure to provide fair compensation to providers could result in explicit or implicit discrimination against patients who are predictably more costly to care for than the average patient (Kronick et al., 2000; Rogal and Gauthier, 1998; Newhouse, 1998; Kronick and Dreyfus, 1997). The objective is to have a measure of risk that predicts future health care use and costs.

1. Characteristics of effective case-mix adjusters

The aim is to identify a measure or set of measures of patient severity or relative risk that assures fair compensation to providers of dialysis services and consequently assures patients' access to care independent of the existence of high-cost comorbidities or other pre-existing conditions. For these purposes, the literature suggests that successful risk-adjusters have several desirable characteristics.

First, risk adjustors should be predictive of differences in costs. Predictive accuracy is typically measured by the fraction of the variation in costs that is explained by the prediction R^2. When patient-specific data are available, case-mix models are usually developed to predict differences in costs among individual patients. If changes in patient condition are to be accounted for, then high predictive accuracy for costs during for each interval of time is also a desirable feature of a case-mix adjustor. However, for the purposes of evaluating the risk to providers, the accuracy of predicting the cost for each provider gives a more relevant calibration. Both the R^2 for variation among patients and the R^2 for variation among providers are useful indices of predictive accuracy for case-mix adjustors.

Second, case-mix adjustors should be feasible to administer. This means that the necessary data are available at an appropriate level of detail with modest data-collection efforts. When data are derived from different data collection streams, the payer must be able to easily link each bill to the data needed for case-mix adjustment.

Third, successful risk-adjusters should be resistant to manipulation. Those health care organizations subject to the risk-adjustment methodology should not find it easy to increase revenues by altering the character of the

data they furnish to the payer. Ambiguous and poorly defined measures of case-mix should be avoided. Consistent and meaningful descriptors of the data elements are important in achieving this goal. The use of measures that are objective, rather than being discretionary or subjective, is also important.

Fourth, risk-adjusters should respect patient confidentiality (Anderson and Bilenker, 1998). It is essential, especially in light of the privacy requirements established in response to the Health Insurance Portability and Accountability Act (HIPAA), to maintain patient records so as to protect confidentiality. Finally, successful risk-adjusters provide incentives for efficiency. They can do so by ensuring that the risk-adjustment built into compensation systems provides compensation at a level sufficient to ensure high-quality care appropriate to the needs of the patient population served.

2. Specific types of case-mix adjusters

The literature describes risk-adjusters based on at least five sets of information: demographic characteristics, clinical characteristics, functional health status, prior use or expenditures, and use of a particular drug or other key service. The advantages and disadvantages of each of these are briefly discussed in turn. For additional discussion of these issues, see Epstein and Cumella (1988) and Ellis et al. (1996).

Risk-adjusters based on the demographic characteristics of patients or members are commonly used. Characteristics employed typically include age and sex. Sometimes race, location of residence or receipt of service, and economic characteristics of the patient are also included. Risk-adjusters based on demographic characteristics are easy to administer and very difficult to manipulate. However, they don't distinguish high- and low-cost enrollees within demographic strata. In addition, they have low accuracy in terms or predicting future health care use or expenditures.

Risk-adjusters based on reported functional health status are less frequently used. These measures require that patients or staff complete questionnaires describing patient health and how it influences their ability to participate in daily activities. The emphasis is on functional consequences of illness, which are expected to predict future use of health care services. These measures generally result in more accurate predictions than do demographic factors alone. However, they are much more subject to manipulation than other measures. Further, they can be costly to administer.

Risk-adjusters based on the patient's prior use or expenditures generally have higher predictive accuracy. With these measures, there is little or no information on the causes of prior use, nor is there information on the appropriateness of past use. Such adjusters are relatively easy to administer, and they are fairly difficult to manipulate at any point in time. However, if the provider can influence current utilization in a way that increases future case-mix adjustments, manipulation can become an issue. Hence, measures should be chosen

either to reflect a baseline utilization rate prior to contact with the provider or to reflect utilization outside the direct influence of the provider.

Risk-adjusters based on clinical descriptors or patient diagnoses are very common in payment systems, most notably the Medicare Prospective Payment System. These systems typically place patients into categories based on diagnostic similarities. They are more costly and difficult to administer, and they are subject to some manipulation.

Risk-adjusters based on the use of specific drugs or key health services are rare. One example is Pharmacy Cost Groups, wherein prior drug use is the basis of the risk-adjuster (Lamers, 1999). Use of drugs can be a particularly useful indicator of chronic conditions and related health care use.

Given the potential importance of risk-adjustment to the establishment of appropriate incentives and the fair compensation of providers, two important points about risk need to be stressed in our review of the opportunities for risk-adjustment for dialysis payment. First, effective risk-adjusters can be difficult and costly to implement. Second, even the best classification systems are of limited effectiveness in explaining variation in patient costs (Newhouse, 1998).

3. Case-mix adjustment and dialysis-related care

Several large studies of the impact of patient case-mix on cost and on patient outcomes are based primarily upon a few patient-level data sources: the Medicare data system, corporate data systems such as those of large multi-unit dialysis providers, and multi-institutional studies sponsored by the National Institutes of Health (NIH). Others have been based on aggregate cost data from the cost reports merged with data from patient-specific sources of case-mix. Several potentially informative studies have not been published but have been presented at national meetings.

A thorough literature search of relevant databases for research related to case-mix adjustments for renal dialysis costs was carried out, including both unpublished work and work in progress and abstracts presented at the 2000-2001 annual meetings of the American Society of Nephrology. A variety of case-mix measures, including patient demographics, direct measures of comorbidity, functional status, and measures based on resource utilization (such as hospitalizations in the prior year) were considered within the scope of this review. We present a brief overview of the results below.

This review is limited to studies with a wide scope (many providers) that were based upon widely available data. Case studies based on data from specific dialysis providers are unlikely to yield generalizable results and were not included in this review. Non-quantitative evaluations, based on opinions regarding the relative costs of providing services to different kinds of patients were also excluded from this review. This review considers

three groups of studies: (1) Studies of the relationship between case-mix and outpatient dialysis costs; (2) Studies of the relationship between case-mix and all costs (including non-dialysis and in-patient costs) of caring for dialysis patients; (3) Studies of patient outcomes and patient mix for ESRD patients.

B. THE RELATIONSHIP BETWEEN CASE-MIX AND DIALYSIS COSTS

A paucity of studies specific to dialysis costs reflects the difficulty in using billing data for generating estimates of cost. For current composite rate services, billing data reflect only payments, and not the costs incurred by facilities. Since the current composite rate is not case-mix adjusted, composite rate dialysis payments (or Medicare Allowable Charges) will not reflect any variation by type of patient even if such variation exists. The variability in reimbursement rates is tied to the wage index for each provider, rather than to different levels of services that are provided by different providers. The payments for these services are aggregated into a composite rate per dialysis session and there is currently little accounting of the frequency, or quality, of provision of the specific components of these services, beyond the count of the number of dialysis sessions provided. This reimbursement system makes it difficult to evaluate how either the payment or level of these services relate to patient case-mix.

However, three studies have used Medicare Cost Report data (Dor et al., 1992; Hirth et al., 1999; Hirth et al., 2003), which reflect the resource cost for Medicare Allowable Cost items rather than payments. These studies employ a statistical cost function approach to assess how facility-level costs vary with factors such as facility size (measured as a function of the numbers of treatments of different types provided), facility ownership, and characteristics of the facilities' patients. Although the number of case-mix measures was limited (particularly in the Dor et al. study), both studies found that most of the available adjusters did not have significant impacts on costs. Even less work has been done on the relationship between case-mix and the cost of separately billable items like EPO.

Despite the lack of strong case-mix relationships to cost, the Hirth et al. (1999) study did find that certain practice patterns (as opposed to case-mix per se) affected costs, including average treatment time, time of membrane, and membrane reuse. Similarly, several other studies have examined the effects of practice patterns such as type of dialysis membrane on costs (Orzol et al.) or the effects of competitive practices and payment systems on facility practices such as staffing (Hirth et al., 2000, Held et al., 1987, and Held et al. 1990). While not directly relevant to developing a case-mix adjustment system, these papers suggest that facilities do respond to economic circumstances by altering the way they deliver dialysis. Hence, if case-mix is more closely and predictably tied to costs than the limited literature implied, failure to take these relationships into account may have unintended consequences.

C. THE RELATIONSHIP BETWEEN CASE-MIX AND ALL COSTS OF CARING FOR DIALYSIS PATIENTS

A larger body of literature has examined the relationship between case-mix and all Medicare payments. Cost estimates are often derived from Medicare claims or from institutional data for patients treated at particular centers. Some of these studies have focused on informing rate setting for capitated payment systems at risk for the entirety of medical spending for ESRD patients (Beddhu et al 2000; Lamers 1999; The Lewin Group 2000). Because many of these costs (and much of the variability in costs) are in areas such as inpatient care that will not be bundled into the expanded outpatient ESRD PPS, these studies are not directly relevant to a case-mix adjustment system for the renal PPS. However, they do demonstrate which patient acuity factors are most strongly related to the overall cost of care. Even under the best of circumstances, case-mix adjusters are much better at predicting how average costs vary across subgroups of patients than at predicting which individuals have the highest costs in a particular year. Therefore, it is not surprising that case-mix often explained a relatively small percentage of variation across patients, but a variety of other factors had statistically significant and empirically meaningful relationships to cost (e.g., diabetes, age, race, sex, history of heart disease). However, it is likely that the majority of these extra predicted costs are in areas such as hospitalization that will remain outside a renal PPS.

Issues that have been examined include total costs of care by modality, the time of costs (e.g., higher costs near incidence and prior to death), and geography. A set of papers by Beddhu and colleagues (Beddhu et al 2000) explores the ability of the Charlson Comorbidity Index to explain costs and other outcomes such as mortality. They conclude that this index generally performs well as a predictor of total costs and other outcomes.

Several patient characteristics were evaluated for case-mix adjustment in the expanded PPS model, including patient comorbidities, patient demographics, and patient anthropometrics. Below we discuss each in turn, highlighting the motivation for consideration of measures for risk adjustment and the results of analyses on each.

D. COMORBIDITIES

Background / Rationale

Risk adjustment for patient comorbidities can improve the ability of the ESRD PPS model to reflect measurable aspects of patient severity beyond measures of age, body size, and patient frailty. Improved risk-adjustment removes the substantial financial risk that facilities may otherwise incur when caring for patients who are more likely to have increased costs associated with their renal care. Adequate payment to facilities for caring for patients with comorbidities associated with higher cost can protect access to care for these patients.

As described in earlier work (2008 bundle pg. 51), an extensive number of acute and chronic comorbidities and data sources were evaluated for inclusion in the model. Here, the balance between model parsimony, reasonable measurement requirement for identification of the existence of the comorbidity, and the magnitude of the relationship to cost were sufficiently salient to support inclusion of the condition in the model. Unlike other measures of case-mix adjusters (age, body size), caution was exercised not to create a perverse incentive whereby the condition was a consequence of inadequate care.

Comorbidity Development

In the research conducted for the initial expanded bundle ESRD PPS, the data for measuring patient comorbidities came from two sources: the End-Stage Renal Disease Medical Evidence Report, Medicare Entitlement and/or Patient Registration Form (CMS 2728) and Medicare claims. The claims diagnoses were used both to identify comorbidities that were not abstracted using Form CMS 2728 and to capture changes in patient condition since the start of renal replacement therapy. It should also be noted that claims-based comorbidities are those that appear on any Medicare claim for the ESRD beneficiary. While it may have been preferable to use only comorbidities reported on dialysis claims (type72x), very few dialysis claims indicated any comorbidities prior to the implementation of the Expanded Bundle (EB) PPS.

Comorbidities initially considered using the diagnostic categories developed for the Medicare Advantage managed care program and categories developed for the comorbidities in the CMS 2728 Form. Potential comorbidity measures were defined for the following conditions: specific types of heart disease (cardiac arrest, congestive heart failure, cardiac dysrhythmia, myocardial infarction, ischemic heart disease, and pericarditis), cerebrovascular disease, diabetes, peripheral vascular disease, chronic obstructive pulmonary disease, AIDS, HIV positive status (without AIDS), hepatitis B, other hepatitis, specific types of infections (septicemia, bacterial pneumonias, pneumococcal pneumonias and opportunistic infections), specific types of bleeding conditions (gastro-intestinal tract bleeding and esophogeal varices), specific types of anemias (acquired hemolytic anemias, hereditary hemolytic anemias, and sickle-cell anemia), cancer (excluding non-

melanoma skin cancers, 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), inability to ambulate, inability to transfer, alcohol dependence, drug dependence, tobacco use, gastro-intestinal ulcer, hyperparathyroidism, monoclonal gammopathy, myelofibrosis, and myelodysplastic syndrome.

The very long list of potential comorbidities was refined by reflecting on multiple considerations. Patient comorbidities were considered for inclusion based on the magnitude and statistical significance of relationship to cost, the potential for adverse incentives, and policy imperatives. Where appropriate, the list of potential case-mix variables identified as having statistically significant associations with cost was refined by combining the clinically similar comorbidity categories that have a similar effect on cost. Case-mix measures were reviewed for accuracy and the objectivity of the diagnostic criteria, timely relationship between comorbidity appearance and cost, and the simplicity of the model. Furthermore, each potential case-mix adjuster was examined to ensure not only that its relationship to cost was statistically significant, but also that the magnitude of the relationship was economically meaningful. These analyses allowed for the identification of acute or short-lived cost associations for some case-mix categories and chronic or long-lived cost associations for others.

Table 4.1 below shows the case-mix adjustment model as proposed in Table 8 of the 2008 Report To Congress. This model includes 11 comorbidities based on considerations discussed above. The magnitude of the modeled case-mix adjusters resulted from the statistical analysis of relationships between comorbidities and both composite rate and separately billable services costs.

The relationships between comorbidities and cost for composite rate services were estimated using a facility-level regression model since data are not available. This facility-level model relates average patient characteristics to the reported facility costs. Among the 11 refined comorbidity measures, potential payment variables were identified using a stepwise selection method. The criterion for selecting and retaining comorbidity variables was statistical significance at the $p<0.05$ level.

The three comorbidity measures (alcohol/drug dependence; septicemia; monoclonal gammopathy) for the facility-level, composite rate model were selected by the stepwise regression as statistically significant predictors of cost. The remaining eight refined comorbidity measures were not found to be statistically significant. Based on this criterion, the model presented excluded them as potential payment variables.

Since resource use for separately billable services can be measured using Medicare claims, a patient-level model was used to identify potential payment adjusters for separately billable services. We developed a

regression model, weighted by the number of dialysis sessions, which included the same control variables and examined the same refined list of patient characteristics as the model of composite rate costs.

All 11 comorbidity variables had statistically significant relationships to cost. However, the magnitudes of the comorbidity effects varied substantially. The largest increase in cost was associated with gastrointestinal (GI) bleeding, two categories of specified infections, and pericarditis (47 percent to 88 percent higher costs). These are the acute conditions where a recent diagnosis (i.e., no more than 3 months ago) leads to a temporary payment adjustment. For most of the remaining comorbidities, the model estimated much smaller effects on cost (4 percent to 16 percent for all other conditions except myelodysplastic syndrome). These are the chronic conditions for which a diagnosis leads to a permanent increase in payment based on the expectation that they will tend to have a more persistent effect on cost.

Finally, the multipliers from the composite rate and separately billable equations were combined to yield a single multiplier for each case-mix adjuster. This combination was achieved by calculating a weighted average of the variable's multipliers in the two equations, with the weight being equal to the share of total costs attributable to that cost component. Accordingly, about two-thirds of the weight was given to the multiplier the composite rate equation. Any adjuster not appearing in a particular equation is assigned a multiplier value of 1.0 for that equation for the purposes of calculating the weighted average multiplier.

The largest combined payment multipliers generally reflect temporary adjustments to the payment amount. This includes upward adjustments for patients with the following diagnoses in the current month or three previous months: pericarditis (20.6 percent), septicemia (28.5 percent), bacterial pneumonia, other pneumonias and opportunistic infections (15.9 percent), and gastrointestinal bleeding (30.0 percent). The remaining adjustments are for comorbidities that are relatively chronic, and will persist following an initial diagnosis. The upward payment adjustment for these comorbidities is frequently either less than 5 percent (cardiac arrest, HIV/AIDS, hepatitis B, and cancer excluding non-melanoma skin cancer) or between 5 percent and 10 percent (hereditary hemolytic or sickle cell anemias and myelodysplastic syndrome). The payment adjustments exceed 10 percent for alcohol/drug dependence (12.2 percent) and monoclonal gammopathy (28.6 percent).

Table 4.1 Modeled case-mix adjustment for an expanded bundle (EB) of composite rate (CR) and separately billable (SB) services (data: 2004-2006)

Variable	Estimated case-mix multipliers based on a two-equation model				Modeled case-mix adjustment*
	Composite rate services		Separately billable services		
	$Mult_{CR}$	P-value	$Mult_{SB}$	P-value	$Mult_{EB}$
Age (years)					
<18	1.421	<.0001	0.449	<.0001	1.091
18-44	1.314	<.0001	1.005	0.0626	1.209
45-59	1.014	0.6951	0.991	<.0001	1.006
60-69	1.000	ref	1.000	ref	1.000
70-79	1.059	0.0929	0.962	<.0001	1.026
80+	1.230	<.0001	0.931	<.0001	1.128
Female	1.049	0.0315	1.163	<.0001	1.088
Body surface area (per 0.1 m^2)	1.034	<.0001	1.038	<.0001	1.035
Underweight (BMI<18.5)	1.066	0.3059	1.031	<.0001	1.054
Duration of renal replacement therapy: < 4 months	1.605	<.0001	1.445	<.0001	1.551
Alcohol/drug dependence (any)	1.121	0.0003	1.125	<.0001	1.122
Cardiac arrest: (any)	1.000^	n.s.	1.090	<.0001	1.031
Pericarditis (from 0-3 months ago)	1.000^	n.s.	1.609	<.0001	1.206
HIV/AIDS (any)	1.000^	n.s.	1.125	<.0001	1.042
Hepatitis B (any)	1.000^	n.s.	1.041	<.0001	1.014
Specified infection (from 0-3 months ago)					
Septicemia	1.071	0.0052	1.701	<.0001	1.285
Bacterial pneumonia and other					
pneumonias/opportunistic infections	1.000^	n.s.	1.469	<.0001	1.159
Gastrointestinal tract bleeding (from 0-3 months ago)	1.000^	n.s.	1.884	<.0001	1.300
Hereditary hemolytic or sickle cell anemias (any)	1.000^	n.s.	1.155	<.0001	1.053
Cancer since 1999(any diagnosis, excluding non-					
melanoma skin cancer)	1.000^	n.s.	1.088	<.0001	1.030
Myelodysplastic syndrome (any)	1.000^	n.s.	1.280	<.0001	1.095
Monoclonal gammopathy (any)	1.382	0.0009	1.099	<.0001	1.286

*The case-mix multipliers for an expanded bundle were calculated as MultEB=0.661*MultCR+0.339*MultSB.
^A multiplier of 1.000 is used for factors that were not determined by regression and is to have a statistically significant association with measures of resource use.

Specific Issues in the Definition and Inclusion of Comorbidities

Several analyses bearing on the cost implications of specific patient comorbidities were conducted in support of the 2008 Report to Congress. The main issues reflected in these analyses are discussed below.

- Extent to which future reporting is likely to differ from measured historical prevalence

UM-KECC noted in the 2008 Report to Congress that if a variable is included in a case-mix adjustment model, it is possible that reporting may increase above the historical levels. This is particularly likely if the condition varies greatly in severity (e.g., mild cases may not have been reported historically) or if the presence of the diagnosis is relatively subjective. In early analyses of post Expanded Bundle (EB) PPS implementation, as indicated later in this report, there is no evidence of increased comorbidity reporting.

- Diagnosis prevalence and the look-back period

Different lengths of look-back periods can affect the prevalence of diagnoses (e.g., percentage of patients with a given diagnosis reported in the prior six months, year, or two years). One comorbidity for which unusually large differences existed between shorter and longer look-back periods was diabetes. Sixty-five percent of patients were reported to have diabetes based on a longer look-back period (based on the CMS 2728 form and claims since 1999), while only 17 percent of patients had a diagnosis reported on claims within the last year. Since the more proximate diabetes mellitus prevalence is low relative to what we and others have previously reported in the literature (e.g., USRDS data), using only a recent diagnosis may inadequately represent the true prevalence of diabetes mellitus.

- Persistence of effect on cost

Chronic conditions (e.g., sickle cell and hereditary hemolytic anemias) are likely to have a persistent effect on costs over time. Once such a condition is identified, it is likely to persist. Certainly, chronic conditions might have acute manifestations that lead to higher costs over a short period of time, but it is unlikely that such acute flare-ups can be predicted. Hence, may be appropriate to use a long time frame to identify chronic conditions, with the resulting payment adjustments persisting for the patient.

Conversely, acute conditions (e.g., GI bleeding) may result in elevated costs for only a short period of time. Therefore, various time frames were examined to determine the length of time post-diagnosis that a payment adjustment should apply. The 2008 Report to Congress presents comparative analyses for various look-back periods for acute conditions. As UM-KECC extended the look-back period from an acute condition (pericarditis), two findings emerged: (1) more patients were classified with the condition and (2) the coefficient indicating the strength of the relationship decreased. Separate models compared the refined look-

back periods of up to two months ago and up to three months ago for pericarditis, specified infection, and gastrointestinal bleeding. For administrative ease, we recommended using the same look-back period for each of these three comorbidities. The results indicated that a look-back period of up to three months improved the fit of the model. Therefore, for these comorbidities, we recommended a look-back period of up to three months.

- Model parsimony

If a model with fewer predictor variables is desired, clinically related conditions could be combined. For example, HIV and AIDS were combined into a single comorbidity measure in our models, as were sickle cell and hereditary hemolytic anemias. In some cases, diagnoses were combined based on clinical judgments regarding their likely comparability of effects on the use of dialysis related services. In other cases, preliminary analyses allowed certain diagnoses or sets of diagnoses to enter the model separately, but they were combined after the preliminary models revealed that their relationships to costs were of similar magnitude.

The following example of measures of infection demonstrates how related diagnoses were grouped. Based on clinical judgment, similar codes were grouped into three categories (septicemia, bacterial pneumonia, and a set of other specified infections, each with a look-back period of three months). Septicemia is the most common, present in 10.1 percent of patient months; bacterial pneumonia and the other specified infections occurred in 1.4 percent and 0.3 percent of months, respectively. Septicemia had a multiplier of 1.70 in preliminary analyses, bacterial pneumonia had a multiplier of 1.43, and other specified infections had a multiplier of 1.50. Because the two relatively uncommon categories had similar multipliers, they were combined into a single category. In a more straightforward specification, septicemia had a multiplier of 1.70 and the combined category had a multiplier of 1.47. This information is useful to develop more precise rules to define infection.

Similarly, in preceding analyses, two groupings of cancer measures were combined into a single measure that includes all cancers except non-melanoma skin cancers. The two original cancer measures had similar multipliers in analyses of both separately billable and composite rate services. Given this result and based on our review of the diagnoses in each category, there appeared to be no conceptual or empirical rationale to maintain separate categories. Combining the categories resulted in a more straightforward model.

Additional research identified other opportunities to reduce the list of patient characteristics without significant loss of predictive power. Any histories of alcohol or drug abuse were combined into one category of "substance abuse." We excluded the following comorbidity categories based on several characteristics, including low economic impact, vague definition, coefficient instability, or high prevalence: congestive heart failure, cardiac dysrhythmia, cerebrovascular disease, peripheral vascular disease, diabetes mellitus, COPD,

other hepatitis, esophageal varices, hyperparathyroidism, other infection, and myelofibrosis. Specifically, CHF and diabetes are present in such a high percentage of patients that they do not serve to predict differentially high treatment costs across facilities.

Analyses of Comorbidities Subsequent to the 2008 Report to Congress

Several issues gave rise to analyses subsequent to the 2008 Report to Congress. Many of these analyses helped to inform the 2011 ESRD PPS Proposed Rule, published in September 2009, and the 2011 ESRD PPS Final Rule, published in August 2010.

- Removal of comorbidities based only on laboratory claims

In January 2008, UM-KECC dropped comorbidities identified solely by laboratory claims (as well as correcting a coding error for the look-back period) and re-estimated the model in the 2008 Report to Congress. Table 2, below, compares the case-mix model in the 2008 Report to Congress to the model resulting from elimination of the laboratory-only claims using the 2002-2004 data. Diagnoses appearing only on laboratory claims were excluded because it could not be established whether such diagnoses definitively indicated the presence of the condition or only indicated a test being done to rule out a condition. The effects of the re-estimation on the 2008 Report to Congress multipliers are negligible in most cases, with the exceptions of HIV/AIDS and monoclonal gammopathy. The prevalence of HIV/AIDS decreased, but the modeled case-mix multiplier increased from 1.042 to 1.081. This result suggests those identified as having HIV/AIDS through non-laboratory claims are patients who are likely to utilize more medical resources. The already low prevalence of monoclonal gammopathy decreased further from 1.43 percent to 1.21 percent of patients based on non-laboratory claims. In the composite rate model the case-mix multiplier for monoclonal gammopathy is no longer statistically significant and is consequently set equal to 1. This change drives a decrease in the combined case-mix adjustment multiplier from 1.286 to 1.024. Because the changes in the coefficients resulting from the re-estimation did not substantially impact the explanatory power, no changes were recommended for the 2008 Report to Congress. In successive models, using updated data (2005 and beyond), laboratory claims were excluded when defining comorbidities. The Updated Analysis columns show the case-mix adjusters for the 12 comorbidities in the 2009 ESRD PPS Proposed Rule.

Table 4.2 Modeled case-mix adjustment for an expanded bundle (EB) of composite rate (CR) and separately billable (SB) services (without comorbidities based only on laboratory claims) (data: 2002-2004)

Variable	Prior analysis					Updated analysis					Impact of change
	Estimated case-mix multipliers based on a two-equation model				Modeled case-mix adjustment*	Estimated multipliers				Modeled case-mix adjustment*	
	Composite rate services		Separately billable services			Composite rate services		Separately billable services			
	$Mult_{CR}$	P-value	$Mult_{SB}$	P-value	$Mult_{EB}$	$Mult_{CR}$	P-value	$Mult_{SB}$	P-value	$Mult_{EB}$	Updated Prior
Age (years)											
<18	1.421	<.0001	0.449	<.0001	1.091	1.422	<.0001	0.448	<.0001	1.092	0.001
18-44	1.314	<.0001	1.005	0.0626	1.209	1.316	<.0001	1.005	0.0663	1.211	0.001
45-59	1.014	0.6951	0.991	<.0001	1.006	1.010	0.7692	0.992	0.0001	1.004	-0.002
60-69	1.000	ref	1.000	ref	1.000	1.000	ref	1.000	ref	1.000	0.000
70-79	1.059	0.0929	0.962	<.0001	1.026	1.064	0.0693	0.961	<.0001	1.029	0.003
80+	1.230	<.0001	0.931	<.0001	1.128	1.240	<.0001	0.928	<.0001	1.134	0.006
Female	1.049	0.0315	1.163	<.0001	1.088	1.048	0.0366	1.166	<.0001	1.088	0.000
Body surface area (per 0.1 m^2)	1.034	<.0001	1.038	<.0001	1.035	1.033	<.0001	1.038	<.0001	1.035	0.000
Underweight (BMI <18.5)	1.066	0.3059	1.031	<.0001	1.054	1.060	0.3524	1.029	<.0001	1.049	-0.005
Duration of renal replacement therapy: < 4	1.605	<.0001	1.445	<.0001	1.551	1.593	<.0001	1.419	<.0001	1.534	-0.017
Alcohol/drug dependence (any)	1.121	0.0003	1.125	<.0001	1.122	1.152	<.0001	1.128	<.0001	1.144	0.022
Cardiac arrest: (any)	1.000^	n.s.	1.090	<.0001	1.031	1.000		1.089	<.0001	1.030	-0.001
Pericarditis (from 0-3 months ago)	1.000^	n.s.	1.609	<.0001	1.206	1.000		1.588	<.0001	1.199	-0.007
HIV/AIDS (any)	1.000^	n.s.	1.125	<.0001	1.042	1.000		1.240	<.0001	1.081	0.039
Hepatitis b (any)	1.000^	n.s.	1.041	<.0001	1.014	1.000		1.052	<.0001	1.018	0.004
Specified infection (from 0-3 months ago)											
Septicemia	1.071	0.0052	1.701	<.0001	1.285	1.095	0.0001	1.637	<.0001	1.279	-0.006
Bacterial pneumonia and other											
pneumonias/opportunistic infections	1.000^	n.s.	1.469	<.0001	1.159	1.000		1.384	<.0001	1.130	-0.029
Gastrointestinal tract bleeding (from 0-3 months ago)	1.000^	n.s.	1.884	<.0001	1.300	1.000		1.868	<.0001	1.294	-0.005
Hereditary hemolytic or sickle cell anemias (any)	1.000^	n.s.	1.155	<.0001	1.053	1.000		1.203	<.0001	1.069	0.016
Cancer since 1999 (any diagnosis, excluding non-											
melanoma skin cancer)	1.000^	n.s.	1.088	<.0001	1.030	1.000		1.104	<.0001	1.035	0.005
Myelodysplastic syndrome (any)	1.000^	n.s.	1.280	<.0001	1.095	1.000		1.323	<.0001	1.109	0.014
Monoclonal gammopathy (any)	1.382	0.0009	1.099	<.0001	1.286	1.000	0.425	1.071	<.0001	1.024	-0.262

^A multiplier of 1.000 is used for factors that were not selected by the stepwise regression as havinga statistically significant association with measures of resource use.

- Inclusion of Cancer

Toward the end of 2008, UM-KECC developed various additional models to understand the effect of including cancer as a comorbidity adjuster. When cancer was omitted from the models, average expanded bundle (EB) payment multipliers were slightly increased based on differences among other patient characteristics. When cancer was added back into the model, payments for patients with cancer increased substantially. These analyses demonstrated that only a small fraction of the higher costs associated with cancer had been captured by the remaining patient characteristics in the model. To further understand the effects of cancer on the EB multipliers, analyses of patient characteristics for those with versus without a history of cancer showed that patients (aged >18 years) with cancer were more likely to have other comorbidities. This increased their predicted payment amounts when omitting cancer from the model.

For separately billable services, when cancer was omitted from the payment model, predicted SB payments were almost 6 percent lower than actual SB payments. When the cancer comorbidity was included in the SB model, it reduced the payment error for patients with cancer, leading to a predicted SB payment slightly higher (1.4 percent) than actual SB payments.

CMS expressed concern that a history of cancer was too broad to be clinically meaningful. UM-KECC had previously conducted research showing that disaggregation of all cancer into the categories of cancers defined by the Medicare Advantage program resulted in coefficients that were similar across the categories. In order to have straightforward models, cancer categories were combined.

Identification of Comorbidities by Claim Source

Analyses showing the percentage of patient months for comorbid conditions used in the case-mix models were completed in July 2009. Results compared comorbidities that were identified using all claims types (excluding laboratory claims) to those comorbidities identified using only type 72 claims. These analyses demonstrated that relatively few of the comorbid conditions were identified on the type 72 claims. The comorbid conditions reported most frequently on type 72 claims are septicemia and hepatitis B, which are reported at one-quarter to one-third of the rate reported on all types of claims. Other comorbid conditions were rarely if ever reported on type 72 claims.

Re-estimation of 2011 ESRD PPS Proposed Rule Model with 2006-2008 data update

With new data (2006-2008), all comorbidities used in the 2011 ESRD PPS Proposed Rule remained statistically significant except for hereditary hemolytic and sickle cell anemias (no long significant in the CR model). The HIV/AIDS multiplier was larger and alcohol/drug dependence was smaller with new data.

Models with fewer comorbidities (from 12 in the 2011 ESRD PPS Proposed Rule) were estimated. The effects of excluding the following comorbidities were estimated: alcohol/ drug dependence, HIV/AIDS, septicemia, and

cancer. The R^2 declined with removal of these comorbidities. Other comorbidities had an increase in multiplier values when four comorbidities were removed from the model. UM-KECC also noted that when comorbidities were removed from the base model (that included race and ethnicity), race and ethnicity captured a relatively small portion of the cost differences associated with comorbidities.

CMS expressed interest in evaluating comorbidities defined with shorter look-back periods (specifically, current month or previous three months). Communication and meetings between UM-KECC and CMS discussed the practical basis for a shorter look-back period to define costs associated with GI bleeding, bacterial pneumonia, and pericarditis. Consideration and additional review related to a longer look-back period for heredity hemolytic anemia and myelodysplastic syndrome. The following excerpt is from a document sent to CMS from UM-KECC on April 1, 2010. The recommendation made below was to exclude cardiac arrest, hepatitis B, and septicemia from the expanded bundle. Also, with more specific diagnostic criteria, UM-KECC suggested that the following comorbidities be included in the expanded bundle: pericarditis, bacterial pneumonia and opportunistic infections, GI bleeding, hereditary hemolytic/sickle cell anemia, myelodysplastic syndromes, and monoclonal gammopathy. Additional research was recommended before making a decision to include the cancer comorbidity.

As we consider inclusion of comorbidities in the case-mix adjustment for an expanded ESRD bundle, the risk/benefit considerations must include assessment of 1) impact of inclusion/exclusion, 2) strength of supporting data, 3) ability to create accurate clinical definitions, 4) potential for adverse incentives regarding quality of care, 5) potential for ESRD providers to directly influence the prevalence of comorbidity, either by altering dialysis care, diagnostic testing patterns, or liberalizing diagnostic criteria.

Exclusion of comorbidities carries risk to patients in the form of potential reduced access to care, particularly for those patients with a high comorbidity burden resulting in increased resource utilization. On the other hand, inclusion of comorbidities which are not rigorously defined carries risk of inappropriate redistribution of payments for ESRD dialysis services. Striking a reasonable balance, based on the above criteria should minimize these risks.

1. **Cardiac Arrest** - Stable predictor of SB cost in multiple iterations of our models. There is inherent problem including this comorbidity in an expanded PPS in that dialysis facilities' care could influence the prevalence of cardiac arrest through volume management or electrolyte management decisions. In addition, potential for liberalization of diagnostic criteria (e.g., transient unresponsiveness during dialysis related to volume removal) without specific diagnostic criteria definition. **Recommendation: Exclusion.**

2. **Pericarditis** - Stable predictor of SB cost in multiple iterations of our models. Inherent face validity in that this inflammatory condition, often treated with increased dialysis intensity, should be associated with increased cost. In addition, clinical face validity for increased erythropoiesis-stimulating agents (ESA) utilization in presence of inflammatory pericarditis. **Recommendation: If diagnostic criteria can be defined with high specificity, would include in model.**

3. **Hepatitis B** - Stable predictor of SB cost in multiple iterations of our models. Prevention of hepatitis B is a central tenet of current ESRD Conditions for Coverage regulations. Inclusion of increased payment for hepatitis B would create inappropriate financial incentive for dialysis providers. **Recommendation: Exclusion.**

4. **Septicemia** - Stable predictor of SB cost in multiple iterations of our models. Likely to be associated with increased ESA resistance, and therefore has strong clinical face validity as predictor of ESA utilization. Similar to hepatitis B above, prevention of vascular access infection, a major cause of bacteremia/septicemia in ESRD patients, is a fundamental tenet of appropriate dialysis facility care. Use of septicemia as a payment variable would create an inappropriate financial incentive for dialysis providers to provide care that is contrary to care specified in current Conditions for Coverage. **Recommendation: Exclusion.**

5. **Bacterial pneumonia and opportunistic infections-** On further review of ICD-9 codes contributing to this category, we recommended inclusion of a more limited set of diagnostic codes, resulting in a more consistent grouping of only bacterial pneumonias. Major bacterial infection, exemplified by bacterial pneumonia has strong face validity as a cause of ESA resistance and therefore increased ESA requirement. If specific diagnostic criteria for the presence of bacterial pneumonia can be identified, this comorbidity could be considered for inclusion in the expanded PPS case-mix list. **Recommendation: Would consider use of radiographic diagnosis in definition of this comorbidity.**

6. **GI bleeding** - This comorbidity has significant face validity as a cause for increased ESA utilization. Careful definition of the comorbidity is important to avoid evolution of an overly liberal diagnosis. The ICD-9 codes (see list) used in our modeling typically included codes for luminal ulcers with associated hemorrhage. It would be inappropriate to use, for example, presence of occult stool blood without documentation of bleeding source as diagnosis justifying payment. **Recommendation: Inclusion with specific diagnostic criteria to minimize inappropriate upcoding.**

7. **Hereditary hemolytic/sickle cell anemia** - Small but consistent effect on SB costs in our serial iterations of models predicting SB cost**. Recommendation: Inclusion if specific diagnosis criteria are available.**

8. **Cancer (excluding non-melanoma skin cancer)**- Likely an important contributor to the overall predictive power of the SB model, based on models with long look-back periods (up to six prior years of claims data). Some face validity for association between cancer, particularly those under active treatment and ESA resistance. Many comments from providers outlined their limited knowledge about presence of historical cancer diagnoses. **Recommendation: Further exploration of new comorbidity variable (new cancer diagnosis) for consideration in the case-mix model.**

9. **Myelodysplastic syndromes** - Face validity for this group of bone marrow conditions to be associated with increased ESA resistance. Specific diagnostic criteria are available. **Recommendation: Inclusion in the case-mix model.**

10. **Monoclonal gammopathy-** The lack of specificity of the Medicare Advantage managed care diagnosis grouping "monoclonal gammopathy" must be recognized, particularly if the increased utilization of separately billed medications in ESRD patients identified by the predictive models is related only to the subset of patients with more severe clinical manifestations. An appropriate definition of monoclonal gammopathy for payment purposes should be specific enough to identify those patients with severe monoclonal gammopathy, who are most likely to have a medical

requirement for increased utilization of services. Specific diagnostic criteria for multiple myeloma are available in the hematology literature. **Recommendation: Inclusion**

CMS Decisions on Comorbidities in the CY 2011 ESRD PPS Final Rule (FR)

Exclusion of Comorbidities from Expanded Bundle

Based on discussions with CMS and in response to comments received in the rule-making process, modifications were made both in terms of specific codes that could or could not be used to identify a particular comorbidity, and which comorbidities were included in the final model. In the Final Rule, published in August 2010, CMS made the following rulings, supported in part by the analyses discussed above:

- Hepatitis B and Septicemia

An important goal of the expanded ESRD PPS is to establish financial incentives that are consistent with the provision of high-quality care. A potential unintended consequence of implementing a case-mix adjustment that accounts for comorbidities is that by awarding higher payments to facilities for medical conditions that might have been avoided through facility practices; the payment system may be rewarding poor quality of care. There may be a greater risk of this occurring with certain types of infections that were part of the case-mix adjustment in the Proposed Rule, including hepatitis B and septicemia.

A disadvantage of establishing higher payment rates for patients with hepatitis B and septicemia is that it penalizes facilities for taking prompt preventive measures to avoid these infections, specifically through hepatitis B vaccination and avoidance of catheter use for vascular access to minimize the risk of septicemia. In attempting to establish a case-mix adjustment that is consistent with the goal of encouraging high-quality care, CMS decided that the ESRD PPS should not include adjustments for hepatitis B and septicemia.

Furthermore, septicemia is a clinical syndrome consisting of a number of non-specific symptoms and signs. In the context of a suspected or known infection, the diagnosis of sepsis is considered when some or all of the defining signs and symptoms are present, depending upon the severity of those signs and symptoms. The inherent ambiguity of this definition adds a subjective component to this diagnosis, and creates an opportunity for providers to increase their payments by changing the sensitivity of the diagnostic criteria for this condition.

- Cancer

The CY 2011 ESRD PPS Proposed Rule included a proposed 12.8 percent payment adjustment for patients with a history of cancer, which was identified using Medicare claims data. Given differences across cancer types and stages, as well as differences between patients currently being treated versus having a past history of cancer, this adjustment would be applied for patients who vary greatly in clinical severity. As a result, the appropriateness of this adjustment may also vary greatly among patients with a history of cancer, and CMS decided that there was

insufficient information available to target the adjuster to the specific cancer diagnoses, stages, and treatment status that result in higher outpatient dialysis costs.

- Bacterial pneumonia/other pneumonia/opportunistic infection

Table 4.3 shows three models that include various combinations of "bacterial pneumonias" and "other pneumonias." "Other pneumonias" had substantially weaker relationships to cost. In Table 4.3 the exclusion of diagnoses reflecting "other pneumonias" has a limited effect on the magnitude of the adjustment for patients with bacterial pneumonia and only slightly reduces the number of pneumonias that would be used to determine eligibility for this adjustment. Note that this model excludes primary plague pneumonia (020.3), unspecified pneumonia (020.5), primary coccidioidomycosis, unspecified (114.5) in addition to those diagnoses that were excluded from the bacterial pneumonia/other pneumonia/opportunistic infection category for the CY 2011 ESRD PPS Proposed Rule (Table 15 of the Proposed Rule).

The only changes in the definition of bacterial pneumonia/opportunistic infection from the CY 2011 ESRD PPS Proposed Rule were the exclusion of a small number of rare non-bacterial opportunistic infections and nonspecific pneumonia diagnoses. This was done to create a more objective diagnostic category to facilitate accurate reporting of comorbidity definitions after implementation of the new payment system.

Conclusion

Table 4.4 presents the final comorbidities, look-back periods, and multipliers in the CY 2011 ESRD PPS Final Rule. In this model, presented to CMS in late April 2010, cancer was excluded, acute comorbidities had a three month look-back period, and chronic comorbidities had a look-back period from 2000. As described above, issues of model parsimony, measurement objectivity, clarity, and consistency led to the final payment adjusters for comorbidities.

Table 4.3 Estimated payment multipliers for bacterial pneumonia and other pneumonias in the SB model, ages 18 and older (n=8,697,451 patient months; 2006-2008)
Longer claims history used to identify monoclonal gammopathy (in absence of multiple myeloma)
No adjustments for race or ethnicity

Variable	Percent of Medicare HD-equivalent dialysis treatments	SB model		
		Model 1	Model 2	Model 3
		PmtMultSB	PmtMultSB	PmtMultSB
Adjustments for patient characteristics				
Age (years)				
18-44	13.5%	1.000	1.000	1.000
45-59	26.9%	0.995	0.996	0.996
60-69	23.8%	1.000	1.000	1.000
70-79	22.8%	0.967	0.967	0.967
80+	12.9%	0.927	0.927	0.927
Female	45.8%	1.119	1.119	1.119
Body surface area (per 0.1 m^2)	1.87	1.023	1.023	1.023
Underweight (BMI < 18.5)	4.0%	1.097	1.097	1.097
Time since onset of renal dialysis < 4 months	4.9%	1.450	1.449	1.449
Pericarditis from same month to 3 months ago	0.4%	1.360	1.360	1.360
Gastro-intestinal tract bleeding from same month to 3 months ago	1.1%	1.574	1.574	1.574
Hereditary hemolytic or sickle cell anemia (claims since 2000)	2.3%	1.229	1.229	1.229
Myelodysplastic syndrome (claims since 2000)	1.6%	1.312	1.312	1.312
Monoclonal gammopathy (claims since 2000)**	1.2%	1.075	1.075	1.075
Pneumonia from same month to 3 months ago				
Bacterial pneumonia or other pneumonias	2.03%	1.423	--	--
Bacterial pneumonia	1.99%	--	1.426	--
Other pneumonia	0.83%	--	1.011	--
Bacterial pneumonia only	1.20%	--	--	1.430
Other pneumonia only	0.04%	--	--	1.097
Bacterial pneumonia and other pneumonia	0.78%	--	--	1.434

**Excludes multiple myeloma.

Table 4.4 Calculation of payment multipliers for an expanded ESRD PPS, ages 18 and older (2006-2008)
Use of a patient-month level SB model; No adjustments for sex, race, or ethnicity
Adjustment for bacterial pneumonia excludes other pneumonias; Low volume facility threshold at 4,000 treatments

Variable	Percent of Medicare HD-equivalent dialysis treatments	CR model, 2006-2008 n=12,999 R^2:41.0%	SB model, 2006-2008 n=8,617,576 patient months; R^2 at patient-year level: 5.2%^	Modeled case-mix adjustment*
		$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics				
Age (years)				
18-44	13.50%	1.256	0.995	1.173
45-59	26.90%	1.021	0.992	1.012
60-69	23.80%	1.000	1.000	1.000
70-79	22.80%	1.04	0.964	1.016
80+	12.90%	1.067	0.916	1.019
Body surface area (per $0.1m^2$)	1.87	1.023	1.014	1.020
Underweight (BMI<18.5)	4.00%	1.000	1.078	1.025
Time since onset of renal dialysis < 4 months	4.90%	1.518	1.450	1.496
Pericarditis (acute^^)	0.40%	1.000	1.355	1.114
Bacterial pneumonia (acute^^)	2.00%	1.000	1.422	1.135
Gastro-intestinal tract bleeding (acute^^)	1.10%	1.000	1.571	1.183
Hereditaryhemolyticor sickle cell anemia (chronic^^)	2.30%	1.000	1.238	1.076
Myelodysplasticsyndrome (chronic^^)	1.60%	1.000	1.310	1.099
Monoclonalgammopathy (chronic^^)**	1.20%	1.000	1.074	1.024
Low-volume facility adjustment				
Facility size < 4,000 treatments during each year from 2006-2008	1.60%	1.60%	1.60%	1.60%

Note: In the CR model presented above, the percentage of home dialysis training treatments in the facility was included as an additional control variable.
*The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility-level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient-level model of separately billable MAP. Based on total estimated costs of $177.88 per session for composite rate services, $83.94 per session for separately billable services, and $261.82 per session for composite rate and separately billable services ($177.88+$83.94), the relative weights are $Weight_{CR}$=0.6794 for composite rate services ($177.88/$261.82) and $Weight_{SB}$=0.3206 for separately billable services ($83.94/$261.82). The combined low volume multiplier was calculated relative to all other facilities.
**Excludes multiple myeloma.
^The R^2 value reported above for the SB model was based on a regression model that used the average predicted SBMAP per treatment during each patient year, which was calculated by averaging the monthly predicted values for each patient from the patient-month SB model, to explain variation in the average observed MAP per treatment or the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R^2 value for the patient-month level log-linear SB model was 3.3 percent.
^^Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.
- The above payment model reflects the refined bacterial pneumonia category which now excludes" other pneumonias". Note that we have also excluded additional facilities that we determined either opened or closed during the study period, resulting in somewhat smaller sample sizes for the CR and SB models.
-Comparedtothepaymentmodeldated4/19/10(TableA-3, which excludes female from the model), the adjustments in the model above are slightly larger for both younger and older age groups and somewhat smaller based on time since onset of dialysis. The other patient-level adjustments in the above table are relatively similar to the model dated 4/19/10. The low volume adjustment of 19.1 percent above is slightly smaller than the 20.0 percent adjustment from the 4/19/10 model.

E. DEMOGRAPHIC CHARACTERISTICS

Payment Adjustments for Demographic Characteristics: Age, Sex, and Race

Patient demographic characteristics are often related to costs in a variety of health care contexts. Age is likely to be related to overall health status in the presence of unmeasured comorbid conditions. Sex also has systematic relationships to costs in a variety of contexts (due to factors such as maternal care and differential prevalence of various chronic conditions by sex). Likewise, race/ethnicity is sometimes related to costs for a variety of potential reasons (differential prevalence of chronic conditions, differentials in average socioeconomic status across racial and ethnic groups, differential access to care). ESRD-related spending has been shown to differ across these categories (USRDS, 2015 Annual Data Report).

In addition to being predictive of costs, demographic characteristics often meet other criteria for selection as case-mix adjusters. First, they can often be measured objectively using administrative data (though as discussed below, ascertainment of race/ethnicity in administrative data is not always straightforward). Second, demographic factors are enduring characteristics of a patient and are not affected by the quality of care delivered by a provider. By way of contrast, providing a case-mix adjustment for the presence of a condition that may itself be a consequence of inadequate care decreases a provider's incentive to deliver care that could prevent that condition. For example, providing an adjustment for a vaccine-preventable condition would decrease incentives to ensure that patients receive all recommended immunizations.

The ESRD basic case-mix adjusted payment system (BCMA) implemented in 2005 provided empirically-derived adjustments for five age groups. The research underlying the ESRD PPS built upon that work, and also explored adjustments for sex and race/ethnicity.

Age

Research to support the development of the Basic Case-Mix Adjustment (BCMA) investigated the relationship between age and composite rate (CR) costs. Age was considered an objective measure for which data are readily available and a significant relationship between age and composite rate costs was found.

Several age categorization models were considered and are described in detail in the following report: "Methodology for Developing a Basic Case Mix Adjustment for the Medicare ESRD Prospective Payment System," UM-KECC, April 1, 2005.

Specifically, groups of three, five, and ten adult age categorizations were analyzed in relation to composite rate costs. In all models, a U-shaped relationship existed between age and CR cost, with the youngest and oldest age categories showing the higher costs in comparison to the middle age categories. The use of ten age

categories did not add substantial explanatory power to the model. In some cases, the multipliers of the ten age categories did not significantly differ across some of the age categories, suggesting that combining these categories was statistically viable and more parsimonious. The analytical model with three age categories did not capture as much of the composite rate cost variation as did the use of five age categories. Therefore, it was decided that the five age categories provided a statistically sound balance between model parsimony and explanatory power for the BCMA payment system. This approach resulted in significant and substantial CR cost multipliers and good explanatory power, as indicated in Table 4.5.

Table 4.5 The Basic Case-Mix Adjustments for the Composite Rate, 2000-2002[1]

Case-mix factor	Estimated multiplier	P-value	95% CI
Age (years)			
18-44	1.223	<0.001	(1.142,1.308)
45-59	1.055	0.115	(0.987,1.127)
60-69	1.000	Reference	
70-79	1.094	0.005	(1.028,1.164)
80+	1.174	<0.001	(1.089,1.264)
Body surface area(per 0.1 m^2)	1.037	<0.001	(1.029,1.044)
Body mass index			
<18.5kg/m^2	1.112	0.043	(1.003,1.232)
>18.5kg/m^2	1.000	Reference	
All covariates: case-mix and control variables	**R^2**		
	0.3595		
Control variables only	0.3488		

[1]n=8,236. Facility control variables include: SNF wage index, facility size, hospital based (versus freestanding), chain ownership, % with URR≥65, % pediatric, payment exception status, and year of cost report.

Analyses to support the Expanded Bundle (EB) Prospective Payment System (PPS) began with the five age categories used in the BCMA payment system. The relationship between age and separately billable (SB) costs was analyzed using the 2006-2008 claims. The relationship between the SB Medicare Allowable Payments (MAPs) and the five age categories had a similar U-shaped relationship to the pattern observed for composite rate costs in the basic case-mix adjustment payment system. Costs were higher for the youngest and oldest adult age groups in comparison to the referent group.

The regression analyses performed for the development of the ESRD PPS indicated that age continued to be a strong predictor of facility differences in composite rate costs and patient-specific differences in separately billed payments. Therefore, age was incorporated as a case-mix payment variable in the proposed and final ESRD PPS. Specifically, the same five age groups that had been used in the CR BCMA were implemented as payment adjustment factors by applying the two-equation model described in the UM-KECC 2008 report,

Structure of the Model section starting on page 39. The report is available here: http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/UM_KECC_ESRD_Bundle_Report.pdf, as well as described in the CY 2011 Final Rule.

The proposed and final CY 2011 payment multipliers for the five age categories are shown in Table B. As stated in the CY 2011 Final Rule (page 49088), changes in the age category payment multipliers between the proposed rule and final rule resulted from modifications in the payment model (updated data, elimination of sex and race/ethnicity, revisions in comorbidities used for payment, modification of low volume threshold, etc.). With the model modifications, the referent category for age, which indicates the age category with the lowest impact on cost, changed from 45-59 years to 60-69 years. The magnitudes of the oldest two categories also have been attenuated by the model changes between the proposed and final rule.

Age group (years)	Proposed Multiplier	Final Multiplier
18-44	1.194	1.171
45-59	1.000	1.013
60-69	1.012	1.000
70-79	1.057	1.011
80+	1.076	1.016

Several analyses found very high estimates of cost for pediatric patients (under age 18 years old). Using regression to estimate an age adjuster for pediatric patients produced unstable and imprecise results due to the small fraction of pediatric patients in most ESRD facilities. Therefore, a separate approach to adjusting payment to reflect cost of pediatric patients was taken. This approach is discussed in Section IX. Pediatric Patients in this report.

Sex

Patient sex was found to be a strong predictor of variation in payments for ESRD patients. In addition, patient sex has been determined to be an objective measure, and data on patient sex are readily available.

There was an adjustment for sex as part of the proposal for the basic case-mix adjusted composite rate payment system in the CY 2005 Physician Fee Schedule (PFS) proposed rule (69 FR 47487 through 47730), published August 5, 2004. Analytical models showed the effect of a combination of sex and age on composite rate costs compared to the lowest cost combination (that is, females aged 65–79). No data on separately billable services were analyzed because those services were excluded from the basic case-mix adjusted composite rate payment system. Male patients had consistently higher costs than females.

As was explained in the CY 2005 PFS final rule with comment period (69 FR 66235 through 66915), published on November 15, 2004, sex was proposed as a surrogate measure for body size. The use of actual height and weight to measure body size were preferred 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 sex was reported on the outpatient bill.

The eventual mandatory reporting of patient height and weight enabled the development of case-mix measures that included the superior predictors related to body size: body mass index (BMI) and body surface area (BSA). As a result, the BCMA final rule employed BSA and a low BMI indicator, and eliminated sex as a patient classification variable for purposes of case-mix adjustment.

In developing the proposed ESRD PPS (FR2011 pg 49950), patient sex was included in preliminary models to explain variation in composite rate and separately billable payments. In analyzing more data on patient sex from the REMIS system, MAPs (for both composite rate and separately billable services) were higher for female patients even when body size measurements were included. In the regression analysis, 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, an adjustment of 13.2 percent for female patients was proposed in the CY 2011 Proposed Rule.

Concern was raised in public comments about the incentive effects of such a large payment adjustment based on patient sex. In particular, there was concern that facility admission practices might come to favor female patients, perhaps limiting access to care for some male patients. CMS was not convinced that a patient sex adjustment was necessary to ensure beneficiary access to ESRD services and believed that there might be sex-neutral factors that had not been identified thus far in the ESRD PPS modeling that would explain the

increased cost associated with providing renal dialysis services to female patients. As a result, the CY 2011 ESRD PPS did not include a patient adjustment based on a patient's sex.

Race/Ethnicity

UM-KECC conducted several analyses to assess the feasibility and desirability of adjusting for race in the PPS. Two main issues were addressed: (1) the ability to measure race objectively and (2) the relationship between race as measured and cost. In addition, the appropriateness of a policy of adjusting payment for race was discussed with CMS.

Because race and ethnicity are subjective, socially constructed characteristics, it is necessary to determine whether patients can be classified by race in a consistent way. To evaluate consistency in reporting race, we compared race categorizations from two separate Medicare sources, the ESRD Medical Evidence Report (CMS Medical Evidence Form 2728) and the Medicare enrollment data base (EDB). The CMS Medical Evidence Form 2728 race designation is based on provider reporting. It uses four race categories: white, black or African American, American Indian/Alaska Native, and Asian/Native Hawaiian or other Pacific Islander (hereafter referred to as Asian/Pacific Islander). It also has a separate designation for Hispanic ethnicity. The EDB race designation uses patient self-reporting, sometimes modified by administrative rules. The EDB categories are somewhat different, and Hispanic ethnicity is treated as a distinct racial category. Table C presents a comparison of the distribution of race/ethnicity of Medicare patients in the two databases.

Table 4.6 Race/ethnicity of Medicare dialysis patients[1,2]

CMS Medical Evidence Form 2728		Medicare Enrollment Database (EDB)	
Race	**Percent**	**Race**	**Percent**
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 Medical Evidence Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

Table 4.7 presents an analysis of the consistency of race categorization between the two databases.

Table4.7 Comparison of race/ethnicity from (a) the Medicare Enrollment Database versus (b) the CMS Medical Evidence Form 2728, 2004-2006

Race from CMS Form 2728		(a) Race from the Medicare Enrollment Database							
		North American Native	Asian	Black	White	Hispanic	Other	Unknown	Total
American Indian/Alaska Native	Patient yrs (n)	10,313	166	664	1,240	301	407	226	13,317
	% of row	77.40%	1.30%	5.00%	9.30%	2.30%	3.10%	1.70%	100.00%
	% of column	84.90%	0.70%	0.20%	0.30%	0.70%	2.10%	1.10%	
Asian/ Pacific Islander	Patient yrs(n)	116	19,565	601	1,521	477	8,118	730	31,128
	% of row	0.40%	62.90%	1.90%	4.90%	1.50%	26.10%	2.40%	100.00%
	% of column	1.00%	86.60%	0.20%	0.30%	1.10%	42.60%	3.40%	
Black	Patient yrs(n)	225	212	308,278	4,199	1,306	1,977	7,712	323,909
	% of row	0.10%	0.10%	95.20%	1.30%	0.40%	0.60%	2.40%	100.00%
	% of column	1.90%	0.90%	97.40%	0.90%	3.00%	10.40%	36.00%	
White	Patient yrs(n)	1,414	1,997	5,846	443,651	39,004	7,685	12,587	512,184
	% of row	0.30%	0.40%	1.10%	86.60%	7.60%	1.50%	2.50%	100.00%
	% of column	11.60%	8.80%	1.90%	97.50%	88.50%	40.30%	58.80%	
Other	Patient yrs(n)	71	639	864	4,114	2,926	842	158	9,614
	% of row	0.70%	6.70%	9.00%	42.80%	30.40%	8.80%	1.60%	100.00%
	% of column	0.60%	2.80%	0.30%	0.90%	6.60%	4.40%	0.70%	
Unknown	Patient yrs(n)	4	14	145	364	64	27	6	624
	% of row	0.60%	2.20%	23.20%	58.30%	10.30%	4.30%	1.00%	100.00%
	% of column	0.00%	0.10%	0.10%	0.10%	0.20%	0.10%	0.00%	
Total	Patient yrs(n)	12,143	22,593	316,398	455,089	44,078	19,056	21,419	890,776
	% of row								
	% of column	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	

Ethnicity from CMS Form 2728		(b) Race from the Medicare Enrollment Database							
		North American Native	Asian	Black	White	Hispanic	Other	Unknown	Total
Hispanic	Patient yrs(n)	457	617	3,337	53,552	39,691	4,873	1,999	104,526
	% of row	0.40%	0.60%	3.20%	51.20%	38.00%	4.70%	1.90%	100.00%
	% of column	3.80%	2.70%	1.10%	11.80%	90.10%	25.60%	9.30%	
Not Hispanic	Patient yrs(n)	11,484	21,112	296,581	392,182	2,811	13,720	18,076	755,966
	% of row	1.50%	2.80%	39.20%	51.90%	0.40%	1.80%	2.40%	100.00%
	% of column	94.60%	93.40%	93.70%	86.20%	6.40%	72.00%	84.40%	
Unknown	Patient yrs(n)	202	864	16,480	9,355	1,576	463	1,344	30,284
	% of row	0.70%	2.90%	54.40%	30.90%	5.20%	1.50%	4.40%	100.00%
	% of column	1.70%	3.80%	5.20%	2.10%	3.60%	2.40%	6.30%	
Total	Patient yrs(n)	12,143	22,593	316,398	455,089	44,078	19,056	21,419	890,776
	% of row								
	% of column	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	

Agreement between the two data sources ranged from 95.2% for black race to 62.9% for Asian race. A difference in the definition of Asian race and the inclusion of Hispanic as an EDB race category tended to decrease levels of agreement. However, for certain categories, there was substantial discordance between the two sources that did not reflect differences in definition.

We analyzed the relationships between race and cost using both classification schemes. The resulting potential payment models are presented in Table 4.8, which is Table 20 in the CY 2011 ESRD PPS proposed rule.

Table 4.8 Modeled case-mix adjustment for an expanded ESRD prospective payment system comparison of payment models with vs. without patient race/ethnicity

	Modeled case-mix adjustment[1]		
	Payment model without race/ethnicity	Payment model with race/ethnicity from SIMS/CMS Form 2728	Payment model with race from the Medicare EnrollmentDatabase(EDB)
	MultiplierEB	MultiplierEB	MultiplierEB
Adjustments for dialysis patient characteristics			
Age (years)			
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	--	1.646	0.939
Hispanic[2]	--	1.000	0.956
Non-Hispanic[2]	--	1.065	--
Body surface area (per 0.1m^2)	1.034	1.014	1.006
Underweight (BMI<18.5)	1.020	1.012	1.013
Duration of RRT: <4months	1.473	1.493	1.439
Alcohol/drug dependence (claims since 2000 or Form 2728)	1.150	1.085	1.074
Cardiac arrest (claims since 2000 or Form 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 Form 2728)	1.316	1.197	1.237
Hepatitis B (claims since 2000)	1.089	1.083	1.081
Specified infection from same month to 3 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 (claimssince2000)	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 2004-2006	1.202	1.209	1.202

[1]The combined payment multipliers for patient characteristics were calculated as PmtMultEB = WeightCR × PmtMultCR + WeightSB × PmtMultSB, where PmtMultCR was the estimated multiplier from a facility level model of composite rate costs and PmtMultSB was 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 were 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 was reported separately from race on the CMS Medical Evidence Form 2728, while Hispanic was a race category in the Medicare Enrollment Database.

In the analysis using race data submitted on the Medical Evidence Form, combined composite rate and separately billable payments were 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 were 12.6 percent costlier; Whites were 14.2 percent costlier; Blacks were 20.7 percent costlier; and individuals in the category Other were 64.6 percent costlier. In the analysis using Standard Information Management System (SIMS) data to examine ethnic background, we found that non-Hispanic patients were 6.5 percent more costly than Hispanic patients.

In the analysis using EDB race data, combined composite rate and separately billable payments were lowest among those individuals categorized as Other and Hispanic. In using the category Asian as the reference group, individuals categorized as Other and Hispanic had approximately 6 percent and 4 percent lower costs, respectively than the reference group. Individuals categorized as North American Native had 7.4 percent higher costs; individuals categorized as White had 11.9 percent higher costs; and individuals categorized as Black had 17.8 percent higher costs.

In summary, UM-KECC's analyses of Medical Evidence Form and EDB race and ethnicity data demonstrated associations between race and combined CR costs and SB MAP. Hence, including race may improve the predictive value of the proposed ESRD PPS. However, there were important concerns raised in public comments about the quality of the race data in both the Medical Evidence Form 2728 and the EDB. Specifically, differing versions of Medical Evidence Form 2728 were reported on SIMS. Therefore, it was necessary to assign some beneficiaries to the Other category, making it difficult to assess the effect of race and ethnicity on composite rate costs and separately billable payments. Race and ethnicity classification on behalf of some segments of the population was either unavailable or defaulted into the Unknown category within the EDB. Because of these concerns, adjusting for race using these data sources could result in over- or under-payment of some dialysis facilities. It was concluded that use of these data, particularly as applied to the detailed race and ethnicity categories, was at present insufficiently reliable for calculating differential treatment costs in a payment system.

The CY 2011 ESRD PPS final rule (section "g. Race/Ethnicity" page 49108) explains that case-mix adjustment for race or ethnicity would not be included in the expanded bundle PPS. Further improvement in the accuracy of race and ethnicity data collection is needed.

Conclusion

The research underlying the ESRD PPS built upon earlier work for the BCMA. The BCMA's five age categories were retained, but new multipliers were derived with more recent data and reflected the impact of age on both CR and SB costs. Additional demographic adjusters for sex and race/ethnicity were also

researched, but were ultimately not adopted by CMS as part of the ESRD PPS. An upward adjustment for female patients appeared in the proposed rule, but was dropped following the public comment period. Race/ethnicity was found to be related to costs, but was not adopted as an adjustment factor due to concerns about the accuracy and consistency of administrative data identifying patients' race/ethnicity.

F. MEASURES OF PATIENT BODY SIZE IN THE ESRD EXPANDED BUNDLE PROSPECTIVE PAYMENT SYSTEM

Background/Rationale

The Centers for Medicare & Medicaid Services (CMS) has included adjustments for patient body size in the dialysis payment system since the 2005 implementation of the Basic Case Mix Adjustment (BCMA) for Composite Rate (CR) services. This section describes the research underlying the measures selected to represent patient body size in the BCMA, and the updating of the associated payment adjustment in the expanded bundled prospective payment system implemented in 2011.

The rationale for exploring patient size as a case-mix adjuster is twofold. Based on clinical input, larger patients would be expected to have higher costs due to factors such as the need for more dialysis resources (e.g., time on machine, membrane, dialysate) to achieve a comparable "dose" of dialysis as smaller patients. In addition, larger patients would be expected to require greater dosages of injectable medications than smaller patients to achieve the same clinical outcomes (this is particularly relevant to the injectable medications added to the bundle in 2011). The analyses described below considered several measures of body size, arriving at body surface (BSA) area as a recommended measure.

Clinical input also suggested that it may be more costly to care for frail patients, who may be malnourished or suffering from conditions such as wasting syndrome. Adjusting only for larger body size might underestimate the costliness of caring for frail (underweight) patients who might require extra resources such as staff attention. Therefore, the analysis also considered measures of frailty (that is, low Body Mass Index (BMI)) and malnourishment as adjusters to offset the downward payment adjustment for small patients that would arise from adjusting only for larger body size. Notably, while frailty and size have some correlation, they are measuring distinct concepts: as described in more detail below, BSA is a continuous variable reflecting *absolute* size while BMI is a dichotomous variable reflecting respective frailty or robustness (low weight *relative* to height).

Patient Body Size in the Basic Case Mix Adjustment (BCMA) for the Composite Rate

In the development of the BCMA system for CR services, which was implemented in 2005, analyses were conducted of the relationships between various measures of body size and CR costs. Patient weight (kg) and height (m) recorded at the onset of dialysis were obtained from CMS Form 2728 and were used to calculate BMI (kg/m^2) and in the calculation of several measures of body size. BSA was calculated as a function of height (H) and weight (W) using the following formula (Dubois and Dubois 1916): BSA = 0.007184 x H0 $^{.0725}$

x $W0^{.0425}$. BMI values below 18.5 kg/m^2 were used to identify patients who were underweight (CDC 2004; NIH 2004).

Average ESRD patient BSA was a statistically significant and consistent predictor of average treatment costs, indicating higher costs for larger adult patients. The estimated increment in cost was 3.7 percent for every 0.1 m^2 increase in patient BSA. In the same models that included BSA, underweight status was found to be an independent predictor of treatment costs. Average treatment costs are an estimated 11.2 percent higher for patients who are considered to be underweight, independent of the lower average treatment costs that were observed based on their smaller body size. These results suggest that average treatment costs are lowest for patients who are smaller but are not considered to be underweight. Adjusting payment downward for small body size (i.e., for low BSA) without adjusting payment upward for underweight (i.e., for BMI below 18.5 kg/m^2) could result in significant underpayment for frail patients. These results were reflected in the BCMA payment model, which is shown in Table 4.9 below.

Table 4.9 The Basic Case-Mix Adjustments for the Composite Rate, 2000-02[1]

Case-Mix Factor	Estimated Multiplier	P-value	95% CI
Age			
18-44	1.223	<0.001	(1.142, 1.308)
45-59	1.055	0.115	(0.987, 1.127)
60-69	1.000	Reference	
70-79	1.094	0.005	(1.028, 1.164)
80+	1.174	<0.001	(1.089, 1.264)
Body surface area (per 0.1 m^2)	1.037	<0.001	(1.029, 1.044)
Body mass index			
<18.5 kg/m^2	1.112	0.043	(1.003, 1.232)
≥18.5 kg/m^2	1.000	Reference	
		R^2	
All covariates: case-mix and control variables		0.3595	
Control variables only		0.3488	

[1]n=8,236. Facility control variables include: skilled nursing facility (SNF) wage index, facility size, hospital-based (versus freestanding), chain ownership, % with URR≥65, % pediatric, payment exception status, and year of cost report.

Alternative Body Size Measures

Before selecting the body size measures in the CY 2011 ESRD PPS Final Rule, we studied the relationship between body size and average treatment costs using several body size measures, including weight, five alternative formulas for calculating BSA (Du Bois and Du Bois, 1916; Boyd, 1935; Gehan and George, 1970; Haycock, Schwartz, and Wisotsky, 1978; Mosteller, 1987), total body water (TBW) calculated using the Chertow formula (Chertow et al., 1997) and BMI. The ability of each body size measure to explain variation in average treatment costs was evaluated by comparing R-square (R^2) values from models that added a measure of average body size to a base model that included facility control variables, age (five groups) and underweight.

All body size measures that were tested were statistically significant predictors of cost. Compared to a base model that did not include a body size measure (R^2=33.01 percent), models that included average body size yielded R^2 values that ranged from a low of 33.06 for BMI to a high of 33.73 percent for TBW (Table 4.10). TBW was slightly more predictive of costs than was BSA (R^2=33.69 percent). Given the typical patient-to-patient variation in each of these measurements, the magnitudes of the effects were similar for BSA (4 percent higher costs for every 0.1 m^2 increase in BSA), weight (5 percent per 10 kg) and TBW (4 percent per 4.0 L.), while a smaller effect was observed for BMI (1 percent per 3 kg/m^2). However, calculation of TBW using Chertow's method requires information about the patient's age, sex and diabetic status in addition to measurements of height and weight, which are sufficient for calculating BSA. BSA calculated using the Du Bois and Du Bois formula (1916) was slightly more predictive of costs than BSA calculated using one of the other four formulas (Boyd 1935; Gehan and George 1970; Haycock, Schwartz and Wisotsky 1978; Mosteller 1987). Therefore, this measure was employed in the model in the CY 2011 ESRD PPS final rule.

Table 4.10 Analyses of Alternative Measures of Body Size, 2000-2002[1]

Body size measure	R^2	Multiplier	P-value
None	0.3301	N/A	N/A
Body surface area (per 0.1 m^2)	0.3369	1.04	<0.001
Weight (per 10 kg)	0.3353	1.05	<0.001
Total Body Water (per 4.0 DL)	0.3373	1.04	<0.001
BMI (per 3 kg/m^2)	0.3306	1.01	0.013

[1]n=8,471. Other facility covariates include: SNF wage index, facility size, hospital-based (versus freestanding), chain ownership, % with URR≥65, year of cost report, % by age group (pediatric and five adult age groups) and % underweight.

Alternative Underweight Measures

A standard clinical definition of underweight status, BMI < 18.5 kg/m2 (NIH 2004; CDC 2004), was used in testing whether patients who are underweight or malnourished may be more costly to treat. We also tested whether higher costs are also observed for patients with BMI values that are relatively low but slightly exceed 18.5 kg/m^2. While the average facility had 4.6 percent of patients with a BMI less than 18.5, 5.4 percent of patients had a BMI between 18.5 and 20, which is the low end of the normal BMI range of 18.5 to 25 (NIH, 2004; CDC, 2004). As shown in Table 4.11 treatment costs were not significantly elevated for BMI values between 18.5 and 20 kg/m^2 relative to BMI greater than 20 (multiplier = 1.04 which equals 4 percent higher costs, p=0.459). This result does not support expanding the range for the upward payment adjustment for underweight patients to include those with a BMI between 18.5 and 20. A model that combines all patients with BMI less than 20 kg/m^2 estimates a single multiplier that is marginally significant (7 percent higher costs, p=0.06). However, this multiplier represents the average effect across two BMI groups that do not appear to have similar effects on cost, and the model is slightly less predictive overall (slightly lower R^2).

Table 4.11 Low BMI multipliers, 2000-2002[1]

BMI category	Average % of patients	Multiplier	P-value	R^2
<18.5 kg/m^2	4.6	1.11	0.043	0.3595
≥18.5 kg/m^2	95.4	1.00	Reference	
<18.5 kg/m^2	4.6	1.12	0.039	0.3595
18.5 to 20 kg/m^2	5.4	1.04	0.459	
≥20 kg/m^2	90.0	1.00	Reference	
<20 kg/m^2	10.0	1.07	0.060	0.3594
≥20 kg/m^2	90.0	1.00	Reference	

[1]n=8,236. Other facility covariates include: SNF wage index, facility size, hospital-based (versus freestanding), chain ownership, % with URR≥65, year of cost report, payment exception status, % by age group (pediatric and five adult age groups), and average BSA.

Applying the Basic Case-Mix Adjustment

The multipliers reported in Table 4.9 can be used to derive case-mix adjusted payment rates for individual patients in the following way. The principal step is to calculate a patient specific multiplier that will be applied to the facility's composite rate. This calculation applies the estimated multipliers to the patient's characteristics (age, BSA, and underweight status). The necessary patient-specific information, which includes age, weight and height, has been collected on Medicare outpatient dialysis facility claims since January 1, 2005 (Federal Register, 2004a).

A patient-specific multiplier (PM) can then be calculated as

$$PM = MAge * MUnderweight * MBSA$$

where MAge is the relevant age multiplier for the patient (1.223 for ages 18-44, 1.055 for ages 45-59, 1.000 for ages 60-69, 1.094 for ages 70-79, and 1.174 for ages 80+), MUnderweight is the relevant underweight multiplier (1.112 if underweight and 1.000 if not underweight), and the BSA multiplier, MBSA, reflects a payment adjustment of 1.037 for every 0.1 m^2 increase in a patient's BSA (see Methods for BSA formula). That is,

$$PM = MAge * MUnderweight * 1.037((BSA-1.84)/0.1)$$

Note that the BSA multiplier is calculated such that a patient having exactly the average BSA value of 1.84 m^2 that was observed among Medicare dialysis patients in 2002 will have a BSA multiplier of 1.000, or will have

no payment adjustment based on BSA. Patients having BSA values that are above average (>1.84 m^2) and below average (<1.84 m^2) will have BSA multipliers that are above and below 1.000, respectively.

For example, using the formula above, the case-mix multiplier for a 47-year old person (MAge = 1.055) who is not underweight (MUnderweight=1.000) and has a BSA of 2.0 m^2 is calculated as:

$$PM = 1.055 * 1.000 * 1.037((2.0-1.84)/0.1) = 1.055 * 1.000 * 1.060 = 1.118.$$

For this patient, there is an upward payment adjustment of 5.5 percent based on age, no payment adjustment for being underweight, and an upward payment adjustment of 6.0 percent based on having a larger than average BSA.

Patient Body Size in the Expanded Bundle Prospective Payment System

The same measures of BSA and low BMI employed in the BCMA were used in the Expanded Bundle Prospective Payment System (ESRD PPS) implemented in 2011. The ESRD PPS continued to use the measures of body size (BSA calculated using the Du Bois and Du Bois 1916 formula, and BMI < 18.5); no alternative measures of body size were considered in the development of the ESRD PPS. Multipliers for BSA and low BMI were estimated for both composite rate and separately billable services costs using data for 2006-2008. The resulting adjustments in the CY 2011 ESRD PPS proposed rule (75 FR 49029) are a BSA adjustment of 1.020 per 0.1m^2 and a BMI<18.5 adjustment of 1.025. Note that these multipliers reflect the impact of body size on both CR and separately billable (SB) costs, whereas the BCMA reflected only the impact on CR costs. The two equation method of obtaining overall multipliers is described in detail in Section II. of this report.

In addition to estimating a new multiplier that reflects more recent data and the impact on both CR and SB costs, the treatment of BSA ESRD PPS differs from the BCMA due to a re-standardization of the average BSA in the dialysis population. The BSA reference value in the BCMA was 1.84, based on the national average BSA among Medicare dialysis patients from 2000 through 2002. This average BSA was calculated using height and weight values reported at start of dialysis on the CMS Medical Evidence Form (CMS Form 2728), the only available data source for these measurements prior to the implementation of the BCMA. Using more recent height and weight values reported on dialysis facility claims for patients treated from 2006 through 2008, the national average BSA rose to 1.87. In developing the payment adjustments for the expanded PPS, a BSA reference value of 1.87 was used. (Recall that the BSA multiplier for the average patient (reference value) is set to 1.000; this implies that all patients above (below) the reference value receive upward (downward) payment adjustments for BSA).

To illustrate the impact of Increasing the BSA reference value, we calculate the ratio of payments with the ESRD PPS reference value relative to the BCMA reference value, while holding the multiplier constant at the original BCMA level (this isolates the impact of the re-standardization independent of the impact of the change in the multiplier). The re-standardization reflects the net impact of the change in data source (height and weight at incidence as reported in Form 2728 for the BCMA vs. current height and weight reporting in claims for the ESRD PPS) and any changes in the overall patient population between 2000 and 2002 and 2006 through 2008. The re-standardization would have the effect of reducing the BSA adjustment by a factor of:

$$1 / (1.037^{((1.87-1.84)/0.1)}) = 0.9892. \quad (1)$$

For example, as described above, a patient with a BSA of 1.94 (holding the BSA multiplier constant at the BCMA level of 1.037) would have a BSA adjustment of

$$\text{Multiplier}_{BSA} = 1.037^{(1.94-1.84/0.1)} = 1.0370 \quad (2)$$

under the BCMA which includes a BSA reference value of 1.84.

However, if a BSA reference value of 1.87 was used, a smaller BSA adjustment would result:

$$\text{Multiplier}_{BSA} = 1.037^{(1.94-1.87/0.1)} = 1.0258. \quad (3)$$

The ratio of the two BSA adjustments is:

$$1.0258 / 1.0370 = 0.9892. \quad (4)$$

as implied by equation (1). This corresponds to a reduction of 1.08 percent (1 - 0.9892 = 0.0108) in payment for ages 18 and older by increasing the BSA reference value from 1.84 to 1.87.

Conclusion

Extensive research on the measures of body size most predictive of cost was undertaken in the development of the BCMA. The measures selected as a result of that research were retained in the development of the ESRD PPS, but were updated in three ways. First, the multipliers were recalculated using 2006-2008 data rather than 2000-2002 data. Second, because the ESRD PPS incorporated formerly separately billable services, the payment multipliers reflected a weighted average of the multipliers based on the two equation model (composite rate and separately billable). Third, the reference group was re-standardized to reflect changes that could have arisen due to changes in average patient size over time as well as changes in the data

available to ascertain size (Medical Evidence CMS Form 2728 reflecting size at incidence for the BCMA vs. claims-reported current size for the ESRD PPS).

G. ONSET OF RENAL REPLACEMENT THERAPY

Background/Rationale

The initiation of dialysis is a tumultuous time for many patients. Despite increased attention to dialysis planning for patients who are followed by a nephrologist, many dialysis patients are either not seen by a nephrologist or do not have their chronic kidney disease identified until very late in the progression toward end-stage renal disease (ESRD). This contributes to a high prevalence of patients who have not received adequate modality education, do not have an established permanent vascular access (potentially exposing them to greater infection risks from catheters), and do not have prior treatment for anemia or mineral and bone disease (potentially requiring higher doses of drugs until their condition stabilizes). Markers of this instability also include hospitalization and death rates higher than those experienced by patients who have been on dialysis for a year or more. Interruptions in care arising from hospitalization leave dialysis chairs unexpectedly empty, potentially raising the average cost per treatment delivered. Due to all of these factors, there was an expectation that treating patients at or near the onset of ESRD would be particularly costly to dialysis facilities. This expectation led to concerns that a bundled payment system might impair access to care for new patients absent an adjuster that captured these temporarily high costs.

In this section, we describe a series of analyses that were conducted to establish the path of costs as a function of time from the onset of ESRD. Initially, costs were broken out based on how many months the patient had been receiving dialysis. These analyses indicated that costs were substantially higher during the early months of therapy and declined gradually throughout the first year.

Development of Adjuster for Time Since Onset of Dialysis

The onset of ESRD was determined from the date of first dialysis reported on the Centers for Medicare & Medicaid Services (CMS) Form 2728 and the onset period continues through the first four months a patient is receiving dialysis (Calendar Year (CY) 2011 ESRD Prospective Payment System (PPS) Proposed Rule: 74 FR 49952). As described in earlier work and noted above, month by month analyses demonstrated that separately billable payments were highest in the first four months, with a significant decline and stabilization thereafter. The regression model presented in the proposed rule (74 FR 49952) reflected the substantial costs of dialysis near onset, with a 1.473 adjustment factor to be applied to both in-center and home dialysis patients (see far right column in Table 4.12). Those higher costs could reflect a number of the factors described in the Background/Rationale section above.

The cost analyses for patients receiving dialysis were based on Medicare claims data. Therefore, the elevated cost in the initial months largely reflected the experience of patients who were already covered by Medicare at

dialysis onset (mostly those over age 65). Those individuals whose Medicare eligibility is solely based on ESRD and who are treated by in-center hemodialysis face a waiting period for Medicare eligibility (eligible on the 1st of the month at least 90 days post-initial treatment, so effectively a 90-120 day waiting period depending on the date of first treatment). As a result, most of the defined onset period will have passed before those individuals appear in the Medicare claims.

In March 2010, the still evolving models were updated with CY 2006-2008 data (Table 4.12). Here, the onset of dialysis multiplier increased to 1.529, somewhat higher than the onset dialysis multiplier of 1.473 presented in the proposed rule with CY 2004-2006 data. In addition to newer data, CMS decided to exclude from these analyses patients who had home dialysis training treatments reported on the claims for the month.

Additional models were developed as the number of comorbidities was iteratively reduced from the 12 adjusters in the proposed rule. In a model which included only 8 comorbidities, onset of dialysis was first included and then excluded to assess changes in the model's predictive power. When onset was removed, model predictive power declined slightly for the composite rate (CR) model (42.4 percent to 42.2 percent) and more substantially for the separately billable (SB) model (6.6 percent to 5.4 percent), reinforcing the importance of the onset variable on the SB model's predictive power. (Note that the R^2 values mentioned are not directly comparable to those found in Table 4.12 because onset was removed from a model with fewer comorbidities.) When onset was removed, the adjustments for the oldest age groups increased: there was a 3.1 percent adjustment for ages 70-79 and a 3.9 percent adjustment for ages 80+. These two age groups would be most likely to be eligible for the onset adjustment since they would be Medicare eligible for all four months. The adjustments for most comorbidities were similar in the model that included or excluded onset.

We considered other models that shortened the eligibility time for the onset period from four months to only three months. With the four-month onset period, if a patient had not been Medicare eligible at the start of dialysis, in the fourth month of treatment he/she would surpass the 90 day waiting period and the facility would receive an onset adjustment for at least part of the final month, whereas the three-month onset period would effectively preclude those whose Medicare eligibility was based solely on ESRD from receiving the adjustment. The model in the CY 2011 ESRD PPS Final Rule was analyzed with both four-month and three-month onset periods. Table 4.13 shows the impact on the SB model when limiting the onset of dialysis adjustment to the first three months. The frequency of the adjustment declined from 4.9 percent to 3.2 percent of the treatments, but the magnitude of the adjustment increased from 1.450 to 1.581. This suggests that the onset of dialysis adjustment was not driven by new patients who became Medicare eligible in the fourth month of treatment; had those patients been the primary ones experiencing high costs near onset, their effective exclusion by switching to a three-month definition of onset would have decreased the onset adjuster. The magnitude of other adjustments did not change significantly.

The model appearing in the CY 2011 ESRD PPS Final Rule and presented in Table 4.14 includes a payment multiplier of 1.510 for patients in the first four months of dialysis.

Table 4.12 Calculation of payment multipliers for an expanded ESRD PPS, ages 18 and older: Proposed Rule models

Variable	Percent of Medicare HD-equivalent dialysis treatments	CR model, 2006-2008 n=13,236 R^2: 43.2%	SB model, 2006-2008 n=951,761 R^2: 10.3%	Modeled case-mix adjustment* (based on 2006-2008 data)	Modeled case-mix adjustment in Proposed Rule (based on 2004-2006 data)
		$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$	$PmtMult_{EB}$
Adjustments for dialysis patient characteristics					
Age (years)					
18-44	13.5%	1.197	1.126	1.175	1.194
45-59	26.9%	0.965	1.092	1.006	1.000
60-69	23.8%	0.995	1.093	1.026	1.012
70-79	22.8%	1.003	1.046	1.017	1.057
80+	12.9%	1.000	1.000	1.000	1.076
Female	45.8%	1.085	1.135	1.101	1.132
Body surface area (per 0.1 m^2)	1.87	1.027	1.027	1.027	1.034
Underweight (BMI <18.5)	4.0%	1.000	1.066	1.021	1.020
Time since onset of renal dialysis < 4 months	4.9%	1.546	1.491	1.529	1.473
Alcohol/drug dependence (claims since 2000 or 2728)	9.8%	1.065	1.134	1.087	1.150
Cardiac arrest (claims since 2000 or 2728)	3.6%	1.000	1.116	1.037	1.032
Pericarditis from same month to 3 months ago	0.4%	1.000	1.566	1.181	1.195
HIV/AIDS (claims since 2000 or 2728)	2.5%	1.574	1.201	1.455	1.316
Hepatitis B (claims since 2000)	2.8%	1.113	1.053	1.094	1.089
Specified infection from same month to 3 months ago					
Septicemia	9.5%	1.000	1.741	1.237	1.234
Bacterial pneumonia and other pneumonias/opportunistic infections	2.4%	1.457	1.418	1.444	1.307
Gastro-intestinal tract bleeding from same month to 3 months ago	1.1%	1.000	2.023	1.327	1.316
Hereditary hemolytic or sickle cell anemias (claims since 2000)	2.3%	1.074	1.192	1.112	1.226
Cancer (claims since 2000; excludes non-melanoma skin cancer)	21.9%	1.151	1.091	1.131	1.128
Myelodysplastic syndrome (claims since 2000)	1.5%	1.000	1.253	1.081	1.084
Monoclonal gammopathy (claims since 2000)	1.8%	1.000	1.059	1.019	1.021
Low volume facility adjustment					
Facility size < 3,000 treatments during each year from 2006-2008	0.6%	1.412	0.916	1.210	1.202

Table 4.13 Separately billable payment multipliers for an expanded PPS, ages 18 and older: Onset of dialysis adjustment at three versus four months

Variable	Percent of Medicare HD-equivalent dialysis treatments	SB model, 2006-08 (n=8,603,325 patient months)	
		Onset of dialysis adjustment applies for up to 4 months R^2 at patient-month level: 3.3%	**Onset of dialysis adjustment applies for up to 3 months** R^2 at patient-month level: 3.3%
		$PmtMult_{SB}$	**$PmtMult_{SB}$**
Adjustments for patient characteristics			
Age (years)			
18-44	13.5%	0.996	0.996
45-59	26.9%	0.992	0.992
60-69	23.8%	1.000	1.000
70-79	22.9%	0.963	0.964
80+	13.0%	0.915	0.916
Body surface area (per 0.1 m^2)	1.87	1.014	1.014
Underweight (BMI <18.5)	4.0%	1.078	1.078
Time since onset of renal dialysis < 4 months	4.9%	1.450	--
Time since onset of renal dialysis < 3 months	3.2%	--	1.581
Pericarditis (acute^^)	0.4%	1.354	1.358
Bacterial pneumonia (acute^^)	2.0%	1.422	1.425
Gastro-intestinal tract bleeding (acute^^)	1.1%	1.571	1.572
Hereditary hemolytic or sickle cell anemia (chronic^^)	2.0%	1.225	1.224
Myelodysplastic syndrome (chronic^^)	1.6%	1.309	1.310
Monoclonal gammopathy* (chronic^^)	1.2%	1.074	1.074
Low volume facility adjustment Facility size < 4,000 treatments during each year from 2006-08	1.6%	0.975	0.975

^^Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.
*Excludes multiple myeloma.

Table 4.14. Payment Multipliers for an Expanded Bundle of Services, ages 18 and older, 2006-08 (Base Rate - $229.63)

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3, 4]
	Composite rate services[1]	Separately billable services[2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics			
Age (years)			
18-44	1.254	0.996	1.171
45-59	1.023	0.992	1.013
60-69	1.000	1.000	1.000
70-79	1.033	0.963	1.011
80+	1.063	0.915	1.016
Body surface area (per 0.1 m^2)	1.023	1.014	1.020
Underweight (BMI <18.5)	1.000^	1.078	1.025
Time since onset of renal dialysis < 4 months	1.539	1.450	1.510
Pericarditis (acute*)	1.000^	1.354	1.114
Bacterial pneumonia (acute*)	1.000^	1.422	1.135
Gastro-intestinal tract bleeding (acute*)	1.000^	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic*)	1.000^	1.225	1.072
Myelodysplastic syndrome (chronic*)	1.000^	1.309	1.099
Monoclonal gammopathy[5] (chronic*)	1.000^	1.074	1.024
Low volume facility adjustment Facility size < 4,000 treatments during each year from 2006-08	1.347	0.975	1.189

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

1The CR payment multipliers (PmtMultCR) are based on a facility level log-linear regression model of the average composite rate cost/session for 2006-08 (n=12,974 facility years). This model also include facility characteristics (an indicator of low volume facilities as a potential payment variable and control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate exception, % of patients in the facility with URR<65%, and % of home dialysis training treatments in the facility) and the percent of pediatric patients as additional covariates (R2 =41.0%).

2Based on a patient-month level log-linear regression model of separately billable Medicare Allowable Payments/session for 2006-08 (n=8,603,325 patient months) that includes facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates. An R2 value of 5.1% was calculated at the patient level based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain the variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R2 for the patient-month level log-linear SB model was 3.3%.

3The 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 MAP. Based on total estimated costs of $177.72 per session for composite rate services, $83.97 per session for separately billable services, and $261.69 per session for composite rate and separately billable services ($177.72+$83.97), the relative weights are WeightCR=0.6791 for composite rate services ($177.72/$261.69) and WeightSB=0.3209 for separately billable services ($83.97/$261.69). The combined low volume multiplier was calculated relative to all other facilities.

4To 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 model (which correspond to the CR and SB multipliers of 1.347 and 0.975, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.189. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

5Excludes multiple myeloma.

*Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

Conclusion

Costs were particularly high during the first four months of dialysis. Therefore, after estimating a number of alternative models, we concluded that the most parsimonious way of capturing the highest cost period was to include a single case-mix adjuster for the first four months. The single adjuster successfully captured a substantial majority of the excess costs that occur during the first year of dialysis relative to the baseline spending levels achieved among longer-term patients.

V. FACILITY-LEVEL ADJUSTMENT (LOW-VOLUME FACILITIES)

A. BACKGROUND/RATIONALE

One of the requirements of the Medicare Improvements for Patients and Providers Act (MIPPA) for the development and implementation of the expanded End Stage Renal Disease (ESRD) Prospective Payment System (PPS) was the inclusion of a payment adjustment for low-volume dialysis facilities. According to the statute, the new payment system:

> shall include 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.[1]

As a starting point for developing a low-volume adjustment that satisfied the MIPPA requirements, we examined the overall relationship between facility size and average facility costs for the services being considered for the expanded ESRD PPS. Results of a facility-level analysis of the total costs for composite rate and separately billable services were presented in the report, "End Stage Renal Disease Payment System: Results of Research on Case-mix Adjustment for an Expanded Bundle," (UM-KECC 2008, pp. 37-39). For these analyses, dialysis facility size was measured based on the total number of hemodialysis-equivalent treatments reported on Medicare Cost Reports. The results of this analysis indicated significantly lower average cost per treatment for larger dialysis facilities, suggesting economies of scale in providing dialysis-related services. Previous research had also identified economies of scale among dialysis facilities (Dor et al. 1992; Hirth et al. 1999).

Extensions of this type of analysis, using facility categories that were defined principally based on facility size, were used to inform the development of a low-volume payment adjustment under the expanded ESRD PPS. These further analyses would be used to inform CMS policy decisions on key issues such as the facility size threshold used to ascertain low-volume facility status, the use of other criteria to determine eligibility for the low-volume payment adjustment, and the magnitude of the payment adjustment under the PPS. These aspects of the low-volume adjustment and key related analyses and supporting materials that were provided by UM-KECC are reviewed below.

[1] The requirements for a low-volume facility payment adjustment as part of the expanded ESRD PPS were included on p. 2554 of the legislation.

B. FACILITY SIZE THRESHOLDS AND OTHER ELIGIBILITY CRITERIA

A key consideration in establishing a payment adjustment based on facility size involved determining the threshold(s) that would be used to identify the small dialysis facilities that would be eligible for the adjustment. Alternative thresholds were considered for defining groups of smaller facilities that could potentially be designated as low-volume facilities (Table 5.1). Two relevant factors in selecting the low-volume threshold(s) were the number of facilities that might be eligible for the adjustment and the extent to which facilities falling within that threshold incurred higher costs.

Table 5.1 Facility size and ownership type, 2004-2006

Total dialysis sessions at facility based on cost reports	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%
2,000-3,000	140	27.0%	63	12.1%	301	58.0%	15	2.9%	519	100.0%	4.2%
3,000-4,000	156	20.7%	86	11.4%	493	65.4%	19	2.5%	754	100.0%	6.2%
4,000-5,000	161	18.9%	102	12.0%	580	68.0%	10	1.2%	853	100.0%	7.0%
5,000 to 10,000	628	15.3%	361	8.8%	3,079	75.2%	29	0.7%	4,097	100.0%	33.5%
10,000+	1,061	18.8%	574	10.2%	3,900	69.2%	104	1.8%	5,639	100.0%	46.2%
Total	2,277	18.6%	1,233	10.1%	8,500	69.6%	203	1.7%	12,213	100.0%	100.0%

One option for the low-volume adjustment was to base it on a single facility size threshold. This threshold would distinguish facilities that would be eligible for the full low-volume adjustment (within that threshold) from facilities that would not receive the low-volume adjustment (exceeded that threshold). Especially if the low-volume adjustment was relatively large, a potential unintended consequence might be that this would provide a disincentive for facilities approaching this threshold to continue to grow such that they would exceed this threshold and possibly operate at a more efficient scale. Another option that was identified was to phase out the adjustment gradually, so that there were no size thresholds that would lead to a sharp decrease in payment. However, a potential drawback was that this would increase the complexity of the low-volume adjustment. Regardless of which option was used, it was necessary to identify a range of facility sizes to determine eligibility for the adjustment.

Facility size was classified using three categories for the total number of hemodialysis-equivalent treatments: <5,000, 5,000-9,999, and 10,000 or more. The largest facility size category included close to one half of the

facilities. The category of facilities having less than 5,000 total treatments, which corresponds to approximately 32 full-time equivalent dialysis patients per year (assuming 156 treatments/patient/year), included the smallest 20percent of facilities nationally (Table 5.1). This group of facilities was then divided into several smaller groups of facilities (e.g., <2,000, 2,000-2,999, 3,000-3,999, 4,000-4,999) to explore potential thresholds for a low-volume adjustment. These more detailed facility size categories included a progressively larger number of facilities as facility size increased. It was noted that within this group of facilities with less than 5,000 treatments, there was a tendency for the smallest facilities to be less likely to be owned by a large dialysis organization (Table 5.1).

Further analyses were used to distinguish facilities that were consistently operating at a smaller scale, in contrast to facilities that may have recently opened or may only occasionally have fallen below a given small facility threshold. This refinement of the low-volume definition had the effect of reducing the number of facilities that would be eligible for the adjustment. For example, a group of potential low-volume facilities was defined to include those with less than 3,000 total treatments for each of three consecutive years and not opening or closing during that three-year period. Most of the facilities having less than 3,000 total treatments in the most recent year that were excluded from consideration for the low-volume adjustment either opened sometime during the three-year period or had ≥ 3,000 treatments in at least one of the two earlier years (Table 5.2). The remaining smaller facilities that satisfied these other low-volume criteria were found to be more likely to be located in a rural area, less likely to be owned by an Large Dialysis Organization (LDO), more likely to be hospital-based facilities and more likely to be pediatric facilities compared to larger facilities (Table 5.3).

Table 5.2 Reasons that facilities were not considered eligible for the low-volume facility adjustment for those with less than 3,000 dialysis sessions during 2007

Reason	Facilities	
	n	%
Opened during 2005-07 (based on Medicare certification date)	81	25.1%
Probable opening date during 2005-07 (no Medicare certification date was available, but no dialysis sessions were reported in either the Medicare claims or SIMS for 2005-06)	109	33.7%
Closed during 2007	1	0.3%
Facility reported >=3000 sessions:		
In both 2005 and 2006	69	21.4%
In either 2005 or 2006	45	13.9%
Satellite facility with no identified parent hospital	5	1.5%
SIMS data on number of dialysis sessions not available for 2005 and/or 2006	12	3.7%
Invalid facility closing date (prior to 2007)	1	0.3%
Total	323	100.0%

Table 5.3 Facility characteristics for the potential low-volume adjustment, 2006

	Dialysis facilities*		Medicare sessions	Rural	Facility ownership: Large dialysis organization	Hospital based	% Medicare (based on sessions from cost reports^)	Facilities with at least 50% of Medicare sessions for pediatric patients	Isolated Essential Facility (IEF) prior to 2005
	n	% of all facilities (n=4,399)	% of total (n=34.5M)						
Low-volume facility definition									
Did not open or close and reported < 3,000 sessions for each year from 2004-2006	89	2.0%	0.4%	52.8%	56.2%	13.5%	75.8%	4.5%	1.1%
Did not open or close and reported <3,000 sessions during 2006	309	7.0%	1.7%	38.8%	44.7%	22.7%	69.9%	1.9%	1.3%
Facilities with ≥ 3,000 sessions	4,014	91.2%	98.1%	20.9%	69.8%	7.2%	72.2%	0.2%	1.0%

*Excludes facilities that opened or closed during 2006 (n=76).
^Excludes approximately 1% of facilities where the % Medicare was not available.

C. Magnitude of Potential Payment Adjustment for Low-Volume Facilities

Multivariate analyses of the relationship between facility size and average facility costs for services to be included in the expanded PPS were used to consider the potential magnitude of the low-volume adjustment. The average cost per treatment for composite rate services was found to be substantially higher for smaller dialysis facilities (Table 5.4). This component of dialysis facility costs, which includes the cost of providing dialysis and certain other services covered under the composite rate, would reflect any efficiencies that result from spreading costs that are relatively fixed (e.g., facility overhead) over a larger number of treatments. The magnitude of this association varied depending on the threshold that was used for small facilities, and became progressively larger as the threshold was reduced from 4,000 to 3,000 to 2,000 total treatments per year (Table 5.4, Models 1-3). In contrast, the estimated costs for separately billable services, which were based on claims data and would primarily reflect variation in the use of these services, were not found to be higher for similarly defined groups of smaller facilities (Table 5.4, Models 1-3).

Consideration was also given to the possibility that the costs incurred by small facilities may be largest for those located in rural areas, after accounting for differences in wage rates (which would be accounted for separately through the wage adjustment). However, based on the same three alternative facility thresholds mentioned above, the increment in costs associated with smaller facility size was found to be relatively similar

for facilities in both urban and rural areas (Table 5.4, Models 4-6). That is, there were similar additional costs being incurred by smaller facilities regardless of whether they were located in urban or rural areas.

Table 5.4 Analysis for low-volume facility size, 2004-2006, Models 1-6

Analysis for low-volume facility size, 2004-2006, Model 1					
	*Facility level log-linear model of average cost per session (n=11,814) R^2: 36.64% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R^2: 8.69% Average $82.45/session		
Variable	**CR Multiplier**	**P-value**	**SB Multiplier**	**P-value**	**Combined**
Facility size: < 2,000 treatments	1.431	<.0001	1.007	0.5739	1.293
Facility ownership type					
Large dialysis organization	1.019	0.0001	1.158	<.0001	1.065
Regional chain or other organization	1.023	0.0003	1.060	<.0001	1.035
Unknown	1.037	0.0018	1.002	0.6808	1.025
Independent	1.000	ref	1.000	ref	1.000
Hospital-based facility	1.412	<.0001	1.021	<.0001	1.284

Analysis for low-volume facility size, 2004-2006, Model 2					
	*Facility level log-linear model of average cost per session (n=11,814) R^2: 38.09% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R^2: 8.70%		
Variable	**CR Multiplier**	**P-value**	**SB**	**P-value**	**Combined**
Facility size: < 3,000 treatments	1.365	<.0001	0.955	<.0001	1.231
Facility ownership type					
Large dialysis organization	1.021	<.0001	1.158	<.0001	1.066
Regional chain or other organization	1.024	0.0001	1.060	<.0001	1.036
Unknown	1.038	0.0009	1.001	0.7907	1.026
Independent	1.000	ref	1.000	ref	1.000
Hospital-based facility	1.413	<.0001	1.021	<.0001	1.285

Analysis for low-volume facility size, 2004-2006, Model 3					
	*Facility level log-linear model of average cost per session (n=11,814) R^2: 39.92% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R^2: 8.70% Average $82.45/session		
Variable	**CR Multiplier**	**P-value**	**SB**	**P-value**	**Combined**
Facility size: < 4.000 treatments	1.298	<.0001	0.979	<.0001	1.193
Facility ownership type					
Large dialysis organization	1.021	<.0001	1.158	<.0001	1.066
Regional chain or other organization	1.024	<.0001	1.060	<.0001	1.036
Unknown	1.040	0.0005	1.002	0.7338	1.027
Independent	1.000	ref	1.000	ref	1.000
Hospital-based facility	1.418	<.0001	1.021	<.0001	1.288

*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 the 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, monoclonalgammopathy, calendar year, composite rate payment exception, and % of patients in the facility with URR<65%.

Table 5.4 Analysis for low-volume facility size, 2004-2006, Models 1-6 (continued)

Analysis for low-volume facility size, 2004-2006, Model 4					
	*Facility level log-linear model of average cost per session (n=11,814) R^2: 36.22% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R^2: 8.69% Average $82.45/session		
Variable	**CR Multiplier**	**P-value**	**SB Multiplier**	**P-value**	**Combined**
Facility: <2,000 treatments, rural	1.343	<.0001	0.936	0.0005	1.210
Facility ownership type					
Large dialysis organization	1.018	0.0002	1.158	<.0001	1.064
Regional chain or other organization	1.023	0.0003	1.060	<.0001	1.035
Unknown	1.036	0.0021	1.002	0.7274	1.025
Independent	1.000	ref	1.000	ref	1.000
Hospital-based facility	1.411	<.0001	1.021	<.0001	1.284

Analysis for low-volume facility size, 2004-2006, Model 5					
	*Facility level log-linear model of average cost per session (n=11,814) R^2: 36.91% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R^2: 8.70% Average $82.45/session		
Variable	**CR Multiplier**	**P-value**	**SB**	**P-value**	**Combined**
Fac: <3,000 treatments, rural	1.335	<.0001	0.931	<.0001	1.203
Facility ownership type					
Large dialysis organization	1.019	0.0001	1.158	<.0001	1.065
Regional chain or other organization	1.023	0.0002	1.060	<.0001	1.035
Unknown	1.038	0.0013	1.001	0.7996	1.026
Independent	1.000	ref	1.000	ref	1.000
Hospital-based facility	1.412	<.0001	1.021	<.0001	1.284

Analysis for low-volume facility size, 2004-2006, Model 6					
	*Facility level log-linear model of average cost per session (n=11,814) R^2: 37.61% Average $169.67/session		**Patient level log-linear model of MAP per session (n=890,776) R^2: 8.70% Average $82.45/session		
Variable	**CR Multiplier**	**P-value**	**SB Multiplier**	**P-value**	**Combined**
Fac: <4,000 treatments, rural	1.272	<.0001	0.958	<.0001	1.170
Facility ownership type					
Large dialysis organization	1.020	<.0001	1.158	<.0001	1.065
Regional chain or other organization	1.024	0.0002	1.060	<.0001	1.036
Unknown	1.039	0.0008	1.001	0.805	1.027
Independent	1.000	ref	1.000	ref	1.000
Hospital-based facility	1.413	<.0001	1.021	<.0001	1.285

*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 the 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 the facility with URR<65%.

The implications of the magnitude of the low-volume adjustment for other facilities not eligible for the adjustment were considered. We found that increasing the potential payment adjustment for smaller facilities over a range of 10 percent (the minimum low-volume adjustment required by MIPPA) to approximately 20 percent (model estimate of the additional costs incurred by small facilities) did not lead to a substantial reduction in the payments to other facilities that would be needed to fund the adjustment (Table 5.5). The larger potential adjustment of approximately 20 percent was based on estimates of the increment in costs for composite rate and separately billable services among facilities with less than 3,000 total treatments compared to other facilities (Table 5.6). These results were also included in the CY 2011 ESRD PPS Proposed Rule (74 FR 49922).

Table 5.5 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 2004-2006

	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	--	--	--	--	--	--
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%

Table 5.6 Payment multipliers for an expanded bundle of services, ages 18 and older, 2004-2006

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]
	Composite rate services[1]	Separately billable services[2]	
	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for dialysis patient characteristics			
Age (years)			
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	1.000	1.000	1.057
80+	1.014	1.006	1.076
Female	1.105	0.960	1.132
Body surface area (per $0.1m^2$)	1.150	0.923	1.034
Underweight (BMI<18.5)	1.124	1.149	1.020
Duration of RRT: <4 months	1.035	1.033	1.473
Alcohol/drug dependence (claims since 2000 or 2728)	1.000^	1.060	1.150
Cardiac arrest (claims since 2000 or 2728)	1.508	1.401	1.032
Pericarditis from same month to three months ago	1.155	1.139	1.195
HIV/AIDS (claims since 2000 or 2728)	1.000^	1.098	1.316
Hepatitis B (claims since 2000)	1.000^	1.595	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
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- 2006	1.383	0.940	1.202

^A multiplier of 1.000 was used for factors low-volume 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 2004-2006 (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^2=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 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^2=8.7%).

[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, 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.

Other analyses that were presented in the CY 2011 ESRD PPS Proposed Rule indicated that the costs for smaller facilities were not found to be elevated if they were in a rural location or if they had no affiliation with an LDO (Proposed Rule 2009; Tables 23 and 24, 74 FR 49972-49973). An examination of alternative low-volume thresholds, which was presented in the CY 2011 ESRD PPS Proposed Rule, revealed that relatively few dialysis facilities (n=25) continued to provide less than 2,000 treatments per year over a three-year period. When increasing the threshold to 3,000 treatments per year, the increment in costs for the small facility group compared to all other facilities fell from approximately 25 percent higher to approximately 20 percent higher when considering both composite rate and separately billable services (74 FR 49974, Tables 25 and 26). However, raising the threshold was projected to lead to a relatively large increase in the number of small dialysis facilities that would be eligible for the adjustment (to n=89 facilities). When further increasing the threshold to 4,000 treatments per year, the increment in costs did not decrease substantially (from 20 percent higher to 19 percent higher as shown in Table 27 – 74 FR 49974), but applied to a much larger number of facilities (n=241 facilities) that would then be potentially eligible for the adjustment.

D. FURTHER ANALYSIS FOR CY 2011 ESRD PPS FINAL RULE

One of the subsequent refinements to the cost analyses for the final rule involved the percentage of patients in the facility with a urea reduction ratio (URR) of less than 65 percent. This URR measure was used as a control variable in the cost models as an indicator of the quality of the hemodialysis treatment in the facility. Prior to this refinement, certain facilities that concentrated on providing home dialysis had been excluded from the model on the basis of having no URR data in the claims. As a result of the refinement, a somewhat larger number of low-volume facilities were included in the model (Table 5.7). Since these additional low-volume facilities tended to have lower costs than other previously identified low-volume facilities, the estimated low-volume multiplier declined from approximately 20 percent to 19 percent (Table 5.8).

Table 5.7 Sample size for composite rate and separately billable analyses, ages 18 and older, 2004-2006

	Includes facilities with no URR values on Medicare outpatient dialysis claims	
	No[1]	**Yes[2]**
CR analyses		
Facilities	4,250	4,314
Low volume	89	100
Other	4,161	4,214
Facility years	11,814	11,976
Low volume	267	300
Other	11,547	11,676
SB analyses		
Patient years	890,776	894,041
Patients	452,850	454,200

[1]Corresponds to the analyses used for the Proposed Rule.

[2]For facilities with no URR value, the overall mean URR in that year was used.

Table 5.8 Modeled case-mix adjustment for an expanded bundle (EB) of services, ages 18 and older, 2004-06 (Effect of URR exclusion on EB payment multipliers)

Variable	Includes facilities with no URR values	
	No[1]	Yes[2]
Adjustments for dialysis patient characteristics		
Age (years)		
18-44	1.194	1.193
45-59	1.000	1.000
60-69	1.012	1.011
70-79	1.057	1.060
80+	1.076	1.081
Female	1.132	1.129
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.034	1.149
Underweight (BMI<18.5)	1.020	1.020
Time since onset of renal dialysis: <4 months	1.473	1.457
Alcohol/drug dependence (claims since 2000 or 2728)	1.150	1.158
Cardiac arrest (claims since 2000 or 2728)	1.032	1.032
Pericarditis from same month to three months ago	1.195	1.195
HIV/AIDS (claims since 2000 or 2728)	1.316	1.312
Hepatitis B (claims since 2000)	1.089	1.087
Specified infection from same month to 3 months ago		
Septicemia	1.234	1.237
Bacterial pneumonia and other pneumonias/opportunistic infections	1.307	1.332
Gastro-intestinal tract bleeding from same month to 3 months ago	1.316	1.318
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.226	1.229
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.128	1.127
Myelodysplastic syndrome (claims since 2000)	1.084	1.084
Monoclonal gammopathy (claims since 2000)	1.021	1.020
Low volume facility adjustment		
Facility size < 3,000 treatments during each year from 2004-2006	1.202	1.188

[1]Corresponds to the EB payment multipliers in the Proposed Rule.
[2]For facilities with no URR value, the overall mean URR in that year was used.

The analyses that were used to inform the development of the low-volume adjustment for the CY 2011 ESRD PPS Proposed Rule were based on data for 2004-2006. Updated analyses for the CY 2011 ESRD PPS Final Rule were based on data for 2006-2008. The results of these analyses that were used to determine the number of eligible low-volume facilities and the magnitude of the payment adjustment were similar to those obtained for the CY 2011 ESRD PPS Proposed Rule using earlier data. That is, we found that extending the low-volume threshold from 3,000 to 4,000 total treatments did not materially affect the size of the adjustment (Tables 5.9 and 5.10). This suggested that facilities with between 3,000 and 4,000 treatments had similarly

elevated costs as did facilities with less than 3,000 treatments. We also found that extending the threshold from 3,000 to 4,000 treatments would also lead to a substantial increase in the application of this adjustment, from 0.7 percent of dialysis claims to 1.9 percent of claims (CY 2011 ESRD PPS Final Rule 75 FR 49030). Further extending the threshold to 5,000 treatments led to a somewhat smaller estimated low-volume multiplier (Table 5.11), suggesting that costs tended to be lower for facilities providing between 4,000 and 5,000 treatments compared to smaller facilities.

Table 5.9 Calculation of payment multipliers for an expanded ESRD PPS, ages 18 and older: Adjustment for bacterial pneumonia excludes other pneumonias. Low-volume facility threshold at 4,000 treatments

Variable	Percent of Medicare HD-equivalent dialysis treatments	CR model, 2006-2008 n=12,999 R^2: 41.0%	SB model, 2006-2008 n=8,617,576 patient months; R^2 at patient- year level: 5.2%^	Modeled case-mix adjustment*
		$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics				
Age (years)				
18-44	13.5%	1.256	0.995	1.173
45-59	26.9%	1.021	0.992	1.012
60-69	23.8%	1.000	1.000	1.000
70-79	22.8%	1.040	0.964	1.016
80+	12.9%	1.067	0.916	1.019
Body surface area (per 0.1 m^2)	1.87	1.023	1.014	1.020
Underweight (BMI <18.5)	4.0%	1.000	1.078	1.025
Time since onset of renal dialysis < 4 months	4.9%	1.518	1.450	1.496
Pericarditis (acute^^)	0.4%	1.000	1.355	1.114
Bacterial pneumonia (acute^^)	2.0%	1.000	1.422	1.135
Gastro-intestinal tract bleeding (acute^^)	1.1%	1.000	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic^^)	2.3%	1.000	1.238	1.076
Myelodysplastic syndrome (chronic^^)	1.6%	1.000	1.310	1.099
Monoclonal gammopathy (chronic^^)**	1.2%	1.000	1.074	1.024
Low-volume facility adjustment Facility size < 4,000 treatments during each year from 2006-2008	1.6%	1.351	0.973	1.191

Note: In the CR model presented above, the percentage of home dialysis training treatments in the facility was included as an additional control variable.

*The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable MAP. Based on total estimated costs of $177.88 per session for composite rate services, $83.94 per session for separately billable services, and $261.82 per session for composite rate and separately billable services ($177.88+$83.94), the relative weights are $Weight_{CR}$=0.6794 for composite rate services ($177.88/$261.82) and $Weight_{SB}$=0.3206 for separately billable services ($83.94/$261.82). The combined low-volume multiplier was calculated relative to all other facilities.

**Excludes multiple myeloma.

^The R^2 value reported above for the SB model was based on a regression model that used the average predicted SB MAP per treatment during each patient year, which was calculated by averaging the monthly predicted values for each patient from the patient-month SB model, to explain variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R^2 value for the patient-month level log-linear SB model was 3.3%.

^^Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

Low-volume facility threshold at 3,000 treatments

Table 5.10 Calculation of payment multipliers for an expanded ESRD PPS, ages 18 and older: Adjustment for bacterial pneumonia excludes other pneumonias

Variable	Percent of Medicare HD-equivalent dialysis treatments	CR model, 2006-2008 n=12,999 R^2: 41.1%	SB model, 2006-2008 n=8,617,576 patient months; R^2 at patient-year level: 5.2%^	Modeled case-mix adjustment*
		$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics				
Age (years)				
18-44	13.5%	1.254	0.995	1.171
45-59	26.9%	1.019	0.992	1.010
60-69	23.8%	1.000	1.000	1.000
70-79	22.8%	1.038	0.964	1.014
80+	12.9%	1.065	0.916	1.017
Body surface area (per 0.1 m^2)	1.87	1.023	1.014	1.020
Underweight (BMI <18.5)	4.0%	1.000	1.078	1.025
Time since onset of renal dialysis < 4	4.9%	1.511	1.450	1.491
Pericarditis (acute^^)	0.4%	1.000	1.355	1.114
Bacterial pneumonia (acute^^)	2.0%	1.000	1.422	1.135
Gastro-intestinal tract bleeding (acute^^)	1.1%	1.000	1.571	1.183
Hereditary hemolytic or sickle cell	2.3%	1.000	1.238	1.076
Myelodysplastic syndrome (chronic^^)	1.6%	1.000	1.310	1.099
Monoclonal gammopathy (chronic^^)**	1.2%	1.000	1.074	1.024
Low-volume facility adjustment Facility size < 3,000 treatments during each year from 2006-2008	0.5%	1.372	0.892	1.176

Note: In the CR model presented above, the percentage of home dialysis training treatments in the facility was included as an additional control variable.

*The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable MAP. Based on total estimated costs of $177.88 per session for composite rate services, $83.94 per session for separately billable services, and $261.82 per session for composite rate and separately billable services ($177.88+$83.94), the relative weights are $Weight_{CR}$=0.6794 for composite rate services ($177.88/$261.82) and $Weight_{SB}$=0.3206 for separately billable services ($83.94/$261.82). The combined low-volume multiplier was calculated relative to all other facilities.

**Excludes multiple myeloma.

^The R^2 value reported above for the SB model was based on a regression model that used the average predicted SB MAP per treatment during each patient year, which was calculated by averaging the monthly predicted values for each patient from the patient-month SB model, to explain variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R^2 value for the patient- month level log-linear SB model was 3.3%.

^^Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

Table 5.11 Calculation of payment multipliers for an expanded ESRD PPS, ages 18 and older: Adjustment for bacterial pneumonia excludes other pneumonias. *Low-volume facility threshold at 5,000 treatments*

Variable	Percent of Medicare HD-equivalent dialysis treatments	CR model, 2006-2008 n=12,999 R^2: 40.8%	SB model, 2006-2008 n=8,697,451 patient months; R^2 at patient- year level: 5.2%^	Modeled case-mix adjustment*
		$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$
Adjustments for patient characteristics				
Age (years)				
18-44	13.5%	1.254	0.995	1.171
45-59	26.9%	1.022	0.992	1.012
60-69	23.8%	1.000	1.000	1.000
70-79	22.8%	1.038	0.964	1.014
80+	12.9%	1.068	0.916	1.019
Body surface area (per 0.1 m^2)	1.87	1.024	1.014	1.021
Underweight (BMI <18.5)	4.0%	1.000	1.078	1.025
Time since onset of renal dialysis < 4 months	4.9%	1.532	1.450	1.506
Pericarditis (acute^^)	0.4%	1.000	1.355	1.114
Bacterial pneumonia (acute^^)	2.0%	1.000	1.422	1.135
Gastro-intestinal tract bleeding (acute^^)	1.1%	1.000	1.571	1.183
Hereditary hemolytic or sickle cell anemia (chronic^^)	2.3%	1.000	1.238	1.076
Myelodysplastic syndrome (chronic^^)	1.6%	1.000	1.310	1.099
Monoclonal gammopathy** (chronic^^)	1.2%	1.000	1.074	1.024
Low-volume facility adjustment				
Facility size < 5,000 treatments during each year from 2006-2008	3.4%	1.288	0.977	1.154

Note: In the CR model presented above, the percentage of home dialysis training treatments in the facility was included as an additional control variable.

*The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ is the estimated multiplier from a patient level model of separately billable MAP. Based on total estimated costs of $177.88 per session for composite rate services, $83.94 per session for separately billable services, and $261.82 per session for composite rate and separately billable services ($177.88+$83.94), the relative weights are $Weight_{CR}$=0.6794 for composite rate services ($177.88/$261.82) and $Weight_{SB}$=0.3206 for separately billable services ($83.94/$261.82). The combined low-volume multiplier was calculated relative to all other facilities.

**Excludes multiple myeloma.

^The R^2 value reported above for the SB model was based on a regression model that used the average predicted SB MAP per treatment during each patient year, which was calculated by averaging the monthly predicted values for each patient from the patient-month SB model, to explain variation in the average observed MAP per treatment for the patient year (with a log transformation applied to both the average predicted and average observed SB values). The R^2 value for the patient-month level log-linear SB model was 3.3%.

^^Comorbidities referred to as "acute" were identified in the current month or previous 3 months of claims. Comorbidities referred to as "chronic" were identified in claims since 2000.

When using updated data and a low-volume threshold of 4,000 treatments, we continued to find that low-volume facilities were more likely to be located in a rural area, less likely to be owned by an LDO, more likely

to be hospital-based facilities and more likely to be pediatric facilities compared to other facilities (Table 5.12). Low-volume facilities were also more likely to treat a higher percentage of Medicare patients, report only home dialysis treatments, and to have been eligible for a composite rate payment exception as an Isolated Essential Facility (April 28, 2010). In the CY 2011 ESRD PPS Final Rule, the low-volume threshold was determined to be 4,000 treatments per year.

Table 5.12 Characteristics of facilities eligible for the low-volume adjustment, 2008*

Facility type	Dialysis facilities		% of Medicare HD-equivalent treatments**	Rural	Facility ownership: large dialysis organization	Hospital-based	% Medicare (based on cost reports)	Facilities with at least 50% of Medicare treatments for pediatric patients	Isolated essential facility (IEF) prior to 2005	Facilities with only home dialysis treatments on cost reports
	n	% of facilities (n=5,108)								
Low-volume facility: Did not open or close and reported < 4,000 treatments each year from 2006-2008^	364	7.1%	1.9%	44.5%	48.1%	29.1%	76.7%	7.7%	1.4%	11.1%
Other facilities that reported <4,000 treatments during 2008	571	11.2%	3.5%	28.4%	37.1%	15.6%	69.3%	1.8%	1.4%	7.6%
Facilities with ≥ 4,000 treatments	4,173	81.7%	94.6%	20.3%	65.1%	9.0%	71.9%	0.2%	0.8%	0.8%

*Data on the total number of treatments for each facility were obtained from SIMS. The reported in-center treatments from SIMS were added to the estimated treatments for home dialysis patients, using the number of home dialysis patients reported in SIMS and the average number of treatments per patient year from Medicare outpatient dialysis claims.

Excludes facilities with data on total treatments not available in SIMS for 2008 (n=75).

**Based on 37.4M HD-equivalent treatments on Medicare claims for 5,108 facilities in 2008.

^For hospital-based facilities, eligibility for the low-volume adjustment was established based on the combined treatment counts for both the parent facility and any affiliated satellite facilities that were identified.

Conclusion

The research performed by UM-KECC to inform the development of the expanded ESRD PPS indicated that smaller facilities continued to incur higher costs in providing dialysis services. In defining a low-volume adjustment that satisfied the statutory requirement for the expanded PPS, alternative approaches and size thresholds for identifying low-volume facilities were considered. Evidence of similarly elevated costs among many of the facilities having less than 4,000 treatments and of a greater decline in facility costs with increasing facility size above 4,000 treatments was used in establishing this facility size threshold for the low-volume adjustment. When using this threshold, the empirical cost models indicated a cost increment of approximately 19 percent for low-volume facilities. The low-volume adjustment that was implemented in the CY 2011 ESRD PPS final rule corresponded to final estimates of the higher costs incurred by low-volume facilities, and satisfied the MIPPA requirement that the adjustment being finalized for CY 2011 be at least 10 percent. Further details regarding eligibility for the low-volume adjustment were described in the CY 2011 ESRD PPS final rule (pp. 49117-49125).

VI. DEVELOPMENT OF AN OUTLIER PAYMENT ADJUSTMENT

A. BACKGROUND/RATIONALE

One of the statutory requirements for the ESRD PPS (Medicare Improvements for Patients and Providers Act (MIPPA) 2008) was that it 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 needed for anemia management. Prospective payment systems often include outlier policies as a means of minimizing the financial risk to providers who treat patients for whom the cost of delivering appropriate care substantially exceeds the prospective payment amount. Generally, outlier payment mechanisms are based on a provider's cost for caring for a patient compared to projected payments under the PPS. To the extent that providers can identify costly patients in advance, an outlier payment adjustment also helps limit providers' incentives to avoid caring for these potentially vulnerable patients. However, the design of an outlier payment system requires the payer to carefully balance several factors. Providing outlier payments for a large number of patients and covering a large portion of their actual costs above the standard PPS payment rate will provide a great deal of protection against risk and nearly eliminate incentives to avoid costly cases. However, such a policy is nearly a fee-for-service payment system, which substantially reduces the incentives for efficiency that motivated the development of a PPS in the first place. Further, financing a generous outlier policy in a budget neutral fashion would require a substantial reduction in the base rate paid for non-outlier cases.

In this report, we summarize previous work by the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) that informed the key decisions regarding the outlier payment adjustment that was implemented as part of the Calendar Year (CY) 2011 ESRD Prospective Payment System (PPS). Key decisions in outlier payment design included: (1) the services eligible for outlier payments; (2) the cost threshold above which outlier payments occur and whether this threshold is the same for each patient or if it is calculated relative to that patient's case-mix adjusted payment rate (hence using a "fixed dollar loss" approach); (3) the percentage of costs above the threshold that are reimbursed; (4) whether outlier payments are targeted to be a certain share of total payments under the expanded PPS, in which case the cost threshold above which outlier payments are made would need to be set in accordance with this target; and (5) whether different outlier models should be used for different types of patients (adult and pediatric).

As a starting point to inform these decisions, the UM-KECC 2008 report described and simulated a hypothetical outlier policy for an expanded ESRD PPS. As part of this policy simulation, UM-KECC estimated the additional payments (payments in addition to the per-treatment, patient and facility-level

adjusted ESRD PPS payment amount) that would be made to facilities for higher cost patients. As noted in the report, both the lack of patient-level data on the cost of composite rate services and the new financial risk to facilities under the expanded PPS resulting from the potentially high cost of separately billable services were consistent with a focus on developing an outlier policy that focused specifically on high-cost users of separately billable services. The report proposed setting the hypothetical outlier payment amount of at least 60 percent of the difference between the separately billable Medicare Allowable Payment (MAP) and a threshold amount. The report also examined a threshold amount that was based on the average separately billable MAP amount per treatment plus 2 standard deviations. To maintain budget neutrality, the 2008 report described an approach that would require an approximately 1 percent reduction in the base rate to fund projected outlier payments.

The analyses that were conducted for the UM-KECC 2008 report served as a starting point for the development of the outlier policy that was proposed and finalized for the CY 2011 ESRD PPS, Further analyses based on more recent data were used to inform the development of this outlier policy. Features of the outlier payment policy that were further evaluated by UM-KECC for the CY 2011 ESRD PPS proposed and final rules are discussed in this section.

B. Analysis of an Outlier Policy for the CY 2011 ESRD PPS Proposed Rule

Outlier Threshold

As part of the approach that was proposed for defining the outlier threshold in the UM-KECC 2008 report, a dialysis facility was considered to be eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeded a threshold. This MAP amount represented the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold was equal to the facility's predicted ESRD outlier services MAP amount per treatment (which was case-mix adjusted) plus the fixed dollar loss amount, defined to yield a target total outlier payment amount under the expanded ESRD PPS. This approach was also used in conducting the analyses for the CY 2011 ESRD PPS proposed rule.

As part of the analyses used to inform the development of the proposed rule, alternative methods for defining the fixed dollar loss amount were assessed. This required first calculating both the predicted and actual or imputed ESRD outlier services MAP amounts as described below.

The outlier services MAP amounts that were predicted for a given patient were determined using their patient-specific case-mix adjusters and the corresponding outlier services payment multipliers. These outlier

services payment multipliers, or separately billable payment multipliers, were based on parameter estimates from the separately billable regression model.

To determine the predicted outlier services MAP amount for a given patient, we first calculated the overall average outlier services MAP amount per treatment. This was calculated based on the payment amounts for outlier services that were reported on the 2007 claims and adjusted to reflect the projected prices for 2011. The overall average outlier services MAP amount per treatment was then multiplied by the outlier services standardization factor (i.e., the reciprocal of the overall average outlier services payment multiplier) and a MIPPA-required 2 percent reduction relative to what would have been paid under the prior CR plus SB system to yield the adjusted average outlier services MAP amount per treatment. The outlier service payment multipliers, or separately billable services payment multipliers, were then applied to the adjusted average outlier services MAP amount to yield the predicted outlier services MAP amount.

A dialysis facility's imputed costs for the ESRD outlier services were estimated by applying Medicare payment rates to the reported utilization of separately billable services on the claims. A similar approach had been used to define outliers for the Medicare inpatient hospital prospective payment system.

Medicare prices for outlier ESRD services were based on Average Sales Price data for the Part B ESRD-related drugs (which is updated quarterly), the annual laboratory fee schedule for the previously separately billable laboratory tests, and various pricing mechanisms for the other separately billable ESRD-related services. Specifically, for medical/surgical supplies used to administer separately billable drugs, the predetermined fees that apply to these items under the basic case-mix adjusted composite payment system were used.

Eligibility for outlier payments would be determined by whether the actual or imputed outlier services MAP amount for a patient exceeded the sum of that patient's predicted outlier services MAP amount and a fixed dollar loss amount. When holding all other factors constant, higher fixed dollar loss amounts would result in fewer outlier eligible cases, but would also require smaller reductions to the base rate amount for budget neutrality. The implications of using fixed dollar loss amounts of different magnitudes for the outlier policy were considered.

UM-KECC compared approaches that used fixed dollar loss amounts based on 2, 3, and 4 standard deviations (SDs) of the difference between the actual or imputed outlier services MAP amount per treatment and the predicted outlier services MAP amount per treatment. As shown in Table 6.1, reducing the outlier threshold (e.g., from 4 SD to 2 SD) resulted in more frequent outlier payments (e.g., from 0.3 percent of patient facility months to 4.9 percent of patient months), would require a somewhat larger budget neutrality adjustment to the ESRD PPS base rate (from -0.079 percent to -1.056 percent), and substantially improved

the correspondence between the actual and predicted outlier services MAP amounts across patient facility months (based on the higher R^2 values in Table 6.1). A fixed dollar loss amount of a magnitude that was closer to 2 standard deviations rather than 3 or 4 standard deviations was seen as having the advantage of establishing Medicare payments that better reflected the estimated costs of separately billable services and promoting access to care for high-cost patients, while still avoiding an unnecessarily large reduction to the base rate amount for budget neutrality.

Table 6.1 Example of an outlier payment model for ages 18 and older
Medicare dialysis patient facility months, 2004-06*: 8,658,477
Average MAP/session, 2004-06*: $81.81

In this example, the outlier payment is calculated as 80% of the difference between the actual SB MAP and the outlier threshold.

Statistic		Outlier threshold			
		None (no outlier payment)	Actual SB MAP/session exceeds predicted SB MAP/session by:		
			More than 4 standard deviations	More than 3 standard deviations	More than 2 standard deviations
% of patient facility months with outlier payment		0.0%	0.3%	1.8%	4.9%
Average MAP for patient facility months with an outlier payment					
	Average predicted payment based on case-mix adjustment only	--	$75.45	$75.94	$81.20
	Average outlier payment	--	$62.18	$35.45	$48.36
	Average predicted payment based on case-mix adjustment + outlier payment	--	$137.64	$111.39	$129.56
Average predicted MAP for SB services for all patient facility months (without budget neutrality adjustment for outlier payment)**		$81.81	$81.99	$82.45	$84.18
Budget neutrality adjustment for expanded bundle payment due to the adult outlier payment system		none	0.99921	0.99714	0.98944
Change in base payment rate for expanded bundle due to the adult outlier payment system		none	-0.079%	-0.286%	-1.056%
Average predicted SB MAP with budget neutrality adjustment due to the adult outlier payment system		$81.81	$81.92	$82.21	$83.29
R^2 from linear regression model that uses predicted SB MAP/session to explain variation in actual SB MAP/session across patient facility months		4.4%	6.1%	9.1%	19.7%

*Excludes patient facility months with >$1,000 MAP/session for SB services (0.1% of total patient facility months) or missing wage index or facility size data.
**Note that these amounts reflect a budget neutrality adjustment for the case-mix adjustment for SB services, so that the average predicted SB MAP (in the absence of an outlier payment system) is the same as the average actual SB MAP of $81.81/session during 2004-06.

C. Percentage Reduction in the Base Rate Needed to Finance the Outlier Payments

An important feature of an outlier policy is its share of total payments (or outlier percentage) as part of a prospective payment system. An important consideration in the context of a budget neutral outlier policy is that as the outlier percentage increases, the base rate for patients who do not qualify for outlier payments must be reduced. In analyses that were conducted for the CY 2011 ESRD PPS proposed rule, UM-KECC used 2007 claims data to simulate alternative outlier policies that differed based on whether projected outlier payments across all eligible patients represented 1 percent, 1.5 percent, 2 percent, 2.5 percent, or 3 percent of total projected payments under the ESRD PPS. We performed separate analyses for pediatric and adult patients (discussed further in the next section). As shown in Table 6.2, the percentage of adult patient months qualifying for outlier payments ranged from 4.7 percent with a 1 percent outlier policy to 11.9 percent with a 3 percent outlier policy. Increasing the outlier percentage results in a lower corresponding fixed dollar loss amount and outlier threshold which are expected to yield the desired outlier percentage, and consequently a greater number of patient months qualifying for outlier payment.

Table 6.2 Impact of outlier percentage on patient months qualifying for outlier payment

	Outlier percentage				
	1%	1.50%	2%	2.50%	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

*The fixed dollar loss amounts were calculated using 2007 claims data to yield total outlier payments that represent a certain percentage (e.g. 1%) of total projected payments in an expanded ESRD PPS, and reflect an outlier loss sharing percentage of 80%. In determining the fixed dollar loss and outlier payment amounts, EPO and darbepoetin payments were capped to reflect the medically unbelievable edit thresholds in place under the ESA monitoring policy startingJanuary1, 2008 (400,000 units for EPO and 1,200 mcg for darbepoetin). The outlier payment would be based on 80% of the outlier services MAP that exceeds the sum of the predicted outlier services MAP for each patient and the fixed dollar loss amount for the patient's age group (<18 or 18 and older).

In the CY 2011 ESRD PPS proposed rule, CMS proposed to implement a 1 percent outlier policy.

D. PERCENTAGE OF COSTS ABOVE THE THRESHOLD THAT WERE REIMBURSED

The loss sharing percentage is the percentage of costs exceeding the fixed dollar loss amount that is paid by Medicare. In the UM-KECC 2008 report, it was concluded that a loss sharing percentage of at least 60 percent or higher would balance goals of minimizing financial risk to dialysis facilities of treating high-cost patients and avoiding an adverse incentive for facilities to increase their use of separately billable services. In determining the loss sharing percentage that would be applied in the analyses being developed for the CY 2011 ESRD PPS proposed rule, available information on facility costs for separately billable injectable drugs was considered. Prior to the decrease in many of the Medicare ESRD drug payment rates starting in 2005, the Office of the Inspector General (OIG) reported that acquisition costs for the top 10 ESRD drugs averaged 78 percent and 86 percent of MAP for the four largest dialysis organizations and for other dialysis facilities, respectively (OIG 2004). The OIG later reported that costs for darbepoetin alfa averaged 73 percent of MAP as of the first quarter of 2005 (OIG 2006). As long as the cost to facilities of the inputs required to deliver additional ESRD drugs and other services would be greater than 80 percent of the MAP, it was determined that there would be no incentive to increase utilization inappropriately to receive outlier payments. It was also noted that an 80 percent loss sharing percentage would be consistent with policies for other Medicare payment systems.

In the analyses that were developed for the CY 2011 ESRD PPS proposed rule, the outlier payment was determined using an 80 percent loss sharing percentage. That is, the outlier payment per treatment for eligible cases (i.e., patient facility month claims) was calculated to be 80 percent of the amount by which the actual or imputed average ESRD outlier services MAP amount per treatment exceeded the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount. For treatments eligible for the outlier payment, the outlier payment per treatment amount would be added to the applicable case mix and wage adjusted ESRD PPS payment per treatment amount.

E. DIFFERENT OUTLIER MODELS FOR ADULT AND PEDIATRIC PATIENTS

UM-KECC identified differences in the utilization of separately billable services between adult and pediatric Medicare dialysis patients, with lower utilization reported on the claims for pediatric patients. To ensure that additional payments for high-cost patients of both types would be available through an outlier policy, separate fixed dollar loss amounts and outlier thresholds were specified for adult and pediatric patients. For both types of patients, an outlier payment would be made if the sum of the predicted outlier services MAP amount per treatment for each patient and the corresponding fixed dollar loss amount for the patient's age group (i.e., pediatric versus adult) exceeded the actual or imputed outlier services MAP amount per treatment.

Applying an 80 percent outlier loss percentage, targeting total outlier payments to be 1 percent of total payments under the ESRD PPS, and establishing separate fixed dollar loss amounts for pediatric and adult patients resulted in the outlier model shown in Table 6.3. This outlier model was proposed by CMS in the CY 2011 ESRD PPS Proposed Rule (pp. 49987-49993), which was published in 2009 (https://federalregister.gov/a/E9-22486).

Table 6.3 Outlier model for CY 2011 ESRD PPS proposed rule

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 per treatment[3]		$64.54
	Patient age	
	<18 years	18 years 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 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.

F. Analyses for the CY 2011 ESRD PPS Final Rule

As a result of the modifications to the case-mix adjustments that were made for the final rule for both pediatric and adult patients (discussed in a separate section of this report), it was also necessary to revise the outlier policy standardization for the final rule. In addition, given the relatively large differences in the utilization of separately billable services between pediatric and adult patients, it was determined that it would be appropriate to establish separate outlier services MAP amounts for the two patient types. This approach would also help to ensure that the resulting outlier thresholds would allow both high-cost pediatric patients and high-cost adult patients to qualify for outlier payments. This approach would require the use of separate standardization factors and adjusted outlier services MAP amounts for pediatric and adult patients.

Based on 2007 data, the average outlier services MAP amounts were calculated to be $54.14 per treatment for pediatric patients and $86.58 for adult patients (see Table 6.4). In calculating separate standardization factors for pediatric and adult patients, the revised case-mix adjustments for separately billable services were used. For adult patients, adjustments for case mix were made based on patient age (five adult age groups), BSA, underweight (low BMI), onset of dialysis <4 months, six individual comorbidities, and facility low-volume

status. The standardization factor that was calculated for adult patients was 0.9756. For pediatric patients, these adjustments for case mix were made based on patient age (<13 years and 13-17 years) and modality (hemodialysis and peritoneal dialysis). No standardization was necessary for pediatric patients since the overall average case-mix multiplier among pediatric patients was calculated to be 1.0000.

As shown in Table 6.4, the resulting adjusted average outlier services MAP per treatment amounts were $53.06 for pediatric patients and $82.78 for adult patients. When continuing to apply an 80 percent outlier loss percentage and a 1 percent outlier policy, the fixed dollar loss amounts were calculated to be $195.02 for pediatric patients and $155.44 for adult patients. The outlier model in Table 6.4 was implemented in the CY 2011 ESRD PPS final rule (see Table 28, p.49140).

Table 6.4 Revised outlier model for CY 2011 ESRD PPS final rule

	Patient age	
	Ages <18	**Ages 18 and older**
Average outlier services MAP amount per treatment[1]	$54.14	$86.58
Adjustments Standardization for outlier services[2] MIPPA reduction	 1.000 0.98	 0.9756 0.98
Adjusted average outlier services MAP amount per treatment[3]	$53.06	$82.78
Fixed dollar loss amount that was added to the predicted MAP to determine the outlier threshold[4]	$195.02	$155.44

[1] Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts were based on 2007 data. The medically unbelievable edits of 400,000 units for EPO and 1,200 mcg for Aranesp that were in place under the current ESA Claims Monitoring Policy were applied. The outlier services MAP amounts were also inflation adjusted to reflect projected 2011 prices for outlier services.

[2] Applied to the average outlier MAP per treatment. For patients 18 and older, the standardization for outlier services was based on the following patient characteristics: Age, BSA, underweight (BMI < 18.5), time since onset of renal dialysis < 4 months, pericarditis(acute), bacterial pneumonia (acute), gastro-intestinal tract bleeding (acute), hereditary hemolytic or sickle cell anemia (chronic), myelodysplastic syndrome (chronic),monoclonal gammopathy (chronic) and the low-volume adjustment. For patients ages <18, the standardization for outlier services was based on age (<13 and 13-17) and modality (PD or hemodialysis).

[3] This was the amount to which the separately billable (SB) payment multipliers were 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.

Conclusion

An outlier policy can be used to protect access to care for high-cost patients under a prospective payment system, and was one of the statutory requirements for the expanded ESRD PPS. An ESRD outlier policy was found to improve the ability of the expanded ESRD PPS to align payments with facility costs for services that were billed separately prior to January 1, 2011. With a goal of providing additional payments to facilities caring for high-cost patients while avoiding an unnecessarily large reduction in the base rate amount to finance the outlier payments, the outlier policy that was implemented in the CY 2011 ESRD PPS final rule was designed to account for 1 percent of total payments under the PPS. Given the substantially different utilization of separately billable services between pediatric and adult patients, the CY 2011 ESRD PPS final rule implemented different thresholds or levels of utilization beyond which each of these patient types would qualify for an outlier payment. In determining the amount of the additional payment that would be made through the outlier policy, there was an attempt to balance the need to limit the financial risk to facilities of caring for patients who were more costly to treat in ways not captured by the case-mix adjusted payment amount with the need to create incentives for facilities to use resources efficiently. This process yielded outlier payments under the CY 2011 ESRD PPS that were calculated to be 80 percent of the estimated costs

of providing separately billable services above the qualifying outlier threshold. Further details and examples regarding the outlier policy that was implemented are provided in the CY 2011 ESRD PPS final rule (pp. 49134-49144).

VII. HOME DIALYSIS TRAINING

A. BACKGROUND/RATIONALE

CMS has had a longstanding policy to provide additional payments to dialysis facilities to support home dialysis training. The policy that existed for many years under the composite rate system applied add-on adjustments of $12 for Continuous Ambulatory Peritoneal Dialysis (CAPD) training treatments and $20 for home hemodialysis and Continuous Cycling Peritoneal Dialysis (CCPD) training treatments to the composite rate payment. This composite rate policy limited the adjustment to no more than 15 total training treatments for CAPD/CCPD and 25 total training treatments for hemodialysis.

In the process of developing the expanded End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), the extent to which dialysis facilities were continuing to use additional resources in training patients to perform self-dialysis was evaluated using available data. To the extent that dialysis facilities incur additional costs in providing training for home dialysis, a continued policy of making additional payments for home dialysis training treatments might help to promote access to home dialysis therapies under the expanded PPS. This section describes the analyses of home dialysis training treatments that were conducted by University of Michigan Kidney Epidemiology and Cost Center (UM-KECC). The goal of these analyses was to determine whether current data could be used to estimate the additional costs incurred by dialysis facilities in supporting home dialysis training and to inform the development of a payment adjustment for home dialysis training under the PPS. Such an adjustment could either take the form of a payment adjustment that would be applied multiplicatively to the PPS base rate amount and developed using the same type of analytic approach that was being used to define other PPS adjustments, or of an updated add-on adjustment that would be applied to the PPS base rate amount.

B. EXAMINING THE FREQUENCY AND COST OF HOME DIALYSIS TRAINING TREATMENTS

Costs associated with home dialysis training are included among the composite rate costs reported by dialysis facilities on the freestanding dialysis facility and hospital cost reports. As a result, an empirical regression-based approach for developing a home dialysis training adjustment must use the dialysis facility cost report data.

Before examining the costs associated with home dialysis training, we determined the frequency of training reported by dialysis facilities on both Medicare dialysis facility claims and cost reports. Training treatments

were identified in the claims data using condition code 73 (indicating self-care in training). The reported revenue codes and Healthcare Common Procedure Coding System (HCPCS) codes in the claims were used to identify the type of training treatments as either hemodialysis, CAPD, CCPD, or other peritoneal dialysis (PD) (see Table 7.1).

Based on the claims data, home dialysis training treatments accounted for 0.1 percent of total Medicare hemodialysis-equivalent treatments during 2007. Overall, as shown in Table 7.1, approximately 31 percent of home dialysis training treatments were found to occur during the first four months of renal replacement therapy (RRT). The remaining 69 percent of training treatments were reported after the first four months of RRT, when the onset of dialysis payment adjustment would no longer apply. It was clear based on this analysis that for most training treatments, an adjustment other than the onset adjustment would be needed to compensate facilities for any training-related costs.

When linking facility claims and cost report data, there was 96 percent agreement on the facilities that were providing home dialysis training (see Table 7.2.a). However, there was also evidence that the cost reports may understate the overall frequency of training. The total counts of Medicare covered training treatments in the claims exceeded the corresponding counts from the cost reports by approximately 8 percent. The proportionate undercount in the cost reports relative to claims was similar for both hemodialysis (HD) and peritoneal dialysis (PD) training treatments (Table 7.2.b).

Table 7.1.a Frequency of training reported by dialysis facilities by modality, 2007

Counts of training treatments

	All patients				First 4 months of RRT				
Modality	**Min**	**Max**	**Sum**	**HD-equivalent sum**	**Min**	**Max**	**Sum**	**HD-equivalent Sum**	**% of sum for all patients**
HD	0	29	16,284	16,284	0	24	2,084	2,083	12.8%
CAPD	0	31	26,512	11,362	0	31	13,534	5,800	51.0%
CCPD	0	48	21,153	9,066	0	31	7,792	3,339	36.8%
Other PD	0	6	48	21	0	6	28	12	58.3%
All modalities			63,997	36,732	0	92	23,438	11,235	30.6%

Table 7.1.b Medicare payments for training by modality, 2007

Medicare payments

	All patients				First 4 Months of RRT				
Modality	**Min**	**Max**	**Sum**	**HD-equivalent sum**	**Min**	**Max**	**Sum**	**HD-equivalent sum**	**% of sum for all patients**
HD	$0	$5,475	$2,376,905	*n.a.*	$0	$3,646	$329,523	*n.a.*	13.9%
CAPD	$0	$9,225	$4,040,360	*n.a.*	$0	$6,012	$2,022,591	*n.a.*	50.1%
CCPD	$0	$7,219	$3,314,528	*n.a.*	$0	$7,219	$1,222,621	*n.a.*	36.9%
Other PD	$0	$895	$8,070	*n.a.*	$0	$895	$4,603	*n.a.*	57.0%
All modalities			$9,739,864	*n.a.*			$3,579,338	*n.a.*	36.7%

Table 7.2.a Dialysis facilities with Medicare training treatments: claims vs. cost reports, 2007

	Cost Reports	
Claims*	**No**	**Yes**
No	3,215 66.7%	60 1.2%
Yes	129 2.7%	1,415 29.4%

n=4,819 facilities. *Based on type '72X' claims with condition code 73.

Table 7.2.b Dialysis facilities with Medicare training treatments: claims vs. cost reports, 2007

	Claims*		Cost Reports	
Type of training	**HD-equivalent training treatments**	**%**	**HD-equivalent training treatments**	**%**
Hemodialysis	15,215	43.2%	14,115	43.2%
Peritoneal dialysis	19,998	56.8%	18,552	56.8%
Total	35,213	100.0%	32,666	100.0%

n=4,810 facilities (excludes 9 facilities with outlier values for number of training treatments).
*Based on type '72X' claims with condition code 73.

For most facilities providing home dialysis training, reported training treatments accounted for a small percentage of total dialysis treatments (Table 7.3). Of the 4,406 facility-years during 2004-2006 with any training treatments documented in cost reports, 4,196 (or 95 percent) were training treatments that comprised less than 1 percent of total treatments. For these facilities, training treatments averaged 0.2 percent of their total treatments. Even for the 1.8 percent of facilities-years with more than 1 percent training treatments, the average was only 2.9 percent with a maximum of 13 percent. As a result, among the vast majority of facilities providing home dialysis training, there was limited variation across facilities in the frequency of training to inform the development of a potential training adjustment.

Table 7.3 Training treatments as a percent of total facility treatments, Medicare Cost Reports, 2004-2006

Percent of total treatments designated as training	**n (facility years)**	**% of facility years**	**Average % training***	**Average wage-adjusted composite rate cost/treatment***
None	7,552	63.2%	0.0%	$170.40
> 0 and < 1%	4,196	35.1%	0.2%	$168.51
1 to 13%	210	1.8%	2.9%	$191.71
Total	11,958	100.0%	0.1%	$169.84

*Weighted by total HD-equivalent treatments.

Facility composite rate costs were also compared based on categories for the percentage of total facility treatments that represented training treatments (i.e., none, >0 and <1 percent, and 1-13 percent). As shown in Table 7.3, facilities with a greater percentage of training treatments (i.e., comprising more than 1 percent of total treatments) were found to have higher average composite rate costs per treatment. However, these facilities accounted for only 5 percent of the 4,406 facility-years from cost reports with training treatments (i.e., less than 2 percent of the total facility-years that were examined). The other 95 percent of facility-years with training treatments actually had slightly lower composite rate costs ($168.51 per treatment) than the facilities with no training treatments ($170.40).

To examine facility costs associated with training while accounting for other factors that were being considered as PPS adjustment factors, we included measures of the frequency of training in facility-level composite rate cost models (Table 7.4). As a group, facilities that reported any home dialysis training did not have significantly higher composite rate costs (Model 2). A separate model distinguished facilities that provided training based on the percentage of training treatments (<1 percent vs. ≥1 percent training treatments in Model 3). For facilities reporting a relatively smaller concentration of training treatments (<1 percent), costs were similar to facilities reporting no training. Facilities with a relatively greater concentration of home dialysis training treatments (≥ 1 percent) had 2.8 percent higher costs (p=0.02) than facilities with no training reported, but as noted earlier these facilities represent only 5 percent of all facilities that offered training. Expanding the model to include an adjustment for the percentage of home dialysis treatments resulted in very different estimates (Model 4). Both lower and higher concentrations of training treatments were associated with higher costs, while the prevalence of home treatments overall was associated with lower costs. These results suggested that higher costs associated with training were largely offset by lower costs for home dialysis, which is more common in facilities that provide training.

It should also be noted that the magnitude of the potential payment adjustment for training based on the results for Model 4 are implausibly large. For example, the multiplier of 1.029 for facilities with <1 percent training treatments implies that cost per treatment is 2.9 percent higher across *all* treatments (training or otherwise) delivered by those facilities despite the fact that on average, training treatments only represented 0.2 percent of treatments in those facilities (Table 7.3). Similarly, the 1.103 multiplier associated with providing >1 percent training treatments implies that cost per treatment is 10.3 percent higher across all treatments (training or otherwise) delivered by those facilities despite the fact that on average, training treatments only represented 2.9 percent of treatments in those facilities (Table 7.3). Together, the results in Table 7.4 show there is substantial variation in estimates of the cost associated with training depending on how the models were specified, and suggest that reliable and plausible estimates of the impact of training treatments on facility costs cannot be derived from the empirical model of available cost report data.

Analyses of the relationship between the percentage of training treatments in the facility as a continuous variable and average facility composite rate costs were also explored. Estimates of the incremental cost for training treatments were unstable, and very sensitive to how the model was specified. This may reflect the very low percentage of training treatments in most facilities that do provide training.

Table 7.4 Home dialysis training and facility composite rate costs, 2004-06 (n=11,958)

	Model 1: Base		Model 2: Include training (any)		Model 3: Include training (none, <1%, 1% or more)		Model 4: Include training and home dialysis	
	R-sq=46.4%		R-sq=46.4%		R-sq=46.4%		R-sq=47.2%	
Variable	**CR multiplier**	**p value**	**CR multiplier**	**p value**	**CR multiplier**	**p value**	**CR multiplier**	**p value**
Age								
18-44	1.288	<0.001	1.280	<.0001	1.278	<0.001	1.336	<0.001
45-59	1.000	ref	1.000	ref	1.000	ref	1.000	ref
60-69	1.024	0.454	1.024	0.447	1.024	0.447	1.008	0.800
70-79	1.106	<0.001	1.104	0.000	1.104	<0.001	1.104	<0.001
80+	1.152	<0.001	1.151	<.0001	1.151	<0.001	1.139	<0.001
Female	1.114	<0.001	1.113	<.0001	1.114	<0.001	1.127	<0.001
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.032	<0.001	1.032	<.0001	1.032	<0.001	1.034	<0.001
Time since onset of renal dialysis: <4 months	1.491	<0.001	1.479	<.0001	1.475	<0.001	1.532	<0.001
Alcohol/drug dependence (claims since 2000 or 2728)	1.153	<0.001	1.159	<.0001	1.159	<0.001	1.126	<0.001
HIV/AIDS (claims since 2000 or 2728)	1.337	<0.001	1.341	<.0001	1.344	<0.001	1.334	<.0001
Hepatitis B (claims since 2000)	1.107	<0.001	1.108	<.0001	1.109	<0.001	1.117	<.0001
Bacterial pneumonia and other pneumonias/opportunistic infections	1.309	0.006	1.307	0.006	1.306	0.006	1.271	0.014
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.245	<0.001	1.242	0.000	1.243	<0.001	1.236	<0.001
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.142	<0.001	1.139	<.0001	1.139	<0.001	1.134	<0.001
Facility size < 3,000 treatments during each year from 2004-06 (for computing low volume adjustment)	1.363	<0.001	1.366	<.0001	1.365	<0.001	1.381	<0.001
Training treatments in facility								
None	--	--	1.000	ref	1.000	ref	1.000	ref
Any (> 0%)	--	--	1.005	0.117	--	--	--	--
Less than 1%	--	--	--	--	1.004	0.178	1.029	<0.001
1% or more	--	--	--	--	1.028	0.021	1.103	<0.001
Home dialysis (% of treatments)	--	--	--	--	--	--	0.842	<0.001

Conclusion

The development of a payment adjustment for home dialysis training using the same type of regression analysis that was used to develop other PPS payment adjustments was considered. Such an approach would yield a training adjustment that would be applied multiplicatively to the PPS base rate, replacing the training add-on adjustment that was previously applied to the composite rate amount. However, based on our analyses of the training treatments that were identified on the dialysis facility cost reports from 2004 to 2007, this empirical approach has limitations. One potential limitation is that the cost reports may understate the number of home dialysis training treatments, which was suggested by our comparison of cost report data and claims data. In addition, for most facilities that provided home dialysis training, training treatments accounted for a very small percentage of total dialysis treatments. As a result, there was limited variation in the extent of training across dialysis facilities that could be related to variation in facility costs for the purpose of defining a training adjustment. This likely explains the lack of stability that we observed in estimates of the cost associated with training treatments based on facility-level analyses. Due to these limitations, a facility-level regression analysis of available cost report data was not recommended as the basis for developing a payment adjustment for home dialysis training.

In the CY 2011 ESRD PPS proposed rule (pp. 49929-49931), CMS proposed to include training payments in the PPS base rate, and did not propose a payment adjustment for training treatments. CMS proposed to treat training costs no differently than an overhead expense, such that an explicit adjustment to the bundled payment amount for training treatments would not be necessary. Based on public comments on the proposed rule, CMS finalized a training add-on adjustment of $33.44 per treatment in the ESRD PPS final rule (pp. 49062-49064) that was determined using the national average hourly wage for nurses based on Bureau of Labor Statistics data and would be subject to a geographic wage adjustment.

VIII. DEVELOPMENT OF THE BASE RATE

A. BACKGROUND

As discussed in the February 2008 End Stage Renal Disease (ESRD) Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle report written by the University of Michigan-Kidney Epidemiology and Cost Center (UM-KECC), the foundation of a case-mix adjusted per treatment payment amount is the establishment of a base payment rate. For the ESRD PPS, this base payment rate represents the per treatment payment amount to which other adjustments are applied in determining Medicare payments to dialysis facilities for the services included in the expanded bundle. Given an estimated frequency and magnitude of other adjustments to be applied in determining dialysis facility payments, the base payment rate is calculated to yield a targeted amount for total Medicare expenditures under the ESRD PPS.

The legislation that mandated the development and implementation of the ESRD PPS starting on January 1, 2011, established several requirements for determination of the ESRD PPS base rate amount. In accordance with section 1881(b)(14)(A)(ii) of The Social Security Act, it was required that "the estimated total amount of payments under this title for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments" for services included in the ESRD PPS "that would have been made under this title with respect to services furnished in 2011 if such system had not been implemented." The statute also required that this estimation "shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization." The methodology that was used by UM-KECC to calculate the base rate amount was designed to satisfy these statutory requirements. This section describes the process that was used to calculate base rate amounts for the CY 2011 ESRD PPS proposed and final rules.

B. APPROACH FOR CALCULATING THE BASE RATE FOR THE CY 2011 ESRD PPS PROPOSED RULE

At the time that UM-KECC was conducting analyses for the proposed rule, Medicare claims for 2007-2009 were not yet available to identify the year with the lowest per patient utilization as required by MIPPA for determining the base rate amount. It was expected that more complete data for the 2007-2009 period would be available at the time the analyses for the final rule were conducted. The process of identifying the year that reflected the lowest per patient utilization for services included in the ESRD PPS therefore was planned for the CY 2011 ESRD PPS final rule. For the proposed rule, 2007 data were used in calculating the base rate amount. Based on the ratio of the total Medicare Allowable Payment (MAP) for composite rate and separately billable services proposed for inclusion in the expanded PPS to the total number of Medicare

hemodialysis-equivalent dialysis sessions, the average MAP per treatment was calculated to be $252.99 per treatment (Table 8.1). Further information regarding the types of services that were included in the proposed bundle definition were provided in the CY 2011 ESRD PPS proposed rule (pp. 49927-49931 and 49939-49942).

Table 8.1 Medicare Allowable Payments for composite rate and separately billable services, 2007, for the CY 2011 ESRD PPS Proposed Rule

Description	Actual MAP for 2007, as reported on claims1
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).

For the services that were proposed for inclusion in the expanded PPS, any changes in the prices paid that were projected for 2011 were applied to the 2007 estimated MAP per treatment for composite rate and separately billable services. Details regarding the price adjustments for specific types of services included in

the expanded PPS were described in the CY 2011 proposed rule (pp. 49942-49944). When applying projected 2011 prices to the 2007 utilization data for services included in the expanded PPS, the unadjusted per treatment base rate was calculated to be $261.58. This amount corresponded to the average MAP per treatment that was projected for 2011 under the existing Medicare payment system for composite rate and separately billable services. This was also the amount that would be used to calculate a base rate amount that would satisfy statutory requirements for the projected Medicare spending under the expanded PPS.

For the CY 2011 ESRD PPS proposed rule, payment adjustments were developed based on patient case-mix (including age, sex, BSA, low BMI, <4 months since onset of dialysis, 12 individual comorbid conditions), facility low volume status, and a geographic area wage index. When accounting for the magnitude of these payment adjustments and the projected frequency with which they would be applied using 2007 data, it was estimated that the $261.58 unadjusted base rate amount for 2011 would need to be reduced by 21.73 percent in order for the PPS adjustments to be budget neutral. This estimate yielded a corresponding standardization factor of 0.7827 that would be used in calculating the base rate amount.

In accordance with the 1% outlier policy that was proposed for the expanded PPS and with the statutory requirement that payments under the expanded PPS equal 98% of the combined composite rate and separately billable payments for bundled services that would have otherwise been expected in 2011, factors of 0.99 and 0.98, respectively, were also applied in calculating the base rate amount. Given an unadjusted base rate amount of $261.58, a payment adjustment standardization factor of 0.7827, an adjustment factor of 0.99 for the 1% outlier policy, and an adjustment factor of 0.98 required by the MIPPA legislation, a base rate amount of $198.64 per treatment was calculated for the CY 2011 ESRD PPS proposed rule.

C. Calculation of the Base Rate for the CY 2011 ESRD PPS Final Rule

A similar overall approach for determining the base rate amount was implemented in the CY 2011 ESRD PPS final rule. The analyses that were conducted to determine the finalized base rate amount for CY 2011 applied data and price updates as well as refinements of the payment methodology that had been proposed. The first step in the process of calculating the base rate for the final rule was to use available claims data for 2007, 2008, and 2009 to determine which year reflected the lowest average per patient utilization for services included in the expanded PPS. At the time that the analyses for the final rule needed to be performed to meet rulemaking deadlines, complete claims data for the fourth quarter of 2009 were not available. As a result, only claims for the first three quarters of calendar year 2009 were used. To control for the effects of possible seasonal variation in the utilization of dialysis-related services, only the utilization for the first nine months of each year were compared across the three years from 2007-2009.

Because the statute required a comparison of utilization rather than spending across the three years, it was necessary to adjust for changing price levels. The effects of price inflation on spending were eliminated by adjusting expenditures for 2007 and 2008 to reflect 2009 price levels. This was accomplished using the actual annual rates of inflation for the various components of the bundle.

Payments for composite rate services were inflated to the 2009 base rate of $133.81 per treatment and drug add-on percentage of 15.2 percent. The price inflation factors for Part B drugs and biologicals were based on each drug's actual average sales price (ASP) + 6 percent (as shown in Table 12 of the CY 2011 ESRD PPS proposed rule) to reflect the Centers for Medicare and Medicaid Services (CMS) payment methodology. Payments for laboratory tests were inflated by 4.5 percent from both 2007 to 2009 and from 2008 to 2009, as determined by updates to the laboratory fee schedule. The Part D drugs that were included in the expanded PPS, which consisted of oral equivalents of injectable drugs and biologicals included in the expanded PPS, were inflated by 6.0 percent from 2007 to 2009 and by 3.4 percent from 2008 to 2009 using the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections.

Comparisons of per patient utilization across the first three quarters of each year from 2007-2009 at 2009 price levels were presented in the CY 2011 ESRD PPS final rule (pp. 49071-49074). These analyses indicated that 2007 was the year that represented the lowest per patient utilization for the dialysis-related services included in the expanded PPS. Similar comparisons of per patient utilization based on full year 2007 and 2008 data also indicated 2007 as the year representing the lowest per patient utilization. As a result, CMS determined that the base rate amount for the final rule would be calculated using 2007 data.

Based on levels of utilization in the 2007 claims that were adjusted for price inflation to 2009, the average estimated Medicare Allowable Payments (MAP) for the composite rate and separately billable services included in the ESRD PPS are shown in Table 8.2. The categories of services that are listed in Table 8.2 reflect several modifications and exclusions by CMS between the proposed and final rule. In particular, the Part D drugs included in Table 8.2 are limited to the oral equivalents of injectable drugs that were identified as components of the bundle, and exclude oral-only drugs. Blood and blood products were among other services billed separately by dialysis facilities that were excluded from the bundle by CMS for the final rule. Further details regarding the services included in the final bundle definition were provided in the CY 2011 final rule (pp.49036-49056).

Table 8.2 Average Medicare Allowable Payments for composite rate and separately billable services, 2007, with adjustment for price inflation to 2009*, for the CY 2011 ESRD PPS Final Rule

	Total	Average MAP per treatment
Dialysis patients	328,787	--
Hemodialysis (HD)-equivalent dialysis treatments	36,747,662	--
MAP for services in the expanded ESRD PPS		
Total for Part B and Part D services	$8,947,882,675	$243.65
Total for Part B services		
Composite rate services	$5,792,196,328	$157.62
Separately billable services (Part B)	.	
EPO	$1,937,063,301	$52.71
Darbepoetin	$150,925,735	$4.11
Calcitriol	$2,645,644	$0.07
Doxercalciferol	$89,814,291	$2.44
Paricalcitol	$313,002,443	$8.52
Iron Sucrose	$172,625,432	$4.70
Sodium Ferric Gluconate	$67,575,376	$1.84
Levocarnitine	$4,021,810	$0.11
Alteplase	$27,960,906	$0.76
Vancomycin	$3,176,525	$0.09
Daptomycin	$1,429,021	$0.04
Other injectables	$5,038,108	$0.14
Laboratory tests	$308,732,410	$8.40
Ultrafiltration	$2,563,656	$0.07
Dialysis facility supplies and IV fluids	$38,263,239	$1.04
Durable medical equipment and supplies (method II)	$18,060,483	$0.49
Dialysis support services (method II)	$1,447,484	$0.04
Dialysis patients with Part D spending	221,154	--
HD-equivalent dialysis treatments for patients with Part D spending	24,737,326	--
MAP for Part D services	$11,340,484	$0.46
Calcitriol (oral)	$2,839,032	$0.11
Doxercalciferol (oral)	$5,262,356	$0.21
Paricalcitol (oral)	$3,188,606	$0.13
Levocarnitine (oral)	$50,490	<$0.01

*The estimates above exclude patient facility months with no hemodialysis-equivalent treatments. The monthly Hemodialysis-equivalent treatments were capped at the number of days in the month (e.g., 31 for January). Payments for EPO and darbepoetin were capped to reflect the medically unbelievable edit threshold that applied at the time under the CMS ESA Claims Monitoring Policy (500,000 and 400,000 units of EPO per month in 2007 and 2008-2009, respectively, and 1,500 and 1,200 mcg of darbepoetin per month in 2007 and 2008-2009, respectively).

The first MAP component of the ESRD PPS payment bundle shown in Table 8.2 reflects total CY 2007 payments for composite rate services as obtained from dialysis facility claims (type '72' claims), inflated to 2009 prices. The next 11 line items in Table 8.2 reflect the categories of injectable drugs and biologicals that were included in the bundle. Total Medicare Allowable Payments in 2007 for the top 11 Part B drugs and biologicals included in the bundle definition accounted for 99.8 percent of total spending for Part B drugs billed on dialysis facility (type 72) claims. These categories included drugs used for the treatment of anemia and iron deficiency (which include ESAs and intravenous iron), access management (which include Alteplase), bone and mineral metabolism (which include vitamin D), antibiotics used for the treatment of venous access infections and peritonitis (specifically, vancomycin and daptomycin) and cellular management (specifically, levocarnitine). A category of miscellaneous other injectable drugs accounted for the remaining 0.2 percent of payments for separately billable drugs. It was determined that while these drugs may be used for non-ESRD related conditions (e.g., antiemetics and pain medications), they could be ESRD-related, and were therefore included in the final bundle definition.

The component of the ESRD PPS bundle that represents laboratory tests includes both laboratory tests that were billed by dialysis facilities and laboratory tests that were ordered by physicians receiving Monthly Capitation Payments and billed on carrier claims. Since it was not possible to distinguish laboratory testing that was related to the treatment of ESRD from testing that was not related to ESRD but where samples were drawn and services billed by ESRD facilities for the convenience of the patient, CMS decided to include payment amounts corresponding to all of these laboratory tests in the calculation of the base rate.

Payments for durable medical equipment and supplies were obtained from the CMS-1500 claim forms or the electronic equivalent for Method II home patients. The total of "Dialysis support services" 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 dialysis facility claims. The category of supplies and other services billed by dialysis facilities primarily includes payments for syringes used to administer intravenous drugs during outpatient dialysis.

The category of Part D drugs in Table 8.2 includes the oral equivalents of injectable drugs and biologicals that were included in the final bundle definition. Specifically, these oral equivalent drugs included three vitamin D analogs (calcitriol, doxercalciferol, and paricalcitol) and levocarnitine). The corresponding payments for these drugs were obtained from Part D claims submitted on behalf of Medicare ESRD beneficiaries with payments on dialysis facility claims and Part D coverage in CY 2007. For the final rule, total Part D drug expenditures for these oral equivalent drugs were divided

by the number of HD-equivalent treatments for Medicare dialysis patients enrolled in Part D. The resulting average payment per treatment for oral equivalent Part D drugs computed among Part D enrollees was included in the calculation of the total per treatment amount for all Medicare dialysis patients in Table 8.2.

In calculating the CY 2011 ESRD PPS base rate per treatment, the total MAP amount was divided by the number of Medicare hemodialysis (HD)-equivalent sessions on dialysis facility claims. For peritoneal dialysis (PD) patients, patient weeks were converted to HD-equivalent sessions by considering one week of PD to be equivalent to three HD sessions. For example, a patient on PD for 21 days would have (21/7) × 3 or 9 HD-equivalent sessions. The number of HD-equivalent sessions was capped so as not to exceed the number of days in the month in which treatments were reported.

Summing the Medicare Allowable Payments for the components of the bundle shown in Table 8.2 yielded an average MAP per treatment of $243.19 for Part B services, an average MAP per treatment of $0.46 for Part D services, and an overall average MAP per treatment of $243.65 for all Part B and Part D services included in the ESRD PPS. These estimates were based on 2007 data with adjustments for price inflation to 2009.

In order to establish a final base rate amount that satisfied the statutory requirements for the ESRD PPS, it was necessary to adjust 2007 payments to reflect the most recent estimates of 2011 price levels. CMS determined that the final composite rate amount for CY 2011 would be $138.53 per treatment, and that the drug add-on percentage would be 14.7 percent. CMS also determined price updates for separately billable Part B drugs that were based on the latest available ASP pricing data and an update factor based on the Producer Price Index for drugs. The resulting price updates for separately billable Part B drugs were reported in Table 20 of the CY 2011 ESRD PPS final rule. Using an updated CPI-U forecast, CMS determined that a price update of 3.9 percent would be applied for laboratory tests. Using an updated National Health Expenditure Projection, CMS determined that a price update of 12.9 percent would be applied for the oral equivalent Part D drugs. Based on the adjustments for price inflation to 2011 that were determined by CMS for the final rule, UM-KECC calculated the unadjusted per treatment base rate to be $251.60.

As a result of the modifications that were made to the ESRD PPS payment adjustment factors for the final rule, the corresponding standardization factor for the base rate was recalculated. The payment adjustments that were finalized for the ESRD PPS were based on patient age, BSA, low BMI, <4 months since onset of dialysis, six individual comorbidities, facility low volume status, a

geographic area wage index, and an add-on adjustment for home dialysis training. When accounting for the magnitude of these payment adjustments and projections of the frequency with which they would be applied using 2007 data, it was estimated that the $251.60 unadjusted base rate amount for 2011 would need to be reduced by 5.93 percent in order for the PPS adjustments to be budget neutral. This estimate yielded a standardization factor of 0.9407 for the ESRD PPS final rule.

As with the proposed rule, an adjustment factor of 0.99 was applied to account for a 1% outlier policy and an adjustment factor of 0.98 was applied to satisfy the MIPPA requirement that the ESRD PPS reduce projected payments for bundled services by 2 percent. Given an unadjusted base rate amount of $251.60, a payment adjustment standardization factor of 0.9407, an adjustment factor of 0.99 for the 1 percent outlier policy that was being finalized by CMS, and an adjustment factor of 0.98 required by the MIPPA legislation, a base rate amount of $229.63 was calculated for the CY 2011 ESRD PPS final rule.

Conclusion

The methodology that was used to calculate the base payment rate for the CY 2011 ESRD PPS was designed to satisfy MIPPA requirements for total Medicare payments to dialysis facilities in CY 2011. A comparison involving available claims data for CY 2007, CY 2008, and CY 2009 established CY 2007 as the year that reflected the lowest per patient utilization for services included in the ESRD PPS and therefore also the year that would be the basis for calculating the ESRD PPS base rate. Given both a final definition for the bundle of services to be included in the ESRD PPS and projected price levels for these services in CY 2011 as determined by CMS, the average projected payment per treatment for composite rate and separately billable services to be included in the ESRD PPS was calculated using 2007 data. This overall average projected payment per treatment for 2011 served as a starting point for calculating the final ESRD PPS base rate. A standardization factor was applied to this amount to offset the effects of projected payment adjustments based on patient case-mix, facility low volume status, a geographic area wage index, and home dialysis training. In determining the ESRD PPS base rate, adjustment factors were also applied in accordance with the 1 percent outlier policy and for the 2% reduction in dialysis facility payments that was required by MIPPA for CY 2011.

IX. DEVELOPMENT OF PAYMENT METHODOLOGY FOR PEDIATRIC PATIENTS

A. BACKGROUND/RATIONALE

Developing a case-mix adjustment model for pediatric patients requires the consideration of several key differences between the pediatric and adult dialysis populations. First, while developing the case-mix adjusters for outpatient ESRD patients under age 18, we found that given the small number of pediatric patients, there is a lack of statistical robustness in the payment model with respect to those patients, the clinical comorbidities affecting pediatric patients are quite different than those affecting adult patients, and the distribution of modalities differed, with greater proportions of pediatric patients transplanted and using peritoneal dialysis rather than hemodialysis. Therefore, it is inappropriate to develop case-mix adjusters in accordance with the same methodology and adjusters otherwise applicable to adult Medicare ESRD patients. However, a separate regression based case-mix model is still feasible for pediatric patients using a limited number of variables. In the following sections, we describe the analysis for the pediatric payment methodology in the basic case-mix adjusted (BCMA) composite rate payment system (the predecessor of the current payment system), and the development of the payment adjusters in the PPS that were implemented in 2011 for Medicare pediatric ESRD patients.

B. PEDIATRIC PAYMENT MODEL IN THE BASIC CASE-MIX ADJUSTMENT

The BCMA payment system implemented in 2005 used a set of case-mix adjusters or multipliers based on three variables: age, BSA, and low BMI. These basic case-mix adjustments were derived from a regression methodology that used claims and cost report data from years 2000 through 2002 and the adjustments are multiplicative when determining the per treatment payment amount. Due to the relatively small number of pediatric Medicare patients under 18 years of age at the time of the development of the BCMA composite rate payment system (annual population of approximately 600 (0.2 percent) of Medicare patients), estimates of the cost of treating pediatric patients under 18 years of age relative to those in various adult age categories were imprecise (large statistical confidence intervals) and unstable (substantially different based on which years of data were used in the analyses). The small number of patients reflects not only the low incidence of ESRD among children, but also the fact that most pediatric ESRD patients are treated with transplants rather than dialysis (USRDS, 2015 ADR), and the relatively low Medicare coverage among pediatric patients (many pediatric dialysis patients are covered as dependents on a private insurance policy held by a parent/guardian).

Therefore, the Centers for Medicare & Medicaid Services (CMS) elected to base the pediatric payment on the composite rate exception payments for pediatric facilities that had been paid historically. That resulted in a

payment multiplier of 1.62 applied to treatments for patients under age 18 relative to the lowest cost adult age category (ages 60-69 based on 2000-2002 data) for which the age multiplier is 1.0 (that is, CMS used an age adjustment factor of 1.62 to the composite rate as the payment for pediatric patients).The other basic case-mix adjustments for body surface area and body mass index were not applied to claims for pediatric End Stage Renal Disease (ESRD) patients. The pediatric case-mix payment adjustment was based on the expectations, as reflected in prior CMS exception policy, that pediatric patients were more costly to care for than adult patients, that they represented a particularly vulnerable group of dialysis patients, and that failure to provide some adjustment could impair access to care. The CY 2005 Physician Fee Schedule Final Rule (69 FR 66327) noted that this adjuster was deemed by CMS to be temporary and that further research would be undertaken on the cost of care for pediatric patients in the development of the expanded bundled payment system.

Subsequent to the issuance of the Secretary's 2008 Report to Congress, the University of Michigan-Kidney Epidemiology and Cost Center (UM-KECC) continued research to develop a case-mix model for pediatric patients under the ESRD PPS using a limited number of adjustment variables. In the following sections, we describe the development of the Medicare payment model for pediatric dialysis patients that appeared in the ESRD PPS proposed (IX. Pediatric Patients Vol. 74 Proposed Rules 49981) and final payment rules (II.G. Pediatric Patients Vol. 75 Final Rules 49128) for payment year 2011.

C. SELECTION OF A PEDIATRIC COMPOSITE RATE PAYMENT ADJUSTMENT

One approach to developing a payment adjustment was based on the results of an updated composite rate cost model. Such a model could employ one or several age categories for pediatric patients. Table 9.1 presents a model of composite rate (CR) costs for the purpose of demonstrating a method for arriving at a pediatric CR multiplier, with a single pediatric age category.

This exploratory model was estimated primarily using CMS claims files for Medicare dialysis patients and the Medicare Cost Reports for dialysis facilities for calendar years 2004–2006. Other data sources used included the Medicare Enrollment Database and the CMS Medical Evidence Form (CMS Form 2728), which is completed at onset of renal replacement therapy. Patient comorbidities were measured using a combination of CMS Form 2728 and diagnoses reported on Medicare claims. The claims diagnoses were used both to identify comorbidities that were not abstracted using CMS Form 2728 and to capture changes in patient condition since the start of renal replacement therapy. Dialysis facility characteristics were measured using a combination of the ESRD Standard Information Management System (ownership type and geographic location), the Medicare Cost Reports (facility size), the Online Survey and Certification and Reporting System (hospital affiliation for satellite units) and other information obtained from CMS (composite rate payment

exceptions). No cost data were available for composite services delivered to pediatric patients at the patient level. Therefore, this model used ESRD facility data on composite rate costs and average patient characteristics.

Because pediatric patients comprised 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) were dominated by the characteristics of adult patients. Therefore, while average patient characteristics were shown in Table 9.1 in the model, they were only used as control variables reflecting the characteristics of the primarily adult dialysis population. Although statistically significant payment adjusters are shown in Table 9.1 for patient characteristic variables, there was no actual associated payment adjustment that would apply to composite rate services for pediatric patients.

For example, the pediatric composite rate cost model assumed no payment adjustment for body size (BSA or low BMI), gender, duration of renal replacement therapy, or co-morbidities. The key coefficient from this model was the one for the age category less than age 18. The estimated regression based multiplier of 1.199 reflected an increase in the composite rate portion of the base payment rate of 19.9 percent for patients less than age 18, relative to patients ages 45–59 (the lowest cost adult group in the 2004-2006 data). The type of cost model shown in Table 9.1 could also utilize multiple pediatric age categories to allow for the possibility that costs differ between younger and older pediatric patients. However, dividing the already small number of pediatric patients into even smaller age categories led to imprecise and unstable estimates of the pediatric age multipliers.

Therefore, with respect to a payment adjustment applicable to composite rate services for pediatric patients, we believed that a single age category was most appropriate. Although the proposed payment adjuster of 1.199 for the composite rate portion of the ESRD PPS for pediatric patients was substantially less than the basic case-mix adjustment of 1.62, it should be noted that this is an empirically developed measure derived from data for all Medicare ESRD pediatric outpatients treated by ESRD facilities. The 1.62 value employed by the BCMA was developed from only those facilities that sought and obtained an exception to their otherwise applicable composite payment rates.

Table 9.1 Payment multipliers from a facility level model of composite rate costs

	Composite rate services (n=11,814 facility years; R^2=46.0%)	
Variable*	**$Mult_{CR}$**	**p-value**
Adjustments for dialysis patient characteristics		
Age (years)		
<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.

Given the decline relative to the value used in BCMA, there were concerns about the magnitude of the composite rate portion of the proposed payment multipliers for pediatric dialysis patients. Regardless of whether the pediatric multiplier of 1.199 understated the true costs of care, it would clearly represent a significant reduction in revenues received by facilities caring for this small but vulnerable population, potentially threatening quality of care or access to care. Therefore, CMS suggested that we revise the methodology for calculating the pediatric composite rate payment amount. Instead of using the regression-based composite rate multiplier of 1.199, CMS decided to use the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate services in CY 2007 as the pediatric payment adjustment. Calculation of this difference was based on the 872 pediatric dialysis patients reflected in the data, which represented the year with the lowest per patient utilization of dialysis services. Table 9.2 reveals that the average CY 2007 Medicare Allowable Payment (MAP) for composite rate services for pediatric dialysis patients was $216.46, compared to $156.12 for adult patients. This difference in composite rate payment was reflected in the overall adjustment for pediatric patients calculated below.

Table 9.2 Comparison of pediatric to adult payment for services in an expanded ESRD PPS, 2007

Service	All ages		Ages < 18		Ages 18 and older	
	Average per treatment	Total	Average per treatment	Total	Average per treatment	Total
Dialysis patients	--	328,787	--	872	--	328,004
Hemodialysis-equivalent dialysis treatments	--	36,747,662	--	75,478	--	36,672,184
Medicare Allowable Payments for services in the expanded ESRD PPS						
Total for Part B and Part D services	$239.88	$8,809,732,068.05	$267.66	$20,140,444.32	$239.82	$8,789,591,623.73
Total for Part B services	$239.44	$8,799,031,984.47	$264.55	$19,967,531.39	$239.39	$8,779,064,453.08
Composite rate and other dialysis services	$156.25	$5,741,729,454.44	$216.46	$16,338,032.59	$156.12	$5,725,391,421.85
Composite rate services	$155.65	$5,719,657,831.39	$199.30	$15,043,119.60	$155.56	$5,704,614,711.79
Durable medical equipment and supplies	$0.49	$18,060,482.59	$16.00	$1,207,494.83	$0.46	$16,852,987.76
Dialysis support services	$0.04	$1,447,484.43	$1.08	$81,360.99	$0.04	$1,366,123.44
Ultrafiltration	$0.07	$2,563,656.04	$0.08	$6,057.18	$0.07	$2,557,598.86
Separately billable services (Part B)	$83.20	$3,057,302,530.04	$48.09	$3,629,498.81	$83.27	$3,053,673,031.23
Epogen	$51.08	$1,876,926,573.16	$26.84	$2,026,111.30	$51.13	$1,874,900,461.86
Darbepoetin	$4.57	$167,935,969.83	$1.97	$148,917.20	$4.58	$167,787,052.63
Calcitriol	$0.09	$3,125,612.59	$0.32	$24,190.94	$0.08	$3,101,421.65
Doxercalciferol	$2.09	$76,901,723.05	$0.46	$34,763.13	$2.10	$76,866,959.93
Paricalcitol	$8.79	$322,849,347.85	$5.24	$395,284.33	$8.79	$322,454,063.53
Iron sucrose	$4.52	$166,219,338.55	$1.29	$97,013.96	$4.53	$166,122,324.59
Sodium ferric gluconate	$1.85	$68,086,706.74	$1.00	$75,540.41	$1.85	$68,011,166.33
Levocarnitine	$0.14	$5,026,445.93	$0.18	$13,644.56	$0.14	$5,012,801.36
Alteplase	$0.73	$26,697,321.33	$1.76	$132,629.09	$0.72	$26,564,692.24
Vancomycin	$0.10	$3,583,503.88	$0.16	$11,964.88	$0.10	$3,571,539.00
Daptomycin	$0.03	$1,234,404.70	$0.00	$0.00	$0.03	$1,234,404.70
Other injectables	$0.13	$4,943,934.31	$0.47	$35,594.00	$0.13	$4,908,340.31
Laboratory tests	$8.04	$295,508,409.06	$7.84	$591,436.98	$8.04	$294,916,972.08
Dialysis facility supplies and IV fluids	$1.04	$38,263,239.08	$0.56	$42,408.04	$1.04	$38,220,831.04
Hemodialysis-equivalent dialysis treatments for patients with Part D spending	--	24,737,326.14	--	55,547.79	--	24,681,778.36
Total for Part D services	$0.43	$10,700,083.58	$3.11	$172,912.93	$0.43	$10,527,170.65
Calcitriol (oral)	$0.11	$2,678,711.44	$1.73	$95,936.79	$0.10	$2,582,774.65
Doxercalciferol (oral)	$0.20	$4,965,189.06	$0.56	$31,139.51	$0.20	$4,934,049.55
Paricalcitol (oral)	$0.12	$3,008,544.32	$0.76	$42,381.46	$0.12	$2,966,162.86
Levocarnitine (oral)	$0.00	$47,638.76	$0.06	$3,455.17	$0.00	$44,183.59

D. SELECTION OF A PEDIATRIC SEPARATELY BILLABLE PAYMENT ADJUSTMENT

Although the number of pediatrics patients is small, it was still feasible to estimate a separately billable (SB) model for pediatric patients. However, the small sample size limited statistical power and likely resulted in a limited set of potential payment adjusters. Unlike the adult SB payment model, which included multipliers for particular patient comorbidities, age, body size, and other characteristics, the pediatric SB payment models were based on discrete categories, defined by combinations of patient characteristics including age, presence of comorbidities, and dialysis modality. This model structure was feasible because of the relatively small number of characteristics generating adjustments.

Some key decisions in building this SB payment model were: (1) number and definition of age categories; (2) number and set of comorbidities; (3) reflection of modality in payment; (4) reflection of other patient characteristics, such as sex, duration of renal replacement therapy (RRT), or history of transplantation. Several exploratory models were built for separately billable services in pediatric patients in order to develop a recommended model. A selection of these analyses is presented below, to indicate our analytic approach and provide support for our recommendations.

The analyses presented below were performed using log-linear regression models of the average separately billable MAP per session during the year. Data were pooled over a three-year period, CY 2004-2006, resulting in up to three yearly observations for each pediatric patient. The multipliers from the model often required a "smearing" adjustment to limit bias resulting from retransformation of the values from the log dollar scale used in the regression back to the dollar scale (Duan, 1983). Due to heteroscedasticity that was present with respect to several patient characteristics in the model, separate smearing factors were applied by patient subgroup (Manning, 1998). The smearing adjustments were based on the average retransformed residual for each patient category, which tended to result in substantially smaller average prediction errors for the actuarial cells (comparisons of model-predicted and actual SB costs for each patient group), suggesting that these technical adjustments are appropriate.

UM-KECC examined multiple separately billable payment models to determine the most appropriate age categories, the selection of comorbidity categories, and the use of an adjustment for dialysis modality. Individual comorbidities that were considered for inclusion in the comorbidity categories were each identified as statistically significant predictors of separately billable MAP per treatment based on a stepwise regression model.

1. Use of two age categories: aged <13 years and aged 13–17 years. 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 aged less than 13 years and aged 13–17 years.

2. Omission of hyperparathyroidism as a co-morbidity. Hyperparathyroidism had a relatively low reported incidence in the overall claims data. However, hyperparathyroidism was a frequently encountered condition in pediatric dialysis patients. This co-morbidity had a relatively high potential for over-reporting compared to other co-morbidities. Because hyperparathyroidism was associated with a relatively small cost increase, omitting this diagnosis from the list of comorbidities generating a payment adjustment increased the potential payment multipliers for other comorbidities. However, given the widespread occurrence of hyperparathyroidism in the pediatric dialysis patient population, we believed its omission resulted in minimal distortion in the adjusters for most payment categories.

3. Capping Separately Billable MAPs at $289.00 per treatment for all pediatric patients. The cap of $289.00 was based on a standard outer fence method for identifying statistical outlier values. (For a further explanation on the application of this method, see endnote 35 of the Secretary's February 2008 Report to Congress, https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/downloads/ESRDReportToCongress.pdf). Capping the separately billable MAP did not lead to substantially different payment multipliers. The standard deviation of the prediction error fell substantially for some of the payment groups. 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 suggested that the predicted payments were not biased through the inclusion of outlier values, regardless of whether those values were valid or invalid.

4. Adjustment for dialysis modality. Our analysis revealed that the main problem with a separately billable payment model that did not recognize modality is that it resulted in an underpayment for HD and an overpayment for PD. In models that did not pay differentially by modality, the average prediction errors were all positive for PD and negative for HD. These prediction errors, generated when models did not distinguish between modalities, were large relative to the predicted means. By contrast, the prediction errors in models that did distinguish payment by modality were much smaller and did not consistently favor one modality over the other. Hence, payment by modality reduced the difference between actual and predicted payments. In doing so, it reduced the incentive to steer patients to a particular modality based purely on the payment implications. It also substantially improved the predictive power of the payment models.

   However, payment by modality introduced an inconsistency with how it was treated under the basic case-mix adjusted composite payment system, and with how we were proposing to treat modality for adults under the new ESRD PPS. Paying by modality for pediatric patients was also inconsistent with the policy goal of encouraging home dialysis. However, we noted that partly because of the high prevalence of PD among pediatric patients, it may not be necessary to encourage home therapies for this population.

5. Exclusion of Other Patient Characteristics. Among the other patient characteristics that were considered as potential payment adjusters for separately billable pediatric services, sex and onset of dialysis were not identified as statistically significant predictors of MAPs 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 (fewer than 50 patients).

Given the results of the analyses described, we proposed a pediatric payment adjustment for separately billable services that uses two age categories (aged < 13 years, aged 13–17 years), two comorbidity categories (none, 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 basis for classifying pediatric patients into one of eight mutually exclusive groups. The specified co-morbidities were the only statistically significant predictors of SB MAP in the pediatric population resulting from the application of the stepwise regression. Further, these comorbidities were relatively uncommon and often had similar (though imprecisely estimated) multipliers in models that included them individually. Therefore, the recommendation was made to combine them into a single adjuster for the presence of one or more of the specified comorbidities (very few pediatric patients had more than one of these conditions). Using data available for CY 2004–2006, we arrived at the results presented in Table 9.3.

For purposes of the recommended 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 (aged < 13 years, PD, no comorbidities) having a multiplier set to 1.00.

Table 9.3 Measured and predicted SB MAPs for pediatric patients, 2004-2006. Predicted MAPs based on age, modality, and comorbidity groups

Cell	Patient characteristics			Patients[2]	Patient-facility months	Modeled separately billable (SB) multipliers[3]	Separately billable MAP per session			
	Age	Modality	Comorbidities[1]				Actual mean	Predicted mean[4]	Prediction error	
									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 (aged <13 years vs. aged 13-17 years), modality (PD vs. HD), and comorbidity (none vs. 1 or more) as covariates (R^2=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.

Because of concerns that comorbidities were not prevalent among pediatric dialysis patients, UM-KECC developed an alternative model for payment adjusters for separately billable services for pediatric patients excluding the comorbidities. We developed adjustments for the variables of age (<13 years, 13–17 years) and modality (PD or HD) by using the same methodology described above. All of the analyses were based on CY 2006–2008 data, which had become available by the time these analyses were performed.

As noted above, capping the separately billable MAP had little effect on the magnitude of the payment multipliers, suggesting that the predicted payments were not biased through the inclusion of valid or invalid outlier values. Accordingly, we decided not to apply caps to the computation of the separately billable MAPs for pediatric patients in developing the pediatric payment, except for erythropoietin (EPO) and Aranesp (darbepoetin alfa). Payments for these erythropoiesis-stimulating agents (ESAs) were capped at the same medically unbelievable thresholds that are applied to adult patients. The final CY 2011 pediatric payment adjustments for separately billable services use two age categories (<13 years, age 13–17 years) and dialysis modality (PD or HD), as the basis for classifying pediatric patients, not including co-morbidity categories. With data for CY 2006–2008, we presented the pediatric payment adjuster or multiplier results in Table 9.4 below.

For purposes of the proposed payment adjustments, the relevant column is labeled "separately billable (SB) multiplier". These values reflect the relative costliness of separately billable services for each of the four pediatric patient groups. The SB multipliers were calculated relative to the average SB multiplier among pediatric patients, weighted by treatments, such that the average SB payment multiplier is 1.000.

Table 9.4 Calculating combined payment multipliers for pediatric patients based on adjustments for age and modality

Cell	Patient characteristics		Separately billable (SB) multiplier[1]	Expanded bundle payment multiplier
	Age	Modality		
1	<13	PD	0.319	1.033
2	<13	Hemo	1.185	1.219
3	13-17	PD	0.476	1.067
4	13-17	Hemo	1.459	1.277

[1]Based on a pediatric patient month level regression model of SB MAP/session for 2006-08 (n=17,142 pediatric patient months) that included age (<13 vs. 13-17) and modality (PD vs. HD). An R^2 value calculated at the patient year level was 34.8%. This calculation was based on a regression model that used the average predicted SB MAP per treatment during each patient year (calculated by averaging the monthly predicted values for each patient from the patient-month SB model) to explain variation in the average observed SB MAP per treatment for the patient year. In estimating this R^2 value, a log transformation was applied to both the average predicted and average observed SB values. The R^2 value for this patient month model was 32.8%. Subgroup-specific smearing adjustments were applied to the estimated multipliers from the model. The SB payment multipliers presented above were calculated relative to the average SB multiplier among pediatric patients, weighted by treatment, such that the average pediatric SB payment multiplier is 1.000.

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

In response to concerns about pediatric comorbidities and underrepresentation in the composite rate costs, we revised the methodology for calculating the pediatric payment adjusters to reflect the actual average Part B Medicare payment per treatment for pediatric patients in CY 2007.

Calculation of an overall pediatric adjustment factor should reflect the higher payments for composite rate services, and allow the pediatric payment adjusters for separately billable services to be applied to the total base rate amount. In Table 9.2, the composite rate MAP for pediatric patients was higher than that for adult patients ($216.46 versus $156.12). However, the separately billable MAP was lower for pediatric patients ($48.09 versus $83.27), largely because of the predominance of PD among pediatric patients, in which the utilization of separately billable services was lower, and because of the smaller body size of younger pediatric patients. Overall, CY 2007 MAP was 10.5 percent higher for pediatric patients than for adult patients ($216.46 + $48.09 = $264.55 vs. $156.12 + $83.27 = $239.39; $264.55/$239.39 = 1.105). Use of the 1.105

adjustment would reflect the higher payment for composite rate services and lower utilization of separately billable services among pediatric dialysis patients.

The pediatric payment adjustments shown in Table 9.4 for each of the four classification categories would normally be applied to the separately billable portion of the MAP for pediatric patients. To reflect both the composite rate and separately billable components, the following approach could be used. Let P represent the ratio of the total CR and SB MAP per treatment for pediatric patients relative to adult patients (calculated above to be 1.105), WCR and WSB represent the proportion of MAP for CR and SB services, respectively, among pediatric patients, C represents the average case-mix multiplier for adult patients, and MultSB represents the SB payment multiplier shown in Table 9.4. The expanded bundle payment multiplier for CR and SB services for each of the four pediatric classification cells can be calculated as:

$$MultEB = P * C * (WCR + WSB * MultSB)$$

Based on the average MAP per treatment for CR and SB services of $264.55 for pediatric patients, and $239.39 for adult patients shown in Table 9.2, P was calculated as P=$264.55/$239.39 = 1.105.

The CR and SB weights for pediatric patients were calculated as the ratio of the MAP per treatment for CR and SB services relative to the sum of the CR and SB MAP per treatment in 2007, where

$$WCR = \$216.46/\$264.55 = 0.8182$$

$$WSB = \$48.09/\$264.55 = 0.1818$$

The average case-mix multiplier for adult patients (C = 1.067) was applied to offset the standardization for case-mix adjustments (that is, BSA, low BMI, onset of renal dialysis, and comorbidities) which were not used for pediatric patients. If this standardization factor of 1.067 were not used to increase the otherwise applicable pediatric payment adjustments or multipliers, those multipliers would be inappropriately understated by 6.7 percent. For example, the expanded payment multiplier for pediatric classification group 1 (cell 1) was calculated as:

$$MultEB = 1.105 * 1.067 * (0.8182 + 0.1818 * 0.319) = 1.033$$

This formula yields the four pediatric payment multipliers shown in Table 9.4 that were applied to the overall adjusted base rate amount of $229.63 per treatment, depending upon each pediatric patient's classification cell.

As mentioned above, the payment adjustments developed for adult dialysis patients, such as comorbidities, BSA, low BMI, and onset of dialysis did not apply to pediatric patients. In addition, the low-volume adjustment rule would not apply to pediatric patients given that pediatric payment still reflects the high average payment rate for composite rate services under the prior payment system.

Conclusion

Due to the small share of pediatric patients in the dialysis population, clinical differences between pediatric and adult patients (e.g., body size, comorbidities, distribution of treatment modalities), a pediatric case-mix model was built separately from the adult, two-equation model. The two-equation approach was followed insofar as separate components of the expanded bundle reflected composite rate costs and separately billable costs. However, the composite rate bundle component is based on historical CMS payments for pediatric patients, which are based on the historic composite rate payment exception process. The separately billable component is based on a model that differentiates costs incurred by four groups of pediatric patients (<13 years and 13-17 years, both split by dialysis modality (PD or HD)). This approach makes parsimonious use of the limited amount of data on pediatric patients while still reflecting important sources of variation in the use of separately billable services.

X. CONCLUSION

The ESRD PPS was built progressively on Medicare's prior ESRD payment system and the research done to support it. The basic case-mix adjustment (BCMA) to the composite rate payment system, implemented in 2005, represented an innovation to the prior system by providing empirically based adjustments for patient age and body size. The ESRD PPS was based on further research by UM-KECC to support updating and refinement of the composite rate case-mix model as well as the incorporation of case-mix adjustment for the separately billable services that were being added to the payment bundle.

The basic approach to this research was described in the 2008 Report to Congress, and in proposed and final payment rules for the 2011 implementation of the ESRD PPS. The objective of this report was to provide further detail on the analyses performed between the Report to Congress and implementation, demonstrating how they built upon the earlier work and outlining the information that was considered as the new payment system was finalized.

A critical initial consideration included how to structure the payment model to make best use of the available data. Charges and payments for composite rate services on Medicare claims reflected only the number of treatments and overall facility cost, and not the resources used to deliver those treatments to individual patients. Therefore, the cost of delivering services in the BCMA's composite rate model had to be estimated at the facility level. That model related average case mix characteristics of a facility's patient population (e.g., percent of patients in a particular age group) to average cost per dialysis session. In the intervening years, no new systematic, national data sources had become available to allow the estimation of cost of providing composite rate services at the level of the individual patient. Therefore, the composite rate model remained at the facility level. Because facility level models have less statistical power than patient level models, empirical adjustments could be derived only for patient characteristics showing substantial variation at the facility level. Conversely, Medicare claims identify the use of separately billable services (primarily injectable medications and laboratory tests) being added to the bundle at the patient level. This supported estimation of a patient-level separately billable equation and allowed for estimation of the payment adjusters for a larger set of case mix characteristics.

Due to the unavailability of data on variation in costs of composite rate services across individual patients, it was only possible to estimate a combined composite rate and separately billable model at the facility level. UM-KECC's research demonstrated that a model that did not utilize available data on patient-level variation in separately billable services was less precise, less stable from year to year, and potentially subject to statistic bias. Therefore, the chosen model structure was a two equation model that estimated composite rate costs at the facility level, and estimated separately billable costs at the patient level. The case-mix adjusters from these

two models were then combined into a single equation payment model by taking their weighted average, where the shares of total spending for composite rate and separately billable services served as the weights.

Beyond the statistical model's two equation structure, the critical considerations were components of the expanded bundle of services (which define the model's dependent variables) and the actual definition of the case-mix adjusters. This report describes each of the new components of the payment bundle (dialysis-related laboratory tests, injectable drugs previously paid under Medicare Part B and their oral equivalents previously paid under Part D, and miscellaneous dialysis supplies). Several components ultimately not included in the bundle (blood and blood products, Part D drugs that are not the equivalents of bundled Part B drugs) are also described. Those components and others (e.g., services related to vascular access) could be considered for inclusion in future iterations of the ESRD PPS. The patient case-mix adjusters were developed in an extensive modeling effort. This report described many of these developmental models. Ultimately, adjustments were included for six clinical comorbidities, patient age, body size and low body mass index, and onset of dialysis (first four months of treatment). Other adjusters were considered but were not ultimately included in the final rule payment model (for example, additional clinical comorbidities, sex, and race).

In addition to these patient case-mix adjusters, the development of several other payment adjustments and other features of the ESRD PPS are described in this report. First, an adjustment for small facility size (delivering fewer than 4000 treatments annually for at least three consecutive years) was developed as part of the same statistical model from which the patient case-mix adjusters were derived. While such facilities might have higher costs per treatment due to the lack of economies scale, it was recognized that their continued viability may be important for patient access to care. Second, given the possibility that some high cost cases might not be captured using the existing case-mix adjusters, an outlier payment mechanism was developed. Because patient-level costs could only be observed for separately billable services, the outlier mechanism was limited to those patients with significantly higher than expected utilization of those services. The outlier system provides partial payment of costs that exceed a fixed dollar loss above a patient's case-mix adjusted payment rate. This fixed dollar loss was calibrated with the expectation that outlier payments would constitute one percent of total payments.

Third, because home dialysis training treatments represent a small share of all treatments at the facility level, it was not possible to estimate a reliable training adjuster from the statistical model. Therefore, CMS finalized an alternative approach of an "add on" payment based on the cost of nursing time expected to be associated with training. Fourth, the data used to set the base rate - to which each of these adjustments would be applied - was also described. According to Congressional mandate, the base rate was to be based on the lowest utilization year of 2007, 2008 or 2009, with a two percent reduction to reflect efficiencies anticipated under the ESRD PPS relative to the prior payment system. Fifth, due to the small number of pediatric patients,

several important differences between pediatric patient characteristics and treatment modalities relative to adult patients, and the potential vulnerability in terms of access to care, a pediatric-specific payment adjustment model was developed. That model included adjusters for two age categories (<13 years, 13-17 years) and dialytic modality (hemodialysis, peritoneal dialysis). Overall payments for pediatric patients were based upon historical payments relative to adult patients.

In each payment year following the ESRD PPS's implementation in 2011, several routine refinements have been developed. These include accounting for changes in the wage indices used to adjust for geographic variation in labor costs, changes in the estimated acquisition prices for injectable medications, productivity adjustments, and Congressionally-mandated changes to the overall payment rate. The impact of these refinements on specific facilities and on groups of facilities (e.g., rural vs. urban, facility size, facility ownership) was also assessed each year. Such routine refinements to the ESRD PPS are described thoroughly in each payment year's proposed and final rules. For the CY 2016 payment year, more substantial refinements were undertaken. The most significant are the Congressionally-mandated update of the case-mix adjustment model, and CMS's decision to modify the geographic proximity criteria for receipt of the facility low volume adjustment. These more substantial refinements have been described in the proposed and final payment rules for CY 2016 and the research underlying those changes will be described more thoroughly in a subsequent report.

XI. REFERENCES

Anderson GF, Bilenker JH. Capitation payment rates and implications for the general pediatrician. *Curr Opin Pediatr*. 1998;10(5):480-485.

Beddhu S, Bruns FJ, Saul M, Seddon P, Zeidel ML. A simple comorbidity scale predicts clinical outcomes and costs in dialysis patients. *Am J Med*. 6// 2000;108(8):609-613.

Bovbjerg RR, Held PJ, Pauly MV. Privatization and bidding in the health-care sector. *J Pol Anal Manag*. 1987;6(4):648-673.

Boyd E. *The growth of the surface area of the human body*. Minneapolis, MN: University of Minnesota press, 1935.

Centers for Disease Control and Prevention (CDC). BMI - Body Mass Index: BMI for Adults. *http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-adult.htm*. Accessed December 22, 2015.

Chertow GM, Lazarus MJ, Lew NL, Ma L, Lowrie EG. Development of a population-specific regression equation to estimate total body water in hemodialysis patients. *Kidney Int*. 1997;51(5):1578-1582.

Dor A, Held PJ, Pauly MV. The Medicare Cost of Renal Dialysis: Evidence from a Statistical Cost Function. *Med Care*. 1992;30(10):879-891.

Du Bois D, Du Bois EF. A formula to estimate the approximate surface area if height and weight be known. *Arch Intern Med*. 1916;17:863-871.

Duan N. Smearing Estimate: A Nonparametric Retransformation Method. *JASA*. 1983;78(383):605-610.

Ellis RP, Ash AS, Ayanian JZ, Bates DW, Burstin H, Iezzoni LI, Pope GC. Diagnosis-based risk adjustment for Medicare capitation payments. *Health Care Finan Rev*. 1996;17(3):101-128.

Epstein AM, Cumella EJ. Capitation Payment: Using Predictors of Medical Utilization. *Health Care Finan Rev*. 1988;10(1):51-69.

ESRD Program Amendments of 1978. PL 95–292, 92 USC 307, 13 June 1978. *United States Statutes at Large*. 1978;92:307-316.

Gehan EA, George SL. Estimation of human body surface area from height and weight. *Cancer Chemother Rep*. 1970;54(4):225-235.

Haycock GB, Schwartz GJ, Wisotsky DH. Geometric method for measuring body surface area: A height-weight formula validated in infants, children, and adults. *J Pediatr*. 1978;93(1):62-66.

Health Care Financing Administration. Final rule: Prospective Reimbursement for Dialysis Services. *Federal Register*. 1983;48:21254-21291.

Held PJ, Garcia JR, Pauly MV, Cahn MA. Price of Dialysis, Unit Staffing, and Length of Dialysis Treatments. *Am J Kidney Dis*. 1990;15(5):441-450.

Hirth RA, Chernew ME, Orzol SM. Ownership, competition, and the adoption of new technologies and cost-saving practices in a fixed-price environment. *Inquiry*. 2000;37(3):282-294.

Hirth RA, Held PJ, Orzol SM, Dor A. Practice patterns, Case Mix, Medicare Payment Policy, and Dialysis Facility Costs. *Health Serv Res*. 1999;33(6):1567-1592.

Hirth RA, Roys EC, Wheeler JRC, Messana JM, Turenne MN, Saran R, Pozniak AS, Wolfe RA. Economic Impact of Case-Mix Adjusting the Dialysis Composite Rate. *J Am Soc Nephrol*. 2005;16(5):1172-1176.

Hirth RA, Wheeler JRC, Messana JM, Turenne MN, Tedeschi PJ, Sleeman K, Pearson J, Pan Q, Chuang CC, Turner J, Reimann S. *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle*. Ann Arbor, MI: University of Michigan Kidney Epidemiology and Cost Center, February 2008. *http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/UM_KECC_ESRD_Bundle_Report.pdf .* Accessed December 22, 2015.

Hirth RA, Wolfe RA, Wheeler JRC, Roys EC, Tedeschi PJ, Pozniak AS, Wright GT. Is case-mix adjustment necessary for an expanded dialysis bundle? *Health Care Finan Rev*. 2003;24(4):77-88.

Kronick R, Dreyfus T. The Challenge of Risk Adjustment for People with Disabilities: Health-based Payment for Medicaid Programs: a Guide for State Medicaid Programs, Providers, and Consumers for the Center for Health Care Strategies, Inc. The Center, 1997.

Kronick R, Gilmer T, Dreyfus T, Lee L. Improving Health-Based Payment for Medicaid Beneficiaries: CDPS. *Health Care Finan Rev*. 2000;21(3):29-64.

Lamers LM. Pharmacy Costs Groups: A Risk-Adjuster for Capitation Payments Based on the Use of Prescribed Drugs. *Med Care*. 1999;37(8):824-830.

Leavitt MO. *Report to the Congress: A Design for a Bundled End Stage Renal Disease Prospective Payment System*. February 2008.

Manning WG. The logged dependent variable, heteroscedasticity, and the retransformation problem. *J Health Econ*. 1998;17(3):283-295.

Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), PL 110-275, 122 USC 2494, 15 July 2008. *United States Statutes at Large*. 2008;112: 2494-2597.

Medicare Payment Advisory Commission (MedPAC). *March 2001 Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC, March 2001.

Medicare Payment Advisory Commission (MedPAC). *March 2005 Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC, March 2005.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). PL 108-173, 117 USC 2313, 8 December 2003. *United States Statutes at Large*. 2003;117: 2066-2480.

Medicare Program: Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2008, Final Rule. *Federal Register*. 2008; 73:2568 -2710. https://federalregister.gov/a/07-6308. Accessed December 22, 2015.

Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, Proposed Rule. *Federal Register*. 2004; 69:47488-47730. https://federalregister.gov/a/04-17312. Accessed December 22, 2015.

Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, Final Rule. *Federal Register*. 2004;69: 66236-66915. https://federalregister.gov/a/04-24758

Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program, Final Rule. *Federal Register*. 2011;76:70228- 70316. https://www.gpo.gov/fdsys/pkg/FR-2011-11-10/pdf/2011-28606.pdf. Accessed December 22, 2015.

Medicare Programs: End-Stage Renal Disease Prospective Payment System, Proposed Rule. *Federal Register*. 2009;74:49922 -50102. https://federalregister.gov/a/E9-22486. Accessed December 22, 2015.

Medicare Programs: End-Stage Renal Disease Prospective Payment System, Final Rule. *Federal Register*. 2010; 75: 49029-49214. https://federalregister.gov/a/2010-18466. Accessed December 22, 2015.

Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. PL 106-113, 113 USC 1501, 29 November 1999. *United States Statutes at Large*. 1999;113: 1501-1538.

Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). PL 106-554, 114 USC 2763, 21 December 2000. *United States Statutes at Large*. 2000;114: 2763-et seq.

Mosteller RD. Simplified Calculation of Body-Surface Area. *N Engl J Med*. 1987;317(17):1098-1098.

National Institutes of Health (NIH). Aim for a Healthy Weight: Information for Patients and the Public. *http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm.* Accessed December 22, 2015.

Newhouse JP. Risk Adjustment: Where Are We Now? *Inquiry*. 1998;35(2):122-131.

Office of Inspector General. *end stage renal disease drugs* (OEI-03-04-00120). Washington, DC: Department of Health and Human Services, May 2004.

Office of Inspector General. *Medicare reimbursement for new end stage renal disease drugs* (OEI-03-06-00200). Washington, DC: Department of Health and Human Services, March 2006.

Omnibus Budget Reconciliation Act of 1981. PL 97–35, 95 USC 357, 13 August 1981. *United States Statutes at Large*. 1981;95: 357-933.

Omnibus Budget Reconciliation Act of 1990. PL 101–508, 104 USC 1388, 5 November 1990. *United States Statutes at Large*. 1990;104:1388-et seq.

Orzol SM, Carroll CE, Hirth RA, Pereira BJG, Port FK, Held PJ. Differences in the cost of hemodialysis by dialyzer membrane. *J Am Soc Nephrol*. 1996;7(9):A1058-A1058.

Proposed Rules. *Federal Register*. 1982;42:6556.

Rogal DL, Gauthier AK. Are Health-Based Payments a Feasible Tool for Addressing Risk Segmentation? *Inquiry*. 1998;35(2):115-121.

Social Security Amendments of 1972. PL 92–603, 86 USC 1329, 30 October 1972. *United States Statutes at Large*. 1972;86:1329-1493.

Thompson TG. *Report to Congress: Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System*. Washington, DC: Department of Health and Human Services, May 2003.

United States Government Accountability Office (GAO). *End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility* (GAO-07-77). Washington, DC: GAO, November 2006.

United States Renal Data System. *2015 USRDS Annual Data Report (ADR): Epidemiology of kidney disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2015.

University of Michigan Kidney Epidemiology and Cost Center. *Methodology for Developing a Basic Case-Mix Adjustment for the Medicare ESRD Prospective Payment System*. Ann Arbor, MI: University of Michigan Kidney Epidemiology and Cost Center, report May 2004 and addendum April 2005. Available at: http://www.kecc.sph.umich.edu/projects/esrd-prospective-payment-system-pps-project

Wheeler JRC, Messana JM, Turenne MN, Hirth RA, Pozniak AS, Pan Q, Chuang CC, Slish K, Tedeschi P, Roys EC, Wolfe RA. *Understanding the Basic Case-Mix Adjustment for the Composite Rate. Am J Kidney Dis*. 2006;47(4):666-671.

Wolfe RA, Hirth RA, Wheeler JRC, Tedeschi PJ, Webb R, Roys EC, Wright GT, Turenne MN, Pozniak AS, Ashby VB Brunton CA, Reimann S, Held PJ, Callard S. *An Expanded Medicare Outpatient End Stage Renal Disease Prospective Payment System: Phase I Report*. Ann Arbor, MI: University of Michigan Kidney Epidemiology and Cost Center, August 2002.

XII. APPENDIX

Appendix Table 1 Medicare payments for Part B drugs billed on type '72X' claims, Final 2010 file

Drug category	HCPCS	Medicare Payments*	Units	HCPCS Description
Epogen	J0886	$26,729.41	8,375	Injection, Epoetin Alfa, 1000 Units (For Esrd OnDialysis)
Epogen	Q4081	$1,590,282,898.71	2,090,312,344	Injection, Epoetin Alfa, 100 Units (For Esrd OnDialysis)
Darbepoetin	J0882	$114,859,817.43	50,688,158	Injection,DarbepoetinAlfa,1Microgram(ForEsrdOnDialysis)
VitaminD	J0635	$563.86	51	Injection, Calcitriol, 1 McgAmp.
VitaminD	J0636	$1,700,211.13	5,376,770	Inj Calcitriol Per 0.1Mcg
VitaminD	J1270	$83,085,923.11	34,360,012	Injection,Doxercalciferol
VitaminD	J2501	$256,580,049.06	92,049,246	Paricalcitol
Iron	J1750	$581,820.79	31,755	IronDextran
Iron	J1756	$186,415,220.97	641,249,872	Iron SucroseInjection
Iron	J2916	$24,683,481.33	6,005,918	Na Ferric GluconateComplex
Iron	Q0139	$21,364,784.24	33,807,560	Injection, Ferumoxytol, 1mg
Levocarnitine	J1955	$1,738,934.85	389,271	Inj Levocarnitine Per 1Gm
Alteplase	J2997	$24,527,081.46	854,993	AlteplaseRecombinant
Vancomycin	J3370	$2,521,633.35	1,075,226	Vancomycin HclInjection
Daptomycin	J0878	$3,062,994.04	8,840,875	Injection, Daptomycin, 1mg
Accessmanagement	J1642	$22,758.29	2,153,330	Inj Heparin Sodium Per 10U
Accessmanagement	J1644	$173,176.78	1,239,688	Inj Heparin Sodium Per1000U
Accessmanagement	J1945	$149,700.05	898	Injection, Lepirudin, 50mg
Accessmanagement	J2993	$17,503.42	16	ReteplaseInjection
Accessmanagement	J3364	$29.30	5	Urokinase 5000 iuInjection
Anemiamanagement	J3420	$6,909.21	33,267	Vitamin B12Injection
Antibiotic	J0278	$2,289.12	5,279	Injection, Amikacin Sulfate, 100mg
Antibiotic	J0285	$3,569.31	313	AmphotericinB
Antibiotic	J0289	$757.49	60	Amphotericin B LiposomeInj
Antibiotic	J0290	$3,149.76	1,766	Ampicillin 500 mgInj
Antibiotic	J0295	$13,106.59	6,380	Ampicillin Sodium Per 1.5Gm
Antibiotic	J0456	$310.84	60	Azithromycin
Antibiotic	J0637	$657.30	70	CaspofunginAcetate
Antibiotic	J0690	$151,237.32	323,410	Cefazolin SodiumInjection
Antibiotic	J0692	$48,199.74	32,649	Cefepime Hcl ForInjection
Antibiotic	J0694	$1,099.56	189	Cefoxitin SodiumInjection
Antibiotic	J0696	$30,198.04	37,559	Ceftriaxone SodiumInjection
Antibiotic	J0697	$38.53	17	Sterile CefuroximeInjection
Antibiotic	J0698	$214.83	56	Cefotaxime SodiumInjection
Antibiotic	J0713	$345,295.91	198,836	Inj Ceftazidime Per 500mg
Antibiotic	J0715	$163.55	39	Ceftizoxime Sodium / 500mg
Antibiotic	J0743	$1,100.06	125	Cilastatin SodiumInjection
Antibiotic	J0744	$5,822.71	6,635	CiprofloxacinIv
Antibiotic	J0770	$1,815.39	123	Colistimethate SodiumInj
Antibiotic	J1267	$331.64	755	Injection, Doripenem, 10mg
Antibiotic	J1335	$15,416.57	707	Injection, Ertapenem Sodium, 500mg
Antibiotic	J1364	$233.18	192	Erythro Lactobionate /500mg
Antibiotic	J1450	$865.47	394	Fluconazole
Antibiotic	J1580	$128,696.88	196,865	Garamycin GentamicinInj
Antibiotic	J1590	$1,170.48	6,025	GatifloxacinInjection
Antibiotic	J1850	$0.92	3	Kanamycin Sulfate 75 mgInj
Antibiotic	J1890	$0.00	11	Cephalothin SodiumInjection
Antibiotic	J1956	$125,529.82	30,061	LevofloxacinInjection
Antibiotic	J2020	$600.39	33	LinezolidInjection
Antibiotic	J2185	$8,760.46	3,736	Injection, Meropenem, 100mg
Antibiotic	J2280	$467.72	313	Injection, Moxifloxacin, 100mg
Antibiotic	J2510	$4,692.47	628	Penicillin G ProcaineInj
Antibiotic	J2543	$649.28	145	Piperacillin/Tazobactam
Antibiotic	J2700	$1.60	9	Oxacillin SodiumInjeciton
Antibiotic	J3000	$88.08	12	StreptomycinInjection
Antibiotic	J3243	$385.84	400	Injection, Tigecycline, 1mg
Antibiotic	J3260	$42,543.45	26,174	Tobramycin SulfateInjection
Antibiotic	S0073	$0.00	6	Injection, Aztreonam, 500mg
Antiemetic	J0780	$9,705.09	6,938	ProchlorperazineInjection
Antiemetic	J2405	$19,199.99	178,401	Ondansetron HclInjection
Antiemetic	J2550	$81,897.08	67,933	Promethazine HclInjection
Antiemetic	J2765	$3,156.38	13,872	Metoclopramide HclInjection
Antiemetic	J2950	$0.92	3	Promazine HclInjection
Antiemetic	J3230	$49.35	7	Chlorpromazine HclInjection
Antiemetic	J3250	$1,784.91	519	Trimethobenzamide HclInj
Antiemetic	J3310	$930.13	179	PerphenazineInjeciton
Anxiolytic	J2060	$5,612.64	10,283	LorazepamInjection
Anxiolytic	J2250	$30.49	900	Inj MidazolamHydrochloride
Anxiolytic	J3360	$10,425.41	12,516	DiazepamInjection
Bone &mineral	A9563	$217.44	30	Sodium Phosphate P-32, Therapeutic, PerMillicurie
Bone &mineral	J0610	$11,059.19	54,536	Calcium GluconateInjection
Bone &mineral	J0630	$0.00	11	Calcitonin SalmonInjection
Bone &mineral	J0895	$43,225.30	4,983	Deferoxamine MesylateInj
Bone &mineral	J2430	$921.41	70	Pamidronate Disodium /30mg
Compositerate	J1200	$10,287.35	30,111	Diphenhydramine HclInjectio
Compositerate	J1240	$473.53	147	DimenhydrinateInjection
Compositerate	J1940	$40.47	221	FurosemideInjection
Compositerate	J2001	$9.24	4,353	Injection, Lidocaine Hcl For Intravenous Infusion, 10mg
Compositerate	J2150	$1,355.64	4,512	MannitolInjection
Compositerate	J2720	$50.76	189	Inj Protamine Sulfate/10mg

Drug category	HCPCS	Medicare Payments*	Units	HCPCS Description
Composite ate	J2795	$12.08	630	Ropivacaine HclInjection
Composite rate	J3410	$2.00	12	Hydroxyzine HclInjection
ESRD Px	90947	$470.53	10	Dialysis Procedure Other Than Hemodialysis (For Example, Peritoneal, Hemofiltration)Requiring Repeated PhysicianEvaluations
ESRD Px	90999	$1,942.25	19	Unlisted Dialysis Procedure, In-Patient, OrOutpatient
ESRD Px	96365	$6,409.10	591	IntravenousInfusion,ForTherapy,Prophylaxis,OrDiagnosis(SpecifySubstanceOrDrug);Initial, Up To 1 Hour
ESRD Px	96366	$0.00	1	IntravenousInfusion,ForTherapy,Prophylaxis,OrDiagnosis(SpecifySubstanceOrDrug);Each AdditionalHour
ESRD Px	96372	$1,588.77	105	Therapeutic,Prophylactic,OrDiagnosticInjection(SpecifySubstanceOrDrug);SubcutaneousOr Intramuscular
ESRD Px	96374	$0.00	2	Therapeutic,ProphylacticOrDiagnosticInjection(SpecifySubstanceOrDrug);IntravenousPush, Single Or InitialSubstance/Drug
ESRD Px	A4216	$110.19	318	SterileWater,SalineAnd/OrDextrose,Diluent/Flush,10ml
ESRD Px	A4657	$12.67	53	Syringe, With Or Without Needle,Each
ESRD Px	A4722	$0.00	67	DialysateSolution,AnyConcentrationOfDextrose,FluidVolumeGreaterThan1999ccButLess Than Or Equal To 2999cc, For PeritonealDialysis
ESRD Px	A4750	$725.47	289	Blood Tubing, Arterial Or Venous, For Hemodialysis,Each
ESRD Px	J2912	$0.40	4	Injection, Sodium Chloride, 0.9%, Per 2ml.
ESRD Px	J3411	$8.44	2	Injection, Thiamine Hcl, 100mg
ESRD Px	J3475	$106.59	4,384	Injection, Magnesium Sulfate, Per 500mg
ESRD Px	J3480	$0.21	141	Injection, Potassium Chloride, Per 2Meq
ESRD Px	J7030	$6,137.19	27,173	Infusion, Normal Saline Solution , 1000cc
ESRD Px	J7040	$314.86	1,185	Infusion, Normal Saline Solution, Sterile (500 ml=1Unit)
ESRD Px	J7042	$236.93	230	5% Dextrose/Normal Saline (500 ml = 1Unit)
ESRD Px	J7050	$7,764.07	39,741	Infusion, Normal Saline Solution , 250cc
ESRD Px	J7060	$2,662.50	570	5% Dextrose/Water (500 ml = 1Unit)
ESRD Px	J7070	$16.25	152	Infusion, D5W, 1000cc
ESRD Px	J7120	$0.84	5	Ringers Lactate Infusion, Up To 1000cc
ESRD Px	J7130	$9.40	60	Hypertonic Saline Solution, 50 Or 100 Meq, 20 ccVial
ESRD Px	P9041	$33.79	69	Infusion, Albumin (Human), 5%, 50ml
ESRD Px	P9045	$26,444.35	248	Infusion, Albumin (Human), 5%, 250ml
ESRD Px	P9046	$33,230.15	1,906	Infusion, Albumin (Human), 25%, 20ml
ESRD Px	P9047	$57,516.30	2,707	Infusion, Albumin (Human), 25%, 50ml
FluVaccine	Q2035	$30.33	2	Influenza Virus Vaccine, Split Virus, When Administered To Individuals 3 Years Of Age AndOlder, For Intramuscular Use(Afluria)
FluVaccine	Q2036	$854.59	106	Influenza Virus Vaccine, Split Virus, When Administered To Individuals 3 Years Of Age AndOlder, For Intramuscular Use(Flulaval)
FluVaccine	Q2037	$815.28	24	Influenza Virus Vaccine, Split Virus, When Administered To Individuals 3 Years Of Age AndOlder, For Intramuscular Use(Fluvirin)
FluVaccine	Q2038	$349.65	32	Influenza Virus Vaccine, Split Virus, When Administered To Individuals 3 Years Of Age AndOlder, For Intramuscular Use(Fluzone)
FluVaccine	Q2039	$572.30	25	Influenza Virus Vaccine, Split Virus, When Administered To Individuals 3 Years Of Age AndOlder, For Intramuscular Use (Not OtherwiseSpecified)
FluVaccine	90655	$145.04	6	InfluenzaVirusVaccine,SplitVirus,PreservativeFree,ForChildren6-35MonthsOfAge,For IntramuscularUse
FluVaccine	90656	$42,661.38	2,505	InfluenzaVirusVaccine,SplitVirus,PreservativeFree,ForUseInIndividuals3YearsOfAgeAnd Above, For IntramuscularUse
FluVaccine	90657	$6,787.36	295	Flu Vaccine, 6-35 Mo,im
FluVaccine	90658	$2,053,615.51	175,855	Flu Vaccine, 3 Yrs,im
FluVaccine	90660	$479.74	147	Flu Vaccine,Nasal
FluVaccine	90662	$4,188.17	196	InfluenzaVirusVaccine,SplitVirus,PreservativeFree,EnhancedimmunogenicityViaIncreased Antigen Content, For IntramuscularUse
FluVaccine	90663	$0.00	24	Influenza Virus Vaccine, Pandemic Formulation,H1N1
FluVaccine	G9142	$0.12	324	Influenza A (H1N1) Vaccine, Any Route OfAdministration
HepBVaccine	90371	$7,263.96	72	Hep B Ig,im
HepBVaccine	90740	$9,341,174.82	97,817	Hepb Vacc, Ill Pat 3 Doseim
HepBVaccine	90743	$2,428.72	326	Hep B Vacc, Adol, 2 Dose,im
HepBVaccine	90744	$32,188.52	1,843	Hepb Vacc Ped/Adol 3 Doseim
HepBVaccine	90746	$438,073.11	12,468	Hep B Vaccine, Adult,im
HepBVaccine	90747	$14,640,945.21	176,466	Hepb Vacc, Ill Pat 4 Doseim
Immune system	J1440	$18,853.44	144	Filgrastim 300 McgInjection
Immune system	J1441	$617.82	6	Filgrastim 480 McgInjection
Immune system	J1561	$44,569.86	2,980	Injection,immuneGlobulin,(Gamunex/Gamunex-C/Gammaked),Non-Lyophilized(E.G.Liquid), 500 mg
Immune system	J1566	$0.00	280	Injection, immune Globulin, Intravenous, Lyophilized (E.G. Powder), Not Otherwise Specified,500 mg
Immune system	J1568	$0.00	20	Injection,immuneGlobulin,(Octagam),Intravenous,Non-Lyophilized(E.G.Liquid),500mg
Immune system	J1569	$0.00	770	Injection,immuneGlobulin,(GammagardLiquid),Intravenous,Non-Lyophilized,(E.G.Liquid),500 mg
Immune system	J1572	$0.00	40	Injection,immuneGlobulin,(Flebogamma/FlebogammaDif),Intravenous,Non-Lyophilized(E.G. Liquid), 500mg
Immune system	J2504	$2,577.86	17	Injection, Pegademase Bovine, 25 iu
Immune system	J7500	$1,094.43	9,375	Azathioprine Oral50mg
Immune system	J7502	$87,983.55	34,884	Cyclosporine Oral 100mg
Immune system	J7506	$1,625.61	47,669	PrednisoneOral
Immune system	J7507	$772,666.90	289,430	Tacrolimus Oral Per 1mg
Immune system	J7515	$40,654.79	63,048	Cyclosporine Oral 25mg
Immune system	J7517	$326,695.34	221,088	Mycophenolate MofetilOral
Immune system	J7518	$235,281.97	93,351	Mycophenolic acid, oral, 180mg
Immune system	J7520	$64,283.87	8,138	Sirolimus,Oral
Immune system	Q0512	$69,871.22	5,507	PharmacySupplyFeeForOralAnti-Cancer,OralAnti-EmeticOrimmunosuppressiveDrug(S);ForA Subsequent Prescription In A 30-DayPeriod

Drugcategory	HCPCS	Medicare Payments*	Units	HCPCS Description
NonESRD	J0133	$0.02	1	Injection, Acyclovir, 5mg
NonESRD	J0135	$8,974.44	4	Injection, Adalimumab, 20mg
NonESRD	J0152	$397.06	9	Injection, Adenosine For Diagnostic Use, 30mg
NonESRD	J0170	$6.21	20	AdrenalinEpinephrinInject
NonESRD	J0282	$3.97	45	AmiodaroneHcl
NonESRD	J0330	$6.68	58	SuccinycholineChlorideInj
NonESRD	J0360	$128.32	74	HydralazineHclInjection
NonESRD	J0583	$491.20	502	Injection, Bivalirudin, 1mg
NonESRD	J0735	$20,636.41	991	ClonidineHydrochloride
NonESRD	J1020	$0.00	2	Injection, Methylprednisolone Acetate, 20mg
NonESRD	J1030	$0.00	4	Methylprednisolone 40 mgInj
NonESRD	J1040	$21.41	4	Methylprednisolone 80 mgInj
NonESRD	J1070	$0.00	24	Testosterone Cypionat 100mg
NonESRD	J1080	$8.16	7	Testosterone Cypionat 200mg
NonESRD	J1094	$0.74	4	Injection, Dexamethasone Acetate, 1mg
NonESRD	J1100	$460.30	6,387	Dexamethasone SodiumPhos
NonESRD	J1160	$1.94	238	DigoxinInjection
NonESRD	J1165	$41.70	73	Phenytoin SodiumInjection
NonESRD	J1245	$0.00	6	DipyridamoleInjection
NonESRD	J1250	$4.58	3	Inj Dobutamine Hcl/250mg
NonESRD	J1610	$199.00	9	Glucagon Hydrochloride/1mg
NonESRD	J1630	$87.34	244	HaloperidolInjection
NonESRD	J1631	$43.23	20	Haloperidol DecanoateInj
NonESRD	J1645	$245.06	31	DalteparinSodium
NonESRD	J1650	$318.28	244	Inj EnoxaparinSodium
NonESRD	J1652	$73.86	15	FondaparinuxSodium
NonESRD	J1655	$29.14	13	Tinzaparin SodiumInjection
NonESRD	J1720	$463.67	326	Hydrocortisone Sodium SuccI
NonESRD	J1745	$7,263.60	400	Injection Infliximab, 10mg
NonESRD	J1790	$78.65	51	DroperidolInjection
NonESRD	J1815	$2,070.42	7,480	InsulinInjection
NonESRD	J1817	$12.73	5	Insulin For Insulin PumpUse
NonESRD	J2370	$11.42	19	PhenylephrineHclInjection
NonESRD	J2440	$7.51	32	PapaverinHclInjection
NonESRD	J2560	$30.35	12	PhenobarbitalSodiumInj
NonESRD	J2590	$1.41	3	OxytocinInjection
NonESRD	J2597	$60.67	76	Inj DesmopressinAcetate
NonESRD	J2710	$11.63	206	NeostigmineMethylslfteInj
NonESRD	J2820	$146,504.67	7,790	Injection, Sargramostim (Gm-Csf), 50Mcg
NonESRD	J2910	$98.00	20	Injection, Aurothioglucose, Up To 50mg
NonESRD	J2920	$177.51	155	MethylprednisoloneInjection
NonESRD	J2930	$344.74	153	MethylprednisoloneInjection
NonESRD	J2941	$0.00	87	Injection, Somatropin, 1mg
NonESRD	J3120	$115.26	42	Testosterone EnanthateInj
NonESRD	J3130	$33.18	6	Testosterone EnanthateInj
NonESRD	J3240	$1,685.80	2	ThyrotropinInjection
NonESRD	J3301	$12.63	18	TriamcinoloneAcetonideInj
NonESRD	J3430	$185.01	357	Vitamin K PhytonadioneInj
NonESRD	J7192	$0.00	1,024	Factor ViiiRecombinant
NonESRD	J9310	$9,165.76	20	Rituximab CancerTreatment
NonESRD	Q9967	$172.78	1,849	Low Osmolar Contrast Material, 300-399 mg/ml Iodine Concentration, Perml
Othervaccine	86580	$148.96	206	Tb IntradermalTest
Othervaccine	90470	$0.00	1	H1N1immunizationAdministration(Intramuscular,Intranasal),IncludingCounselingWhen Performed
Othervaccine	90471	$98.18	9	immunizationAdmin
Othervaccine	90474	$7.54	1	immune Admin Oral/NasalAddl
Othervaccine	90585	$9,779.15	112	Bcg Vaccine,Percut
Othervaccine	90632	$407.08	11	Hep A Vaccine, Adultim
Othervaccine	90633	$19.15	1	Hep A Vacc, Ped/Adol, 2Dose
Othervaccine	90647	$0.00	1	Hib Vaccine, Prp-Omp,im
Othervaccine	90648	$18.73	1	Hib Vaccine, Prp-T,im
Othervaccine	90669	$607.72	11	Pneumococcal Vacc, Ped<5
Othervaccine	90703	$132.26	7	Tetanus Vaccine,im
Othervaccine	90714	$1,816.38	108	TetanusAndDiphtheriaToxoids(Td)Adsorbed,PreservativeFree,ForUseInIndividualsSeven Years Or Older, For IntramuscularUse
Othervaccine	90715	$250.80	12	Tetanus,DiphtheriaToxoidsAndAcellularPertussisVaccine(Tdap),ForUseInIndividuals7Years Or Older, For IntramuscularUse
Othervaccine	90718	$92.17	8	Td Vaccine > 7,im
Othervaccine	90732	$1,880,155.30	43,114	PneumococcalVaccine
OtherVaccine	90734	$0.00	1	Meningococcal ConjugateVaccine
Pain management	J1170	$3,542.37	3,064	HydromorphoneInjection
Pain management	J1885	$710.34	3,388	Ketorolac TromethamineInj
Pain management	J2175	$2.88	13	Meperidine Hydrochl /100 mg
Pain management	J2270	$3,024.58	2,928	Morphine SulfateInjection
Pain management	J2271	$1.82	3	Morphine So4 Injection100mg
Pain management	J2275	$171.75	87	Morphine SulfateInjection
Pain management	J2310	$135.23	42	Inj NaloxoneHydrochloride
Pain management	J3010	$407.45	1,553	Fentanyl CitrateInjeciton
Pain management	J3070	$5,368.84	766	PentazocineInjection
Unclassified	A4802	$0.00	1	Protamine Sulfate, For Hemodialysis, Per 50mg
Unclassified	A5126	$0.00	1	Adhesive Or Non-Adhesive; Disk Or FoamPad
Unclassified	A9270	$0.00	786	Non-Covered Item OrService
Unclassified	A9500	$0.00	16	TechnetiumTc-99MSestamibi,Diagnostic,PerStudyDose
Unclassified	A9502	$396.00	1	Technetium Tc99MTetrofosmin

	HCPCS	Medicare Payments*	Units	HCPCS Description
Unclassified	C9121	$0.00	3,070	Injection, Argatroban, Per 5 mg
Unclassified	G0257	$0.00	50	UnscheduledOrEmergencyDialysisTreatmentForAnEsrdPatientInAHospitalOutpatientDepartment That Is Not Certified As An Esrd Facility
Unclassified	J0150	$0.00	15	Injection Adenosine 6 mg Aminophyllin 250
Unclassified	J0280	$0.00	2	mg Inj Injection, Atropine Sulfate, 0.01mg
Unclassified	J0461	$17.21	1,530	Injection, Penicillin G Benzathine, Up To 1,200,000Units Inj
Unclassified	J0570	$75.05	6	Mepivacaine Hcl/10 ml Betamethasone Acet&SodPhosp
Unclassified	J0670	$4.56	3	Cidofovir Injection Inj
Unclassified	J0702	$4.99	1	Codeine Phosphate /30 mgInjection, Cosyntropin
Unclassified	J0740	$7,306.77	12	(Cortrosyn), 0.25 mgInjection, Medroxyprogesterone
Unclassified	J0745	$17.57	20	Acetate, 50 mgInjection, Chlorothiazide Sodium, Per 500
Unclassified	J0834	$199.41	5	mgDimethyl Sulfoxide 50% 50 ml
Unclassified	J1051	$0.00	3	EpoprostenolInjection
Unclassified	J1205	$0.00	32	Eptifibatide Injection Injection,
Unclassified	J1212	$141.11	2	Gamma Globulin, Intramuscular, Over 10 cc Ganciclovir
Unclassified	J1325	$65.98	6	Sodium Injection Injection,
Unclassified	J1327	$76.13	5	Hepatitis B immune Globulin (Hepagam B), Intramuscular, 0.5ml Tetanus immune
Unclassified	J1560	$0.00	2	GlobulinInj
Unclassified	J1570	$5,786.74	235	Injection, Propranolol Hcl, Up To 1mg
Unclassified	J1571	$1,808.93	45	Injection, Levetiracetam, 10mg Injection,
Unclassified	J1670	$0.00	7	Mecasermin, 1 mg Injection, Micafungin
Unclassified	J1800	$0.00	1	Sodium, 1mg Nandrolone Decanoate 200mg
Unclassified	J1953	$0.00	82	INJECTION, NANDROLONE DECANOATE, UP TO 200 MG
Unclassified	J2170	$0.00	57	Injection, Octreotide, Non-Depot Form For Subcutaneous Or Intravenous Injection, 25Mcg
Unclassified	J2248	$391.12	601	Injection, Chloroprocaine Hydrochloride, Per 30 ml Injection, Procainamide Hcl,
Unclassified	J2322	$12.02	1	Up To 1Gm
Unclassified	J2354	$0.00	20	Injection, Regadenoson, 0.1mg Rho D immune GlobulinInj Somatrem
Unclassified	J2400	$0.00	2	Injection Zoledronic Acid
Unclassified	J2690	$0.00	4	DrugsUnclassified Injection
Unclassified	J2785	$325.05	8	UnclassifiedBiologics Antithrombin Iii
Unclassified	J2790	$24,170.33	390	InjectionMethylprednisolone Oral, Per 4mg
Unclassified	J2940	$25.80	1	Prednisolone Oral, Per 5mg
Unclassified	J3487	$708.85	4	Albuterol, Inhalation Solution, Fda-Approved Final Product, Non-Compounded,Administered Through
Unclassified	J3490	$538,286.32	170,597	Dme, Unit Dose, 1 mg Levalbuterol, Inhalation Solution, Fda-
Unclassified	J3590	$408.39	2	Approved Final Product, Non-Compounded, AdministeredThrough Dme, Unit Dose, 0.5 mg
Unclassified	J7197	$3.91	2	Ipratropium Bromide, Inhalation Solution, Fda-Approved Final Product, Non-Compounded,Administered
Unclassified	J7509	$0.00	8	Through Dme, Unit Dose Form, Per Milligram Noc Drugs,Other Than Inhalation Drugs, Administered
Unclassified	J7510	$0.00	187	Through Dme Oral PrescripDrug NonChemo
Unclassified	J7613	$0.20	4	Injection, Doxorubicin Hydrochloride, 10mg Injection, Bortezomib, 0.1 mgInjection, Carmustine, 100 mg Injection, Oxaliplatin, 0.5 mg
Unclassified	J7614	$0.00	2	Mitomycin, 5mg
Unclassified	J7644	$0.57	3	Infusion Therapy, Using Other Than Chemotherapeutic Drugs, Per Visit AzithromycinDihydrate, Oral Diphenhydramine Hydrochloride, 50 mg, Oral, Fda Approved Prescription Anti-Emetic, For Use As
Unclassified	J7799	$0.00	111	AComplete TherapeuticSubstituteForAnIvAnti-EmeticAtTimeOfChemotherapyTreatmentNotToExceedA 48
Unclassified	J8499	$19.60	177	Hour Dosage Regimen Prochlorperazine Maleate,5 mg,Oral,FdaApprovedPrescriptionAnti-
Unclassified	J9000	$0.00	857	Emetic,ForUseAsACompleteTherapeuticSubstituteFor AnIvAnti-
Unclassified	J9041	$0.00	4	EmeticAtTheTimeOfChemotherapyTreatment,NotToExceedA48HourDosage Regimen
Unclassified	J9050	$0.00	1	Prochlorperazine Maleate, 10 mg, Oral,Fda Approved Prescription Anti-Emetic, For Use As A Complete
Unclassified	J9263	$7.78	1	Therapeutic Substitute For AnIv Anti-
Unclassified	J9280	$0.00	8	EmeticAtTheTimeOfChemotherapyTreatment,NotToExceedA48HourDosageRegimen
Unclassified	Q0081	$242.40	2	Ondansetron Hydrochloride 8 mg, Oral, Fda Approved Prescription Anti-Emetic, For Use AsA
Unclassified	Q0144	$53.60	2	CompleteTherapeuticSubstituteForAnIvAnti-EmeticAtTheTimeOfChemotherapyTreatment,Not To Exceed A 48 Hour Dosage Regimen
Unclassified	Q0163	$0.00	38	MicroprocessorControlUnitForUseWithElectricVentricularAssistDevice,ReplacementOnly Fosphenytoin, 50mg
Unclassified	Q0164	$0.00	1	Cast Supplies, Gauntlet Cast (Includes Lower Forearm And Hand), Adult (11 Years +),Plaster Injection,
Unclassified	Q0165	$0.00	20	Perflutren Lipid Microspheres, Per ml High Osmolar Contrast Material, 250-299 mg/ml Iodine Concentration, Per ml High Osmolar Contrast Material, 350-399 mg/ml Iodine Concentration, Per mlOndansetron Hydrochloride,
Unclassified	Q0179	$0.00	2	Oral, 4mg (For Circumstances Falling Under The Medicare High osmolar contrast material, 250-299 mg
Unclassified	Q0481	$0.00	700	
Unclassified	Q2009	$9.32	23	Home Infusion Therapy, Total Parenteral Nutrition (Tpn); Administrative Services,Professional
Unclassified	Q4013	$0.00	1,020	Ondansetron hydrochloride, oral, 4mg
Unclassified	Q9957	$99.90	2	Pharmacy Services, Care Coordination, And All Necessary Supplies And EquipmentIncluding
Unclassified	Q9961	$2.66	20	StandardTpnFormula(Lipids,SpecialtyAminoAcidFormulas,DrugsOtherThanInStandardFormulaAndNursin
Unclassified	Q9963	$0.00	600	gVisitsCodedSeparately),PerDiem(DoNotUseWithHomeInfusionCodesS9365-
Unclassified	S0181	$0.00	8	S9368UsingDailyVolumeScales)
Unclassified	S9364	$0.00	13	
Total		$2,344,015,473.01	2,971,340,389	

^Includes services billed under any of the following revenue centers on type '72X' claims: 0250, 0251, 0252, 0254, 0255, 0258, 0259, 0260, 0261, 0269, 0630, 0634, 0635,0636.

*Does not include the patient co-insurance obligation, where applicable(i.e.,drugs other than vaccines).

Appendix Table.2 Medicare payment and utilization for Part B drugs billed on Type 72x claims for facilities in PPS payments with and without indication of AY in HCPCS modifier

		Facilities opting for PPS		Facilities opting for transition		Facilities opting for PPS		Facilities opting for transition		Total		
Drug Category	HCPCS	Payment Without AY	Units without AY modifier	Payment Without AY	Units Without AY	Payment with AY modifier	Units with AY modifier	Payment with AY modifier	Units with AY modifier	Payment	Units	DESCRIPTION
Epogen	J0886	$0	3,607	$1,39	130					$1,39	3,737	Injection, Epoetin Alfa, 1000 Units (For
	Q4081	$289,54	1,423,830,64	$40,148,59	91,150,64	$0	336,224	$23,49	46,315	$40,461,63	1,515,363,82	Injection, Epoetin Alfa, 100 Units (For
Darbepoetin	J0882	$189,14	21,213,64	$21,483,82	12,905,84	$0	205,032	$1,06	660	$21,674,03	34,325,17	Injection, Darbepoetin Alfa, 1
Vitamin D	J0635	$0	246							$0	246	Injection, Calcitriol, 1 McgAmp.
	J0636	$0	3,714,37	$79,16	327,544	$0	1,453			$79,16	4,043,37	Inj Calcitriol Per 0.1Mcg
	J1270	$33,29	38,787,98	$4,168,66	2,934,86	$0	20,511	$33	266	$4,202,29	41,743,62	Injection,Doxercalciferol
	J2501	$33,28	54,292,66	$5,359,91	3,688,68	$0	13,812	$70,24	33,168	$5,463,43	58,028,33	Paricalcitol
	S0169	$0	8,324	$0	1,950					$0	10,274	Calcitrol, 0.25Microgram
Iron	J1750	$0	23,953	$134,35	8,776	$1,31	62	$2,08	50	$137,74	32,841	IronDextran
	J1756	$17,10	564,755,75	$4,283,22	30,320,32	$0	97,737	$39,25	153,925	$4,339,58	595,327,73	Iron SucroseInjection
	J2916	$63,99	4,390,32	$3,942,92	1,372,03	$0	2,971	$2,22	578	$4,009,14	5,765,90	Na Ferric GluconateComplex
	Q0138	$0	1,530							$0	1,530	Injection, Ferumoxytol, For Treatment
	Q0139	$0	2,127,42	$332,68	865,103	$71,67	132,092	$4,02	7,140	$408,38	3,131,75	Injection, Ferumoxytol, 1mg
Levocarnitine	J1955	$0	160,089	$79,04	21,134	$0	183	$14	28	$79,19	181,434	Inj Levocarnitine Per 1Gm
Alteplase	J2997	$3,65	361,492	$1,193,49	60,013	$0	1,325	$25,35	793	$1,222,50	423,623	AlteplaseRecombinant
Vancomycin	J3370	$54	844,355	$91,32	69,026	$20	39,929	$15,09	7,464	$107,18	960,774	Vancomycin HclInjection
Daptomycin	J0878	$0	6,432,80	$85,60	418,008	$0	285,403	$11,53	32,075	$97,13	7,168,29	Injection, Daptomycin, 1mg
Access management	C9121	$0	2,923							$0	2,923	Injection, Argatroban, Per 5mg
	J1642	$0	57,022	$282	1,237,29					$282	1,294,31	Inj Heparin Sodium Per 10U
	J1644	$0	1,248,15	$78,05	421,100	$0	7,528	$31	432	$78,08	1,677,21	Inj Heparin Sodium Per1000U
	J1945	$0	749	$26,56	145					$26,56	894	Injection, Lepirudin, 50mg
	J2993	$0	10							$0	10	ReteplaseInjection
	J3364	$0	2							$0	2	Urokinase 5000 IuInjection
	J3365			$1,09	4					$1,09	4	Injection, Iv, Urokinase, 250,000 I.U.Vial
Anemia management	J3420	$0	7,571	$598	3,222	$0	101	$1	12	$600	10,906	Vitamin B12Injection
Antibiotic	J0278	$0	1,083	$140	414	$32	64	$2	7	$174	1,568	Injection, Amikacin Sulfate, 100mg
	J0285	$0	165			$35	36			$358	201	AmphotericinB
	J0290	$0	882			$47	23			$47	905	Ampicillin 500 mgInj
	J0295	$0	178	$52	32	$19	87			$251	297	Ampicillin Sodium Per 1.5gm
	J0348							$20	200	$202	200	Injection, Anidulafungin, 1mg
	J0456	$0	5	$4	2			$35	3	$38	10	Azithromycin
	J0530	$0	192							$0	192	Injection, Penicillin G Benzathine And
	J0637			$71	10					$71	10	CaspofunginAcetate
	J0690	$52	266,952	$12,42	15,401	$7,26	13,715	$52	1,306	$20,27	297,374	Cefazolin SodiumInjection
	J0692	$0	19,764	$4,56	2,843	$3,56	1,734	$78	356	$8,91	24,697	Cefepime Hcl ForInjection
	J0694	$0	42	$48	15	$80	19			$128	76	Cefoxitin SodiumInjection
	J0696	$0	23,611	$1,58	3,381	$2,18	3,176	$39	585	$4,16	30,753	Ceftriaxone SodiumInjection
	J0698	$0	20	$0	1			$8	3	$8	24	Cefotaxime SodiumInjection
	J0713	$0	97,613	$7,93	7,469	$15,79	10,130	$2,12	1,577	$25,85	116,789	Inj Ceftazidime Per 500mg
	J0715	$0	8	$12	4					$12	12	Ceftizoxime Sodium / 500mg
	J0743	$0	11	$0	5					$0	16	Cilastatin SodiumInjection
	J0744	$0	5,141	$792	910	$50	57	$9	10	$851	6,118	CiprofloxacinIv

		Facilities opting for PPS		Facilities opting for transition		Facilities opting for PPS		Facilities opting for transition		Total		
Drug Category	HCPCS	Payment withoutAY modifier	Unitswithout AYmodifier	Payment withoutAY modifier	Units withoutAY modifier	Payment with AY modifier	Unitswith AY modifier	Payment with AY modifier	Units withAYmod	Payment	Units	DESCRIPTION
	J0770	$0	1	$31	3			$66	5	$97	9	Colistimethate Sodium Inj
	J1267			$47	150					$47	150	Injection, Doripenem, 10mg
	J1335	$0	395	$930	57	$1,125	49	$1,509	66	$3,563	567	Injection, Ertapenem Sodium, 500mg
	J1364			$0	42					$0	42	Erythro Lactobionate /500mg
	J1450	$0	148	$21	7			$48	12	$68	167	Fluconazole
	J1580	$38	126,286	$6,552	16,780	$7,160	9,595	$782	1,080	$14,531	153,741	Garamycin GentamicinInj
	J1590	$0	2,092							$0	2,092	GatifloxacinInjection
	J1890			$0	34					$0	34	Cephalothin SodiumInjection
	J1956	$39	14,293	$6,280	2,602	$5,389	1,355	$403	92	$12,110	18,342	LevofloxacinInjection
	J2020	$0	6	$515	24			$0	3	$515	33	LinezolidInjection
	J2185	$0	1,088	$1,204	681	$53	80	$82	105	$1,339	1,954	Injection, Meropenem, 100mg
	J2248	$0	100			$1,320	1,600			$1,320	1,700	Injection, Micafungin Sodium, 1mg
	J2280	$0	807	$106	72	$216	80	$11	4	$333	963	Injection, Moxifloxacin, 100mg
	J2510	$0	4	$0	6					$0	10	Penicillin G ProcaineInj
	J2540			$0	1					$0	1	Injection, Penicillin G Potassium, Up To600,000
	J2543	$0	191	$16	6	$31	9			$47	206	Piperacillin/Tazobactam
	J2700	$0	32							$0	32	Oxacillin SodiumInjeciton
	J3243	$0	1,650			$21	321	$318	300	$339	2,271	Injection, Tigecycline, 1mg
	J3260	$0	18,575	$1,783	1,741	$988	661	$263	150	$3,035	21,127	Tobramycin SulfateInjection
	J3465			$304	87			$976	203	$1,280	290	Injection, Voriconazole, 10mg
Antiemetic	J0780	$0	5,349	$262	298	$79	104	$2	1	$343	5,752	ProchlorperazineInjection
	J1260			$120	36					$120	36	Injection, Dolasetron Mesylate, 10mg
	J2405	$6	217,068	$3,485	25,045	$380	3,391	$80	745	$3,951	246,249	Ondansetron HclInjection
	J2550	$0	31,943	$10,640	8,695	$1,221	1,004	$344	241	$12,206	41,883	Promethazine HclInjection
	J2765	$0	10,178	$125	696	$46	162	$5	16	$176	11,052	Metoclopramide HclInjection
	J3230	$0	1							$0	1	Chlorpromazine HclInjection
	J3250	$0	512	$39	17					$39	529	Trimethobenzamide HclInj
	J3310	$0	105							$0	105	PerphenazineInjeciton
	Q0164			$0	5					$0	5	Prochlorperazine Maleate, 5 mg, Oral,Fda
	Q0165	$0	1							$0	1	Prochlorperazine Maleate, 10 mg, Oral,Fda
	Q0168							$0	14	$0	14	Dronabinol, 5 mg, Oral, FdaApproved
	Q0169	$0	2	$0	11	$0	5			$0	18	Promethazine Hydrochloride, 12.5 mg, Oral,Fda
	Q0170	$0	1							$0	1	Promethazine Hydrochloride, 25 mg, Oral,Fda
	Q0171	$0	30			$0	10			$0	40	Chlorpromazine Hydrochloride, 10 mg, Oral,Fda
	Q0175	$0	18							$0	18	Perphenazine, 4 mg, Oral, FdaApproved
	Q0177	$0	25							$0	25	Hydroxyzine Pamoate, 25 mg, Oral, Fda Approved
	Q0179	$0	1	$0	2					$0	3	Ondansetron Hydrochloride 8 mg, Oral,Fda
	S0181	$0	4							$0	4	Ondansetron Hydrochloride, Oral, 4mg(For
Anxiolytic	J2060	$0	4,581	$147	1,210	$559	1,098	$224	388	$930	7,277	LorazepamInjection
	J2250	$0	552	$14	421	$0	16	$1	16	$15	1,005	Inj MidazolamHydrochloride
	J3360	$0	924	$2,037	3,513	$0	52	$73	98	$2,110	4,587	DiazepamInjection
Bone &Mineral	J0610	$0	19,246	$265	1,314	$0	144	$2	4	$266	20,708	Calcium GluconateInjection
	J0630			$0	50					$0	50	Calcitonin SalmonInjection
	J0895	$0	1,856	$7,425	1,274	$0	13	$33	4	$7,458	3,147	Deferoxamine MesylateInj
	J1740			$85	1					$85	1	Injection, Ibandronate Sodium, 1mg
	J2430	$0	52	$9	1					$9	53	Pamidronate Disodium /30mg
	J3487	$0	2							$0	2	ZoledronicAcid

		Facilities opting for PPS		Facilities opting for transition		Facilities opting for PPS		Facilities opting for transition		Total		
Drug Category	**HCPCS**	**Payment withoutAY modifier**	**Units without AY modifier**	**Payment Without AY modifier**	**Units with out AY modifier**	**Payment with AY modifier**	**Units with AY modifier**	**Payment with AY modifier**	**Units withAYmod**	**Payment**	**Units**	**DESCRIPTION**
Composite Rate	A4721	$0	6							$0	6	Dialysate Solution, Any ConcentrationOf
Composite Rate	A4722	$0	151							$0	151	Dialysate Solution, Any ConcentrationOf
Composite Rate	A4726	$0	6							$0	6	Dialysate Solution, Any ConcentrationOf
	A4750	$0	450							$0	450	Blood Tubing, Arterial Or Venous,For
Composite Rate	J0360	$0	32	$2	7			$0	3	$2	42	Hydralazine HclInjection
CompositeRate	J0670					$0	3			$0	3	Inj Mepivacaine Hcl/10ml
Composite Rate	J0735	$0	212	$2,370	349	$2,889	317	$593	69	$5,852	947	ClonidineHydrochloride
	J1200	$0	9,871	$593	5,443	$2,422	5,597	$122	493	$3,137	21,404	Diphenhydramine HclInjectio
	J1205							$0	42	$0	42	Injection, Chlorothiazide Sodium, Per 500mg
	J1240	$0	15							$0	15	DimenhydrinateInjection
	J1940	$0	23	$2	2					$2	25	FurosemideInjection
	J2001	$0	6,095	$0	2,738	$0	4,366	$1	43	$1	13,242	Injection, Lidocaine Hcl For IntravenousInfusion,
	J2150	$0	1,058	$33	809	$9	260	$0	22	$42	2,149	MannitolInjection
	J2720	$0	61	$0	4			$4	11	$4	76	Inj Protamine Sulfate/10mg
	J2795					$0	200			$0	200	Ropivacaine HclInjection
Composite Rate	J2912			$0	1					$0	1	Injection, Sodium Chloride, 0.9%, Per 2ml
	J3410			$1	3	$0	2			$1	5	Hydroxyzine HclInjection
	J3411			$19	10					$19	10	Injection, Thiamine Hcl, 100mg
Composite Rate	J3475	$0	9,878	$35	1,351	$1	182			$36	11,411	Injection, Magnesium Sulfate, Per 500mg
Composite Rate	J3480	$0	5,362	$0	10	$0	1			$0	5,373	Injection, Potassium Chloride, Per 2Meq
Composite Rate	J7030	$0	3,849	$15,978	32,381	$4,760	2,030			$20,738	38,260	Infusion, Normal Saline Solution , 1000cc
Composite Rate	J7040	$0	1,677	$30	92	$11	24	$6	33	$47	1,826	Infusion, Normal Saline Solution, Sterile(500
Composite Rate	J7042	$0	5	$0	1	$4	31	$0	255	$4	292	5% Dextrose/Normal Saline (500 ml = 1Unit)
Composite Rate	J7050	$0	2,259	$3,213	21,800	$56	21	$0	2	$3,270	24,082	Infusion, Normal Saline Solution , 250cc
Composite Rate	J7060	$0	130	$16	33	$0	6			$16	169	5% Dextrose/Water (500 ml = 1Unit)
Composite Rate	J7070	$0	23							$0	23	Infusion, D5W, 1000cc
	J7100			$12	1					$12	1	Infusion, Dextran 40, 500ml
Composite Rate	J7120	$0	4	$63	5					$63	9	Ringers Lactate Infusion, Up To 1000cc
Composite Rate	J7130	$0	245	$0	15	$0	35	$1	1	$1	296	Hypertonic Saline Solution, 50 Or 100 Meq, 20cc
	Q0163	$0	20	$0	449					$0	469	Diphenhydramine Hydrochloride, 50 mg,Oral,
ESRD Px	90940	$0	3							$0	3	Hemodialysis Access Flow Study ToDetermine
	90947	$0	3			$240	1			$240	4	Dialysis Procedure Other Than Hemodialysis(For
	90999	$0	1,033	$155	1					$155	1,034	Unlisted Dialysis Procedure, In-Patient,Or
	96366					$0	3			$0	3	Intravenous Infusion, For Therapy, Prophylaxis,Or
	96367	$0	4							$0	4	Intravenous Infusion, For Therapy, Prophylaxis,Or
	96374	$0	9	$0	33					$0	42	Therapeutic, Prophylactic Or DiagnosticInjection
	96375	$0	3	$0	6					$0	9	Therapeutic, Prophylactic Or DiagnosticInjection
	A4216	$0	83	$0	1					$0	84	Sterile Water, Saline And/OrDextrose,
	A4657	$0	2	$182	13					$182	15	Syringe, With Or Without Needle,Each
	P9041	$0	202	$137	60			$0	102	$137	364	Infusion, Albumin (Human), 5%, 50ml
	P9045	$0	8	$2,531	66					$2,531	74	Infusion, Albumin (Human), 5%, 250ml
	P9046	$0	80	$11,069	1,085					$11,069	1,165	Infusion, Albumin (Human), 25%, 20ml
	P9047	$0	723	$101,525	1,059	$1,447	36			$102,972	1,818	Infusion, Albumin (Human), 25%, 50ml
FluVaccine	90655	$30	2	$501	73	$0	2			$532	77	Influenza Virus Vaccine, Split Virus,Preservative
	90656	$290,446	24,073	$25,893	1,665	$10,782	917	$2,844	211	$329,965	26,866	Influenza Virus Vaccine, Split Virus,Preservative
	90657	$1,682	138	$2,173	124	$24	4			$3,879	266	Flu Vaccine, 6-35 Mo,Im
	90658	$191,931	16,920	$4,834	538	$13,021	1,078	$1,587	146	$211,374	18,682	Flu Vaccine, 3 Yrs,Im

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Drug Category	HCPCS	Payment withoutAY modifier	Unitswithout AYmodifier	Payment withoutAY modifier	Units withoutAY modifier	Payment with AY modifier	Unitswith AY modifier	Payment with AY modifier	Units withAYmod	Payment	Units	DESCRIPTION
	90660	$45	3					$246	12	$291	15	Flu Vaccine,Nasal
	90662	$8,835	655	$3,125	157	$5,390	72	$120	16	$17,469	900	Influenza Virus Vaccine, Split Virus,Preservative
	90663					$0	1			$0	1	Influenza Virus Vaccine, PandemicFormulation,
	90666	$0	1							$0	1	Influenza Virus Vaccine, PandemicFormulation,
	G9142	$0	62	$0	1	$0	21			$0	84	Influenza A (H1N1) Vaccine, Any RouteOf
	Q2035	$25,701	2,162	$8,734	470	$4,491	479	$1,131	103	$40,057	3,214	Influenza Virus Vaccine, Split Virus,When
	Q2036	$145,639	16,470	$19,518	2,231	$12,829	1,447	$1,519	178	$179,505	20,326	Influenza Virus Vaccine, Split Virus,When
	Q2037	$1,045,859	78,710	$50,108	3,517	$7,701	783	$328	131	$1,103,996	83,141	Influenza Virus Vaccine, Split Virus,When
	Q2038	$260,947	20,604	$25,694	1,402	$35,888	2,577	$3,664	272	$326,192	24,855	Influenza Virus Vaccine, Split Virus,When
	Q2039	$32,818	3,098	$11,396	709	$4,168	154			$48,382	3,961	Influenza Virus Vaccine, Split Virus,When
Hep B Vaccine	90371			$680	10					$680	10	Hep B Ig,Im
	90740	$9,865,986	82,573	$484,657	4,738	$245,446	2,087	$22,674	162	$10,618,763	89,560	Hepb Vacc, Ill Pat 3 DoseIm
	90743	$5,870	201	$156	1	$449	17			$6,475	219	Hep B Vacc, Adol, 2 Dose,Im
	90744	$29,116	434	$3,212	51					$32,328	485	Hepb Vacc Ped/Adol 3 DoseIm
	90746	$259,911	4,143	$36,680	478	$3,257	54	$60	1	$299,908	4,676	Hep B Vaccine, Adult,Im
	90747	$13,008,423	113,402	$1,406,328	11,460	$1,286,762	10,212	$214,640	1,965	$15,916,153	137,039	Hepb Vacc, Ill Pat 4 DoseIm
Immunesystem	J1440	$0	89	$279	6					$279	95	Filgrastim 300 McgInjection
	J1441	$0	2							$0	2	Filgrastim 480 McgInjection
	J1459			$4,895	240	$84,185	3,000			$89,081	3,240	Injection, Immune Globulin(Privigen),
	J1561			$0	1,580					$0	1,580	Injection, Immune Globulin,(Gamunex/Gamunex-
	J1566	$0	384							$0	384	Injection, Immune Globulin,Intravenous,
	J1569	$0	960			$36,939	1,200			$36,939	2,160	Injection, Immune Globulin, (GammagardLiquid),
	J1571	$0	2			$2,569	14			$2,569	16	Injection, Hepatitis B Immune Globulin(Hepagam
	J1572	$0	150			$5,144	290			$5,144	440	Injection, ImmuneGlobulin,
	J2504	$0	9							$0	9	Injection, Pegademase Bovine, 25Iu
	J7500	$0	90			$771	7,335			$771	7,425	Azathioprine Oral50mg
	J7502					$77,427	30,204			$77,427	30,204	Cyclosporine Oral 100mg
	J7506	$0	60			$1,100	45,379			$1,100	45,439	PrednisoneOral
	J7507	$0	300	$109	60	$687,954	301,334			$688,063	301,694	Tacrolimus Oral Per 1mg
	J7515					$44,044	66,270			$44,044	66,270	Cyclosporine Oral 25mg
	J7517	$0	240			$144,329	134,524			$144,329	134,764	Mycophenolate MofetilOral
	J7518	$0	180			$463,835	180,450			$463,835	180,630	Mycophenolic Acid, Oral, 180mg
	J7520					$84,827	10,105			$84,827	10,105	Sirolimus,Oral
	J7525	$0	1							$0	1	Tacrolimus, Parenteral, 5mg
	Q0512	$0	28			$69,488	5,487			$69,488	5,515	Pharmacy Supply Fee For Oral Anti-Cancer,Oral
NonESRD	J0135	$0	11			$0	2			$0	13	Injection, Adalimumab, 20mg
	J0171	$0	33	$5	94	$0	1			$5	128	Injection, Adrenalin, Epinephrine, 0.1mg
	J0282	$0	15							$0	15	AmiodaroneHcl
	J0330			$2	25			$0	3	$2	28	Succinycholine Chloride Inj
	J0461	$0	201	$4	910					$4	1,111	Injection, Atropine Sulfate, 0.01mg
	J0583			$382	250					$382	250	Injection, Bivalirudin, 1mg
	J0706			$1	4					$1	4	Injection, Caffeine Citrate,5mg
	J0834	$0	1			$66	2			$66	3	Injection, Cosyntropin (Cortrosyn), 0.25mg
	J1040	$0	2	$16	6					$16	8	Methylprednisolone 80 mgInj
	J1051	$0	3							$0	3	Injection, Medroxyprogesterone Acetate, 50 mg
	J1070					$16	8			$16	8	Testosterone Cypionat 100mg
	J1100	$0	324	$2	1,157	$274	3,852	$0	227	$276	5,560	Dexamethasone SodiumPhos

		Facilities opting for PPS		Facilities opting for transition		Facilities opting for PPS		Facilities opting for transition		Total		
Drug Category	HCPCS	Payment withoutAY modifier	Units without AYmodifier	PaymentWihout AY modifier	Units withoutAY modifier	Payment with AY modifier	Unitswith AY modifier	Payment with AY modifier	Units withAYmod	Payment	Units	DESCRIPTION
Non ESRD	J1160	$0	8	$0	178	$0	1	$0	1	$0	188	DigoxinInjection
	J1165	$0	18							$0	18	Phenytoin SodiumInjection
	J1250	$0	4	$0	22					$0	26	Inj Dobutamine Hcl/250mg
	J1265			$0	10					$0	10	Injection, Dopamine Hcl, 40mg
	J1327	$0	8	$0	1					$0	9	EptifibatideInjection
	J1570	$0	40			$3,402	69			$3,402	109	Ganciclovir SodiumInjection
	J1630	$0	28	$69	52	$96	55			$165	135	HaloperidolInjection
	J1631	$0	5							$0	5	Haloperidol DecanoateInj
	J1645			$0	4	$0	52			$0	56	DalteparinSodium
	J1650	$0	60	$240	157			$61	12	$301	229	Inj EnoxaparinSodium
	J1670	$0	48							$0	48	Tetanus Immune GlobulinInj
	J1720	$0	58	$11	11					$11	69	Hydrocortisone Sodium Succl
	J1790	$0	1			$11	5			$11	6	DroperidolInjection
	J1815	$0	79	$49	673	$36	100	$22	62	$108	914	InsulinInjection
	J1953			$0	10					$0	10	Injection, Levetiracetam, 10mg
	J2170	$0	23	$0	4					$0	27	Injection, Mecasermin, 1mg
	J2353					$2,813	30	$1,026	11	$3,839	41	Injection, Octreotide, Depot FormFor
	J2370	$0	23	$12	9					$12	32	Phenylephrine HclInjection
	J2440	$0	2	$2	10					$2	12	Papaverin HclInjection
	J2505	$0	8							$0	8	Injection, Pegfilgrastim, 6mg
	J2545	$0	1							$0	1	PentamidineIsethionte/300mg
	J2560	$0	201							$0	201	Phenobarbital SodiumInj
	J2590			$0	1					$0	1	OxytocinInjection
	J2597	$0	50	$0	200			$76	36	$76	286	Inj DesmopressinAcetate
	J2710	$0	3	$2	45			$0	2	$3	50	Neostigmine MethylslfteInj
	J2785	$0	8	$251	8					$251	16	Injection, Regadenoson, 0.1mg
	J2910			$60	20					$60	20	Injection, Aurothioglucose, Up To 50mg
	J2920	$0	16	$51	28	$0	3			$51	47	MethylprednisoloneInjection
	J2930	$0	125	$29	28	$0	6	$4	2	$34	161	MethylprednisoloneInjection
	J2941			$468	63					$468	63	Injection, Somatropin, 1mg
	J3120	$0	38							$0	38	Testosterone Enanthate Inj
	J3300	$0	1							$0	1	Injection, Triamcinolone Acetonide,Preservative
	J3301	$0	21	$0	8					$0	29	Triamcinolone AcetonideInj
	J3430	$0	263	$1	2	$18	13	$1	1	$20	279	Vitamin K PhytonadioneInj
	J3486			$8	2					$8	2	Injection, Ziprasidone Mesylate, 10mg
	J3490	$0	66,323	$63,243	16,423	$5,977	4,910	$254	1,070	$69,474	88,726	Drugs UnclassifiedInjection
	J3590	$0	2	$0	3					$0	5	UnclassifiedBiologics
	J7639			$0	25					$0	25	Dornase Alfa, Inhalation Solution,Fda-Approved
	J7799			$0	270					$0	270	Noc Drugs, Other Than InhalationDrugs,
	J8499	$0	3,133	$5	8					$5	3,141	Oral Prescrip Drug NonChemo
	J8999	$0	5			$0	1			$0	6	Prescription Drug, Oral, Chemotherapeutic,Nos
	J9070			$0	8					$0	8	Cyclophosphamide, 100mg
	J9209			$0	4					$0	4	Injection, Mesna, 200mg
	J9370	$0	2							$0	2	Vincristine Sulfate, 1 mg
	Q2009	$0	30	$16	52					$16	82	Fosphenytoin, 50mg
	Q4031	$0	2							$0	2	Cast Supplies, Long Leg Cast, Pediatric(0-10
	Q9957	$0	3							$0	3	Injection, Perflutren Lipid Microspheres, Perml

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Drug Category	HCPCS	Payment withoutAY modifier	Unitswithout AYmodifier	Payment withoutAY modifier	Units withoutAY modifier	Payment with AY modifier	Unitswith AY modifier	Payment with AY modifier	Units withAYmod	Payment	Units	DESCRIPTION
	Q9963	$0	600							$0	600	High Osmolar Contrast Material, 350-399mg/ml
	Q9966	$0	200							$0	200	Low Osmolar Contrast Material, 200-299mg/ml
	Q9967	$0	804	$123	52	$14	100			$137	956	Low Osmolar Contrast Material, 300-399mg/ml
Other Vaccine	86580	$0	113	$41	137			$96	7	$138	257	Tb IntradermalTest
	90471	$0	40	$14	1	$300	7			$314	48	ImmunizationAdmin
	90472	$0	1							$0	1	Immunization Admin, EachAdd
	90474	$0	2							$0	2	Immune Admin Oral/NasalAddl
	90585	$0	56	$3,748	62	$275	3			$4,022	121	Bcg Vaccine,Percut
	90632	$0	3			$41	1			$41	4	Hep A Vaccine, AdultIm
	90633			$13	2					$13	2	Hep A Vacc, Ped/Adol, 2Dose
	90649			$0	4			$0	1	$0	5	Hpv Vaccines For Gardasil(Merck)
	90669	$169	10	$1,759	21					$1,928	31	Pneumococcal Vacc, Ped<5
	90670			$466	3					$466	3	Pneumococcal Conjugate Vaccine, 13 Valent,For
	90703	$0	11							$0	11	Tetanus Vaccine,Im
	90707			$56	3					$56	3	Mmr Vaccine,Sc
	90713							$23	1	$23	1	Poliovirus, Ipv,Sc
	90714	$0	5	$11	1	$122	8	$15	1	$148	15	Tetanus And Diphtheria Toxoids (Td)Adsorbed,
	90715	$0	8	$69	3					$69	11	Tetanus, Diphtheria Toxoids AndAcellular
	90716	$0	1	$0	3			$0	1	$0	5	Chicken Pox Vaccine(Varicella)
	90718	$0	2	$0	5	$14	1			$14	8	Td Vaccine > 7,Im
	90732	$1,941,377	37,002	$132,894	2,584	$74,405	1,466	$9,855	208	$2,158,531	41,260	PneumococcalVaccine
	90733			$0	1					$0	1	Meningococcal Polysaccharide Vaccine,For
	90734			$34	1					$34	1	Meningococcal ConjugateVaccine
Pain Management	J0595	$0	30							$0	30	Injection, Butorphanol Tartrate, 1mg
	J1170	$0	1,395	$939	1,263	$26	19	$82	181	$1,047	2,858	HydromorphoneInjection
	J1885	$0	1,335	$125	658	$358	1,624	$142	638	$625	4,255	Ketorolac TromethamineInj
	J2175	$0	7	$5	4			$6	4	$10	15	Meperidine Hydrochl /100mg
	J2270	$0	513	$190	705	$25	15	$41	17	$256	1,250	Morphine SulfateInjection
	J2271			$0	1					$0	1	Morphine So4 Injection100mg
	J2275			$7	11			$3	1	$10	12	Morphine SulfateInjection
	J2310	$0	13	$0	2					$0	15	Inj NaloxoneHydrochloride
	J3010	$0	1,139	$64	274	$6	19	$12	38	$82	1,470	Fentanyl CitrateInjeciton
	J3070	$0	837							$0	837	PentazocineInjection
Unclassified	J2515	$0	2							$0	2	Injection, Pentobarbital Sodium, Per 50mg
UnspInfuse	96365	$0	305	$256	280	$0	67			$256	652	Intravenous Infusion, For Therapy, Prophylaxis,Or
	96372	$0	6	$0	31					$0	37	Therapeutic, Prophylactic, Or DiagnosticInjection
Misc	85018	$0	1							$0	1	Hemoglobin,Automated
	97032	$0	1							$0	1	Application Of A Modality To One Or MoreAreas;
	A9270	$0	139	$0	14	$0	4			$0	157	Non-Covered Item OrService
	P9016			$998	4					$998	4	Red Blood Cells, Leukocytes Reduced, EachUnit