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ANALYSES TO SUPPORT THE 2016 REFINEMENTS TO THE END-STAGE RENAL DISEASE PROSPECTIVE PAYMENT SYSTEM

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I. Introduction

Objectives

On November 6, 2015, the Centers for Medicare & Medicaid Services (CMS) finalized a significant update to the end-stage renal disease prospective payment system (ESRD PPS) 80 FR 68968 through 69077 Issued November 6, 2015: https://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-27928.pdf.

These updates became effective on January 1, 2016, five years after the initial implementation of the ESRD PPS. Since its implementation, the system has received routine annual updates, including updated wage indices to adjust payments for local labor costs, updated market basket adjustments to account for other input costs, adjustments to the base payment rate, and updated outlier payment parameters to reflect the evolving utilization of the outlier payment system. However, the case-mix adjustment model developed using data from years 2006-2008 remained in place. That model provided payment adjustments for a set of patient characteristics (age, body size, and selected comorbidities) and one facility characteristic (low treatment volume). Section 632(c) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L 112–240) https://www.gpo.gov/fdsys/pkg/PLAW-112publ240/html/PLAW-112publ240.htm requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

This report describes the research undertaken by the University of Michigan-Kidney Epidemiology and Cost Center (UM-KECC) to support the CMS development of this update. Key changes included re-estimation of the case-mix adjustment model using the most recent available data (2012-2013), evaluation of the six comorbidity adjusters, modification of the criteria for the receipt of the low-volume adjuster, and the addition of a rural payment adjuster. As these changes were a refinement of the existing case-mix adjustment system, the basic data and methodology were similar to those underlying the development of the ESRD PPS. These data and methods have been described in detail in prior reports and payment rules. Similarly, this report focuses on these non-routine updates that occurred for payments made for dialysis-related services delivered in calendar year 2016 (CY 2016). The routine updates for CY 2016 and prior payment years are described in the final payment rules for each year.

Key reports and rules to which the reader should refer 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
- 2011 Proposed Rule: https://www.gpo.gov/fdsys/pkg/FR-2009-09-29/pdf/E9-22486.pdf
- 2011 Final Rule: https://www.gpo.gov/fdsys/pkg/FR-2010-08-12/pdf/2010-18466.pdf
- 2012 Final Rule: https://www.gpo.gov/fdsys/pkg/FR-2011-11-10/pdf/2011-28606.pdf.
- 2013 Final Rule: www.gpo.gov/fdsys/pkg/FR-**2012**-**11**-**09**/pdf/**2012**-26903.pdf
- 2014 Final Rule: www.gpo.gov/fdsys/pkg/FR-2013-12-02/pdf/2013-28451.pdf
- 2015 Final Rule: www.gpo.gov/fdsys/pkg/FR-**2014**-11-06/pdf/**2014**-26182.pdf
- 2016 Final Rule: www.gpo.gov/fdsys/pkg/FR-**2015**-11-06/pdf/**2015**-27928.pdf
- UM-KECC 2015 report to CMS: Analyses to Inform the Design and Implementation of the End-Stage Renal Disease Prospective Payment System, December 2015 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-Analysis.pdf

There were two notable differences in the data used to develop the CY 2016 PPS, and they are described in Sections II, A and II, B of this report. First, the data source for laboratory tests and medications has changed. The development of the case-mix model implemented in 2011 necessarily identified the utilization of ESRD-related medications and laboratory tests that were billed on a fee-for-service (FFS) basis from paid Medicare claims, primarily from dialysis providers and independent laboratories. After these medications and laboratory tests were added to the bundle of prospectively paid services under the ESRD PPS, they were assessed on the basis of line-item reporting of utilization on dialysis claims rather than on the basis of FFS payments. Dialysis providers were instructed to report utilization on their monthly claims, and such reporting was necessary in order to identify high-cost outlier cases for which providers would receive additional payment. This reported utilization was then assigned a dollar value based on prevailing CMS allowable charges per unit had those services been paid on a FFS basis. Second, data on comorbidities now also comes from dialysis claims. Prior to 2011, payment to dialysis facilities did not depend on comorbidities, so comorbidities were rarely reported on dialysis claims. Therefore, the development of the case-mix model implemented in 2011 had to rely on other types of claims

(e.g., physician/supplier, hospital) to assess patients' comorbidity status. In this update, patient status for the six comorbidities included as case-mix adjusters was assessed on the basis of dialysis claims, reflecting those cases for which the adjuster was actually paid.

Experience Under the ESRD PPS

Several factors necessitated the update to the case-mix adjustment model. First, the relationships between case-mix characteristics and costs of ESRD-related care may have changed over time due to changes in financial incentives and clinical practices. The original model was developed using data from 2006-2008, which are now almost a decade old, and reflected the incentives under the prior payment system under which injectable medications and non-routine laboratory tests were paid on a FFS basis. That time period also pre-dated widespread concerns regarding the safety of high doses of erythropoietin-stimulating agents (ESAs) used to treat anemia. Anemia is highly prevalent among ESRD patients and the cost of ESAs represented over 70% of the costs of services that were added to the ESRD PPS in 2011 (see Hirth et al., 2013). With the bundling of ESAs and other injectable medications and laboratory tests in 2011, and increasing safety concerns highlighted by the Food and Drug Administration (FDA) June 2011 decision to revise the "black box warning" and recommend more conservative treatment protocols, utilization of the newly bundled services, particularly ESAs, dropped substantially (Hirth et al., 2013; Brunelli et al., 2013; Fuller et al. 2013). Given these changes in practice, it is possible that patients with different characteristics would have been affected differentially. If so, the case-mix adjustment factors (multipliers applied to the base rate) would be different when using more recent data.

Second, limitations in the available data necessitated the use of a two-equation model that estimates multipliers separately for the costs of services previously covered by the composite rate (CR) payment for dialysis and those services that were previously separately billable (SB) hereafter referred to as SB services. Those multipliers were then combined into a single set of payment multipliers by taking their weighted average, with the shares of total costs represented by CR and SB costs serving as the weights. Given the decline in use of SB services, particularly ESAs, following the implementation of the ESRD PPS, the weight assigned to the SB multipliers declined. Therefore, the different weighting would change the payment multipliers even if the values of the multipliers in each equation were held constant.

Third, the reporting of comorbidities for payment on dialysis claims has remained below expectations since the implementation of the ESRD PPS. As noted above, comorbidities were rarely reported on dialysis claims prior to 2011, necessitating projections of their prevalence based on reporting on other types of claims. Those projections overestimated the extent to which dialysis providers actually report them for payment under the ESRD PPS. Updated estimates for the CY 2016 payment rule account for this by using only those comorbidities reported on dialysis claims. This change reduces the amount of money "held back" to fund the comorbidity

adjusters and may also result in changed multipliers if the cases reported on dialysis claims are not a representative sample of all the cases identified on other claim types (e.g., if relatively severe cases are more likely to be reported on dialysis claims, the multiplier might rise). Fourth, CMS' decisions to refine the criteria for receipt of the low-volume adjuster and to explore the addition of a rural location adjuster also affect the resulting payment model. For all of these reasons, refining the case-mix adjustment model is timely.

Refined Adult Case-Mix Model for Calendar Year 2016

The resulting payment multipliers that were finalized for the CY 2016 ESRD PPS (ESRD PPS Final Rule, Federal Register 2015) are shown in Table 1.1. The analyses underlying this payment model are described in the remainder of this report.

Table 1.1 CY 2016 ESRD PPS Payment Adjustments for Adult Patients

Patient or facility characteristic	ESRD PPS Payment Multipliers for CY 2016 ($PmtMult_{PPS}$)
Age	
18-44	1.257
45-59	1.068
60-69	1.070
70-79	1.000
80+	1.109
Body surface area (per 0.1 m^2)	1.032
Underweight (BMI < 18.5)	1.017
Time since onset of renal dialysis < 4 months	1.327
Facility low-volume status	1.239
Comorbidities	
Pericarditis (acute)	1.040
Gastrointestinal tract bleeding (acute)	1.082
Hereditary hemolytic or sickle cell anemia (chronic)	1.192
Myelodysplastic syndrome (chronic)	1.095
Rural	1.008

II. Data and Methods

A. Data Sources

The data sources can be categorized into three groups. The first group consists of primary, recurring, government data sources used to identify End Stage Renal Disease (ESRD) patients and to provide their demographic information. The second group consists of primary, recurring, government data sources that provide information on the care and treatment of dialysis patients. Both of these sources collect data about entire populations rather than samples. The third group consists of primary, recurring, government data sources used to identify and characterize dialysis facilities.

B. Patient Databases

Data Used to Identify Medicare End Stage Renal Disease Patients

Since the beginning of this project, databases from the Centers for Medicare and Medicaid Services (CMS) Renal Management Information System (REMIS), the Patient Master File (IDEN), and the Medical Evidence (ME) databases have been used as the starting point for finding patients who are eligible for Medicare ESRD coverage. Patients are added to the REMIS database using the CMS Enrollment Data Base (EDB) and the Standard Information Management System (SIMS) database. UM-KECC receives data from CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system. Patient identifiers from CROWNWeb are included in the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) database. Using these databases, UM-KECC creates a finder file containing all known cross-referenced Medicare IDs to identify ESRD patients.

The REMIS Medical Evidence database contains data elements concerning dialysis, transplant, and self-care training collected from the CMS Form 2728 ESRD Medical Evidence Report form. A beneficiary may have one medical evidence record for each period of ESRD entitlement. Form CMS-2728 is completed by the provider within 45 days of when the patient was determined to have ESRD and is signed by the physician after the patient begins a regularly scheduled course of therapy (generally the first dialysis session).

Information about death dates is obtained from the REMIS Death Notification database as well as from the Social Security System Death Master File.

The REMIS Death Notification database contains information commonly captured on form CMS-2746. The data include the date of death, the primary and secondary causes of death, the current ESRD provider, if

dialysis had been discontinued prior to death and why, if the patient had received a transplant and the date of transplantation, and if the patient died with a functioning kidney.

The Medicare Enrollment database (EDB) is a relational database that contains demographic information as well as Medicare Part A and Part B entitlement history periods with the reason for entitlement, Healthcare Maintenance Organization (HMO) status data, a history of residences, a list of other Healthcare Identification Codes that have identified that patient, a history of ESRD coverage, and a history of primary payers. For this project, the EDB contributes to the development of finder files for getting other CMS data like the Standard Analytic Files (SAF). The EDB is also used to confirm the primary payer history and the HMO history to exclude bills received in periods when the patient has HMO coverage or when Medicare is a secondary payer.

The Social Security System Death Master File contains information on all persons reported to the Social Security System as being deceased. The Death Master File (DMF) from the Social Security Administration (SSA) contains over 65 million records of deaths that have been reported to SSA. This file includes the following information on each decedent, if the data are available to the SSA: SSN, name, date of birth, date of death, state or country of residence (2/88 and prior), ZIP code of last residence, and ZIP code of lump sum payment. The SSA does not have a death record for all persons; therefore, SSA does not guarantee the veracity of the file. Thus, the absence of a particular person is not proof this person is alive. UM-KECC uses the SSN, the name, and the date of birth to link this file with our other databases and to link with KECC_ID.

Data used to Identify Costs of Care

Using all of the files as described above to create a comprehensive finder file, claims are acquired by using the finder file to subset the CMS Institutional Standard Analytic File (SAF).

UM-KECC predominantly uses the outpatient CMS Standard Analytic Files (SAF), as dialysis facilities are identified in the SAF with TYPE_OF_BILL = '72'. The SAFs are downloaded from CMS with a header portion of the record that contains demographics, total utilization, payments and charges for the entire claim. The SAFs also contain a series of trailer records among which are diagnostic trailers, procedure trailers, claim-related value trailers, claim occurrence trailers, and the revenue center trailers. Table 2.1 provides frequencies for the most common aggregations used in UM-KECC analyses on this project.

Table 2.1 ESRD Medicare Claims Data File Patient and Facility Record Counts by Year

Year	Patient Month Facility Records	Patients	Facilities
2012	3643772	366908	5889
2013	3716090	373764	6098
2014	3797605	380848	6376

C. Facility Databases

The Medicare Cost Reports are a nearly universal provider level database. As detailed on the CMS website, (https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/?redirect=/CostReports/02_HospitalCostReport.asp), "Medicare-certified institutional providers are required to submit an annual cost report to a Medicare Administrative Contractor (MAC). The cost report contains provider information such as facility characteristics, utilization data, cost and charges by cost center (in total and for Medicare), Medicare settlement data, and financial statement data." Therefore, all free-standing and hospital-based dialysis facilities certified by Medicare submit a detailed cost report that provides fiscal and operations review. 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 265-11 and CMS 2552-10, respectively). Models for the CY 2016 Final Rule use cost report data for the years 2012-2013, which was the best available data at the time. These files are public-use files and are available for download from the CMS website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/?redirect=/costreports/

D. Changes to Methods Used in the Development of the Analysis File

The SAFs are a set of paid claims files containing information on facility utilization, charges and payments for services, the attending and operating physicians, the provider, some patient demographic information, International Classification of Diseases, version 9 Clinical Modification (ICD-9-CM) diagnoses and procedures and Current Procedural Terminology (CPT-4) and Health Care Financing Administration (HCFA) Common Procedure Coding System (HCPCS) procedures. Utilization, charges and payments are reported at the revenue center level where they can be directly connected to the revenue center HCPCS, which describe the services performed for the patient. Following implementation of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) in January 2011, for those facilities selecting the bundled payment and not transitioning to the bundle, utilization, not payment, is reported for formerly separately billable items that are now included in the bundled payment.

Prior to the implementation of the ESRD PPS, both payments and utilization were reported on dialysis facility claims. Utilization for each drug and each laboratory service continues to be identified by HCPCS as a separate line item. Following implementation, because payments were bundled, they were no longer available for analysis. Instead, estimated payments were calculated by multiplying line item utilization by relevant price. It is important to note that prices change quarterly. Pricing was done based on payments CMS made for these services in the fee-for-service system, updated on a quarterly basis. The payment amounts for drugs are 106 percent of the Average Sales Price (ASP) calculated from data submitted by drug manufacturers. The quarter to quarter price changes are generally the result of updated data from the manufacturers of these drugs. A calculated payment can be found by multiplying the number of units reported on the claim by the quarterly price. In addition, if there is an AY modifier on the claim line (indicating the item or service is furnished to an ESRD patient that is not for the treatment of ESRD), that claim line is excluded from calculating the estimated bundled payment.

A new set of codes were added to the CMS pricer file to reflect return codes specific to the ESRD PPS. The pricer codes are a field on the header record of the SAF. These return codes were incorporated into the analysis file. Codes 03 through 35 were added to reflect new adjustments for the ESRD PPS, including existence of acute and chronic comorbidities, onset of dialysis, training, low-volume facility status, pediatric, low body mass index (BMI), and combinations of these adjusters (see Table 2.2).

Table 2.2 Pricer Return Codes

Code	Description
00	ESRD PPS payment calculated
01	ESRD facility rate greater than zero
02	no adjustments
03	w/outlier
04	w/acute comorbid
05	w/chronic comorbid
06	w/acute comorbid, outlier
07	w/chronic comorbid, outlier
08	w/onset
09	w/onset, outlier
10	w/low-volume
11	w/training
12	w/low-volume, training
13	w/multiple adjustments (reserved)
14	w/pediatric
15	w/pediatric, training
16	w/pediatric, outlier
17	w/pediatric, outlier, training
18	w/acute comorbid, outlier, low-volume
19	w/acute comorbid, outlier, low-volume, training’
20	w/acute comorbid, low-volume
21	w/acute comorbid, low-volume, training
22	w/acute comorbid, training’
23	w/chronic comorbid, outlier, low-volume’
24	w/chronic comorbid, outlier, low-volume, training
25	w/chronic comorbid, low-volume’
26	w/chronic comorbid, low-volume, training
27	w/chronic comorbid, training
28	w/outlier, low-volume
29	w/outlier, low-volume, training
30	w/onset, outlier, low-volume
31	w/low BMI
32	w/low-volume, onset
33	w/outlier, training
34	w/outlier, training, chronic comorbid
35	w/outlier, training ,acute comorbid

In addition to the pricer return codes, since the implementation of the ESRD PPS, new claim condition codes on the SAF claim trailer record identify detailed beneficiary information about comorbid conditions used for payment. Claim condition codes listed below in Table 2.3 are used to corroborate the pricer return codes. Pricer and condition codes now appear only when the adjustment is paid on a bill type 72x. Comorbid conditions in the previous analysis files were based on diagnosis codes on all claim types except laboratory claims. This represents a substantial change from the methods used to identify comorbid conditions before the payment for these conditions in the bundled payment. Those methods are described fully in KECC Report to CMS: End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle (Hirth et al, 2008).

Table 2.3 Claim Condition Codes Identifying Training and Comorbid Conditions

Condition Code	Description
70	Home dialysis patient who self-administers EPO
71	Full care in dialysis unit
72	Self-care in unit. No staff assistance
73	Self-care training
74	Dialysis services at home
75	Dialysis at home using machine purchased under 100% program
76	Home patient received backup dialysis in facility
80	Skilled Nursing Facility considered home
MA	Gastrointestinal bleeding
MB	Bacterial pneumonia
MC	Pericarditis
MD	Myelodysplastic Syndrome
ME	Hereditary hemolytic anemia/sickle cell anemia
MF	Monoclonal gammopathy
H3	Reoccurrence of gastrointestinal bleeding
H4	Reoccurrence of bacterial pneumonia
H5	Reoccurrence of pericarditis

The outlier payment is found on the SAF-claim-related- value trailer where the code is equal to 17.

The carrier (also called physician supplier) and durable medical equipment (DME) claims are paid claims files containing information on physician or supplier charges and payments, the attending and referring physicians, the supplier, and some patient demographic information. They consist of a header portion with several trailers. There is a diagnostic trailer and a line-item trailer. The line-item trailer is analogous to the revenue center trailers in the SAFs. These files contribute far less information following implementation of the bundle. As Method II was phased out, DME supply claims were no longer used. Labs on carrier claims

included in the ESRD PPS moved into payments as reported on dialysis claims and were no longer reported on a carrier claim.

E. Changes to the Cost Report

Two forms are used for the collection of Medicare Cost Reports. The forms changed to accommodate the ESRD PPS and changes in the hospital cost report. The independent facility (freestanding) forms are CMS 265-94 (1995-2011) and CMS 265-11(2011-2015). The hospital-based renal facility forms are CMS 2552-96 (1996-2010) and CMS 2552-10 (2010-2015) from which the renal minimum dataset is generated from Worksheets S-2 and S-5 and Worksheets I 1-5. The data for hospital-based facilities and for freestanding facilities are generated in the facilities and forwarded directly to CMS. These data are public-use files available for download by fiscal year and type of facility (https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.html).

The majority of the cost report data for this project come from renal facility reports rather than hospital cost reports. The Renal Facility 265-11 Form added worksheets E1, F, and F1. Considerable changes were made to all worksheets with the exception of A-1, A-3, and A-4. Of note, a new sheet was added for S-2 in June 2013.

The changes to the Hospital 2552-10 Form were substantial. However, for this project, only a few worksheets are used and the changes required crosswalks of old and new fields and the addition of some new fields to accommodate the bundle. Table 2.4 displays the number of facility Cost Reports available for analysis.

Table 2.4 Available Cost Reports by Year

Year	Freestanding	Hospital-Based
2012	5517	401
2013	5447	381

III. Payment Adjustments for Demographic Characteristics

A. Age

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 or health behaviors (e.g., adherence to treatment recommendations). end-stage renal disease (ESRD)-related spending has been shown to differ across age categories United States Renal Data System (USRDS), 2015 Annual Data Report; http://www.usrds.org/adr.aspx.)

Analyses to support the expanded bundle ESRD Prospective Payment System (PPS) began with the five age categories used in the basic case-mix adjusted (BCMA) payment system that was implemented on April 1, 2005. In later analyses, 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 calendar year (CY) 2011 ESRD PPS. Specifically, the same five age groups that had been used in the composite rate (CR) basic case-mix adjustment (BCMA) were implemented as payment adjustment factors by applying the two-equation model described in the University of Michigan Kidney Epidemiology & Cost Center (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, and is described in the CY 2011 Final Rule.

The ESRD PPS that went into effect January 1, 2011, included payment adjustments for five age categories with age group 60-69 as the referent (lowest cost group). The other four age categories for patients younger or older than the referent group were paid a multiplicative adjustment beyond this baseline age group (Table 3 1).

Table 3.1 ESRD PPS Payment Multipliers for Age for CY 2011

Age Categories	ESRD PPS Final Rule Multipliers
8-44	1.171
45-59	1.013
60-69	1.000
70-79	1.011
80+	1.016

Analyses of Patient Age and Composite Rate Costs

Re-estimation of the case-mix adjustment model using the most recent available data (2012-2013) began with the CR model. In previous analyses that informed the development of the BCMA for the composite rate system and the CY 2011 ESRD PPS Final Rule, there were patterns of higher CR costs for both younger and older patients that were used as the basis for CR payment adjustments. In Table 3.2, the first column shows the final CR model used in the CY 2011 ESRD PPS. The next three columns apply the same analytical model – with the same set of payment and control variables – but with updated data from the 2012 and 2013 CMS freestanding and hospital-based dialysis facility cost reports. Displayed are three of the age models considered during the initial stages of model re-estimation. The third column (CR age model 1) shows results from re-estimating the same model that was used for the 2011 ESRD PPS Final Rule, using 2012 and 2013 data. There are some differences in the CR model multipliers across the age categories. Most notably, with the updated data, the 60-69 year category no longer has the lowest average composite rate costs per treatment in comparison to other age categories. This change motivated extensive review of the relationship between CR costs and five-year age categories to ensure the new observed relationships are consistent. In Table 3.2, the CR age model 2 shows the same five age categories but with the 70-79 year old category as the referent. In this model, the multipliers for the other age categories are greater than one, indicating that of these five age categories, the 70-79 year old category had the lowest average CR cost per treatment.

In CR age model 2, the multipliers for age categories 45-59 and 60-69 are not significantly different. They are also qualitatively close to the multiplier for the 70-79 year old reference category. This result led to further investigation for possible modification of the age categories. In Table 3.2, CR age model 3 shows preliminary work completed in the CR model that merged groups 45-79 years into a single category that becomes the age referent. The detailed age analyses conducted during the summer of 2015 consistently showed CR costs to be higher for the younger and older age patients, for a variety of age category cut points. CR age model 3 is one of the numerous models that had been under consideration. A more parsimonious age categorization, such as that reflected in CR age model 3, does not lose any predictive power, compared to the models using five age categories, such as those presented in CR age model 1 and CR age model 2. Also, the CR multipliers for the younger age category (18-44 year age category = 1.252) and the older age category (80+ age category=1.049) were similar to the corresponding CR age multipliers from the CY 2011 ESRD PPS. Note that the above analyses of alternative age categorizations focused on the relationship of age with CR costs, where there have previously been larger observed differences across age groups compared to those observed in separately billable (SB) models. Analyses that considered the same alternative age categories for both CR and separately billable (SB) models are presented below.

Table 3.2 Age Models 1–3, Review of Categorical Age Variable Multipliers for 2011 Final Rule and 2016 Updated Composite Rate Model

	2006-2008 data [1]	2012-2013 data [2]	2012-2013 data [2]	2012-2013 data [2]
	CY 2011 ESRD PPS Final Rule	CR age model 1	CR age model 2	CR age model 3
	Referent: 60-69 years	Referent: 60-69 years	Referent: 70-79 years	Referent: combined age group 45-79 years
	Adj R^2 (0.410)	Adj R^2 (0.334)	Adj R^2 (0.334)	Adj R^2 (0.334)
Composite rate model payment variables	**CR multiplier (P-value)**	**CR multiplier (P-value)**	**CR multiplier (P-value)**	**CR multiplier (P-value)**
Age				
18-44	1.254 (<.0001)	1.205 (<.0001)	1.308 (<.0001)	1.252 (<.0001)
45-59	1.023 (0.459)	0.998 (0.960)	1.084 (0.009)	*
60-69	1.000	1.000	1.086 (0.018)	*
70-79	1.033 (0.303)	0.921 (0.018)	1.000	*
80+	1.063 (0.038)	1.054 (0.123)	1.145 (0.001)	1.049 (0.081)
Body surface area (per 0.1 m^2)	1.023 (<.0001)	1.039 (<.0001)	1.039 (<.0001)	1.040 (<.0001)
Time since onset of ESRD <4 months	1.539 (<.0001)	1.307 (0.0024)	1.307 (0.0024)	1.247 (0.0106)
Facility low-volume status	1.347 (<.0001)	1.368 (<.0001)	1.368 (<.0001)	1.367 (<.0001)
Rural	--	1.015 (0.0046)	1.015 (0.0046)	1.014 (0.0079)

[1] Based on log-linear regression models of the average composite rate cost per treatment from CMS cost reports. Includes n=12,974 dialysis facilities during 2006-2008. Model includes control variables for facility size, ownership, rural status, hospital-based status, and year. Onset indicator of renal dialysis < 4 months.

[2.] Based on log-linear regression models of the average composite rate cost per treatment from CMS cost reports. Includes n=10,094 dialysis facilities during 2012-2013. Models include control variables for facility size, ownership, hospital-based status, and year. Onset indicator of renal dialysis < 4 months.

*In CR age model 3, the reference group is combined age group 45-79 years with CR multipliers 1.000.

-- Indicates “not applicable.”

Analyses of Potential Age Adjustments Using CR and SB Costs

The results of preliminary explorations of the relationship of age with CR costs motivated consideration of alternative age categories for payment using both the CR and SB models. These age categorization approaches reflected broader versus narrower age categories, differing numbers of age categories, and alternative reference age categories. A starting point for this work was the use of tightly defined age categories with five-year boundaries. Tables 3.3, Table 3.4, and Table 3.5 show three of the re-estimated payment models with differing age categories.

In Table 3.3, age model 4 includes three age categories. Compared to CR age model 3, the lower age category and upper age category were tightened to capture the evident patterns of higher composite rate costs per treatment. While they represented smaller age categories at more extreme ranges of the overall age distribution than those previously used as the basis for payment adjustments, these upper and lower age categories demonstrated distinct spending patterns in the most recent data. The referent here was extended to one large central age group of 35 to 84 years. As seen in Table 3.3, this model yielded an expanded bundle (EB) payment multiplier for the lower age category (18-34 years) that was 51% higher than the 35-84 year referent group and an EB payment multiplier for the upper age category (+85 years) that was 5% above the referent group.

Table 3.3 Age Model 4, ESRD PPS Payment Adjustments for Adult Patients Three Age Categories with 35-84 Year Old Category as Age Referent

Age for FR model	CY 2011 ESRD PPS Final Rule EB Multipliers (2006-2008 data) [1]	Age categories for model 4 (2012-2013 data) Combined ages: 35-84 years as referent category	EB Multipliers[2]	CR Multipliers[3] (Adj R^2=.334)	SB Multipliers[4] (Adj R^2=.010)
18-44	1.171	18-34	1.521	1.628	1.069
45-59	1.013	--	--	--	--
60-69	1.000	35-84	1.000	1.000	1.000
70-79	1.011	--	--	--	--
80+	1.016	+85	1.053	1.079	0.945
Body surface area (per 0.1 m^2)	1.020		1.035	1.043	1.000
Underweight (BMI < 18.5)	1.025		1.016	1.000	1.085
Time since onset < 4 months	1.510		1.239	1.198	1.411
Facility low-volume status	1.189		1.237	1.365	0.955
Comorbidities					
Pericarditis	1.114		1.039	1.000	1.204
Gastrointestinal tract bleeding	1.183		1.080	1.000	1.416
Hereditary hemolytic or sickle cell anemia	1.072		1.193	1.000	2.004
Myelodysplastic syndrome	1.099		1.095	1.000	1.494
Rural	--		1.006	1.013	0.975

1. EB multipliers from the PY 2011 ESRD PPS Final Rule with 2006-2008 data.
2. Estimated EB multiplier is a weighted average of the CR and SB multipliers. The weights are based on the proportion of the average estimated cost per treatment for CR and SB services, respectively. For example, in Table 3.5, the EB multiplier for ages 18-44 = ((0.8075*1.308)+(0.1925*1.048)) = 1.258. The determination of the weights that are applied to the CR and SB models and the calculation of the EB payment multipliers are discussed in further detail in Section VI, Weighting of Composite Rate and Separately Billable Models.
3. Based on log-linear regression models of the average composite rate cost per treatment from CMS cost reports. Includes n=10,094 dialysis facilities during 2012-2013. Model includes control variables for facility size, ownership, hospital-based status, and year. P <.001 for payment variables.
4. Based on log-linear regression models of the average Medicare Allowable Payment per treatment for separately billable services. Includes n= 6,967,110 Medicare dialysis patient months during 2012 and 2013. Model includes control variables for facility size, ownership, hospital-based status, and year. P < .001 for payment variables.
-- Indicates "not applicable."

In Table 3.4, age model 5 further explores patterns between age and cost with four age categories: 18-34 years; 35-69 years; 70-79 years; 80+ years. As discussed above, the referent age category (70-79 years) was selected because it exhibited lower average composite rate costs per treatment, enabling the payment adjustments for other age groups to be positive, as has been the case for both the BCMA and for the ESRD PPS since 2011. In this model, the lower age category remains tighter, while the upper category is expanded. Here, the estimated multipliers again reflect the expense of the 18-34 year age category in both the CR and SB model, when compared to the referent. The upper age category still exhibits higher costs in comparison to this tighter referent of 70-79 years.

Table 3.4 Age Model 5, ESRD PPS Payment Adjustments for Adult Patients Four Age Categories With 70-79 Age Category as Age Referent

Age for FR model	CY 2011 ESRD PPS Final Rule EB Multipliers (2006-2008 data)[1]	Age categories for model 5 (2012-2013 data) Referent category: 70-79 years Combined ages: 35-69 years	EB Multipliers[2]	CR Multipliers[3] (Adj R^2=.334)	SB Multipliers[4] (Adj R^2=.010)
18-44	1.171	18-34	1.578	1.699	1.072
45-59	1.013	35-69	1.075	1.091	1.007
60-69	1.000	––	––	––	––
70-79	1.011	70-79	1.000	1.000	1.000
80+	1.016	+80	1.107	1.142	0.959
Body surface area (per 0.1 m^2)	1.020		1.034	1.042	1.000
Underweight (BMI < 18.5)	1.025		1.017	1.000	1.087
Time since onset < 4 months	1.510		1.307	1.281	1.415
Facility low-volume status	1.189		1.238	1.367	0.956
Comorbidities					
Pericarditis	1.114		1.039	1.000	1.201
Gastrointestinal tract bleeding	1.183		1.080	1.000	1.418
Hereditary hemolytic or sickle cell anemia	1.072		1.193	1.000	2.003
Myelodysplastic syndrome	1.099		1.096	1.000	1.500
Rural	--		1.007	1.014	0.976

1. EB multipliers from the PY 2011 ESRD PPS Final Rule with 2006-2008 data.
2. Estimated EB multiplier is a weighted average of the CR and SB multipliers. The weights are based on the proportion of the average estimated cost per treatment for CR and SB services, respectively. For example, in Table 3.5, the EB multiplier for age 18-44 = ((0.8075*1.308)+(0.1925*1.048)) = 1.258. The determination of the weights that are applied to the CR and SB models and the calculation of the EB payment multipliers are discussed in further detail in Section VI, Weighting of Composite Rate and Separately Billable Models.
3. Based on log-linear regression models of the average composite rate cost per treatment from CMS cost reports. Includes n=10,094 dialysis facilities during 2012-2013. Model includes control variables for facility size, ownership, hospital-based status, and year. P <.001 for payment variables.
4. Based on log-linear regression models of the average Medicare Allowable Payment per treatment for separately billable services. Includes n= 6,967,110 Medicare dialysis patient months during 2012 and 2013. Model includes control variables for facility size, ownership, hospital-based status, and year. P < .001 for payment variables.
-- Indicates "not applicable."

In Table 3.5, age model 6 also presents CR and SB models with four age categories; however, here, the lower age category extends to what had been used in the CY 2011 ESRD PPS Final Rule: 18-44 years; 45-69 years; 70-79 years; +80 years. This model most closely aligns with findings presented in Table 3.2, above, for age model 2. Here, the two central age categories – which are statistically shown to not differ from each other – are merged into one broader category for patients 45-69 years of age. This model, more parsimonious but without loss of statistical power, still shows the higher costs of lower and upper age categories.

Table 3.5 Age Model 6, ESRD PPS Payment Adjustments for Adult Patients. Four Age Categories with 70-79 Category as Age Referent and 18-44 Younger Age Category

Age for FR model	CY 2011 ESRD PPS Final Rule EB Multipliers (2006-2008 data)[1]	Age categories for model 6 (2012-2013 data) Referent category: 70-79 years Combined ages: 45-69 years	EB Multipliers[2]	CR Multipliers[3] (Adj R^2=.334)	SB Multipliers[4] (Adj R^2=.010)
18-44	1.171	18-44	1.258	1.308	1.048
45-59	1.013	45-69	1.069	1.085	1.003
60-69	1.000	--	--	--	--
70-79	1.011	70-79	1.000	1.000	1.000
80+	1.016	+80	1.109	1.145	0.959
Body surface area (per 0.1 m^2)	1.020		1.032	1.039	1.000
Underweight (BMI < 18.5)	1.025		1.017	1.000	1.088
Time since onset < 4 months	1.510		1.328	1.307	1.416
Facility low-volume status	1.189		1.238	1.368	0.956
Comorbidities					
Pericarditis	1.114		1.038	1.000	1.200
Gastrointestinal tract bleeding	1.183		1.081	1.000	1.418
Hereditary hemolytic or sickle cell anemia	1.072		1.193	1.000	2.001
Myelodysplastic syndrome	1.099		1.096	1.000	1.500
Rural	--		1.004	1.015	0.956

1. EB multipliers from the PY 2011 ESRD PPS Final Rule with 2006-2008 data.

2. Estimated EB multiplier is a weighted average of the CR and SB multipliers. The weights are based on the proportion of the average estimated cost per treatment for CR and SB services, respectively. For example, in Table 3.5, the EB multiplier for age 18-44 = ((0.8075*1.308)+(0.1925*1.048)) = 1.258. The determination of the weights that are applied to the CR and SB models and the calculation of the EB payment multipliers are discussed in further detail in Section VI, Weighting of Composite Rate and Separately Billable Models.

3. Based on log-linear regression models of the average composite rate cost per treatment from CMS cost reports. Includes n=10,094 dialysis facilities during 2012-2013. Model includes control variables for facility size, ownership, hospital-based status, and year. P <.001 for payment variables.

4. Based on log-linear regression models of the average Medicare Allowable Payment per treatment for separately billable services. Includes n= 6,967,110 Medicare dialysis patient months during 2012 and 2013. Model includes control variables for facility size, ownership, hospital-based status, and year. P < .001 for payment variables.

-- Indicates "not applicable."

Table 3.6 shows the re-estimated payment models using the five age categories reflected in both the BCMA and the CY 2011 ESRD PPS. These models use the 70-79 year age category as the reference category that reflected the lowest estimated cost for services included in the expanded bundle. The resulting EB multipliers reflected the largest payment adjustments for the youngest and oldest age groups and relatively smaller payment adjustments for ages 45-59 years and 60-69 years.

Table 3.6 CY 2016 ESRD PPS Payment Adjustments for Adult Patients

Retaining the Same Age Categories Used for the BCMA and the CY 2011 ESRD PPS Final Rule

Patient or facility characteristic	% of Medicare dialysis treatments or average	CR Multipliers for CY 2016	SB Multipliers for CY 2016	ESRD PPS Payment Multipliers for CY 2016
Age				
18-44	12.8%	1.308	1.044	1.257
45-59	27.8%	1.084	1.000	1.068
60-69	25.8%	1.086	1.005	1.070
70-79	21.1%	1.000	1.000	1.000
80+	12.4%	1.145	0.961	1.109
Body surface area (per 0.1 m^2)	1.90	1.039	1.000	1.032
Underweight (BMI < 18.5)	3.3%	1.000	1.090	1.017
Time since onset of renal dialysis < 4 months	4.0%	1.307	1.409	1.327
Facility low-volume status	1.7%	1.368	0.955	1.239
Comorbidities				
Pericarditis (acute)	0.1%	1.000	1.209	1.040
Gastrointestinal tract bleeding (acute)	0.5%	1.000	1.426	1.082
Hereditary hemolytic or sickle cell anemia (chronic)	0.1%	1.000	1.999	1.192
Myelodysplastic syndrome (chronic)	0.3%	1.000	1.494	1.095
Rural	15.0%	1.015	0.978	1.008

As reflected in Tables 3.3 through 3.6, all of the analyses that were conducted to explore potential age adjustments for the CY 2016 ESRD PPS Final Rule indicated a familiar U-shaped relationship between age and cost that has prevailed since the development of the BCMA, with youngest and oldest patients being the most expensive. The explanatory power of the estimated models was not dependent on the age categories employed as potential payment variables. Further, the estimated multipliers for the other (non-age) payment variables were essentially unchanged when considering alternative age categories. The age adjustments serve to capture cost variation that is not otherwise addressed by the other payment adjustments. After consideration of alternative age categories, CMS chose to retain the age groups and payment adjustments in

order to maintain the explanatory power of the system and maintain payments to facilities with patients who are between the ages of 44 through 79, that is, approximately 75 percent of patients.

B. Comorbidities as Patient-Related Risk Adjusters

The ESRD PPS that went into effect January 1, 2011, included risk adjustment for six comorbidities: three reflecting acute conditions (pericarditis, bacterial pneumonia, and gastrointestinal (GI) tract bleeding with hemorrhage) and three reflecting chronic conditions (hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome, and monoclonal gammopathy). The analyses and other considerations supporting the decision to adjust for these comorbidities are fully described in the 2015 report to CMS and the CY 2011 ESRD PPS proposed and Final Rules (74 FR 49947 and 75 FR 49094, respectively). Importantly, these comorbidities were found to be related to separately billable (SB) costs and were therefore entered in that part of the payment model. They were not found to be related to composite rate (CR) costs.

Subsequent to the publication of the CY 2011 ESRD PPS Proposed and Final Rules, various stakeholders expressed an interest in further evaluating whether the number of comorbidities for risk adjustment should be expanded, reduced, or eliminated. Since there appeared to be less public interest in potentially expanding the set of comorbidities, analyses conducted after publication of the final rule did not focus on expanding the set of comorbidities used in risk-adjusting payment.

Comorbidity

Comorbidity information used in analyses to inform the CY 2011 ESRD PPS Final Rule (2011 Final Rule) https://www.gpo.gov/fdsys/pkg/FR-2011-11-10/pdf/2011-28606.pdf. came from Medicare claims for all types of services received by ESRD beneficiaries. Claims for inpatient, outpatient, physician and other provider services were included; laboratory service claims were excluded because a diagnosis reported on a laboratory claim could indicate the presumptive diagnosis for which the test was ordered rather than a confirmed diagnosis. Prior to the implementation of the ESRD PPS, the reporting of non-renal diagnoses on dialysis facility claims (Type 72x claims) was rare. Therefore, reliance solely on dialysis claims to identify comorbidities was not feasible, and diagnoses reported on any non-laboratory claim types were reflected in the analyses. With the implementation of the ESRD PPS, dialysis facilities were required to report patient comorbidities for the six conditions used as payment adjusters on the dialysis facility claims in order to receive the payment adjustment. Therefore, it became feasible for the analyses to support the development of the CY 2016 ESRD PPS Proposed and Final Rules to utilize diagnoses reported on dialysis facility claims to identify the presence of a condition. For a more detailed description of this change in data source for comorbidities between the analyses for the CY 2011 and CY 2016 ESRD PPS final and proposed rules, see Section II, D of this report.

Frequency of Comorbidity Reporting

UM-KECC compared the frequency of comorbidity reporting on the Type 72x claims to that appearing in all Medicare claims for calendar years 2012, 2013, and 2014. Table 3.7 presents the results for 2014; results for 2012 and 2013 are virtually identical to 2014.

Table 3.7 Comorbidity identification by treatment in claims data versus pricer return codes (2014 data)

	Comorbidity on other Medicare Claims	Number of claims with comorbidity not indicated on Type 72x claims	Number of claims with comorbidity indicated on Type 72x claims	Presence of comorbidity based on Medicare claim type[1]	Presence of comorbidity based only on Type 72x claims[2]	Frequency of comorbidity identified on PRC type 72x claims relative to general Medicare claims[3]
Pericarditis (acute)	No	3,781,539	7	0.42%	0.06%	14.35%
	Yes	13,755	2,304	--	--	--
Bacterial pneumonia (acute)	No	3,691,861	43	2.78%	0.19%	6.86%
	Yes	98,451	7,250	--	--	--
Gastrointestinal tract bleeding (acute)	No	3,740,479	22	1.50%	0.30%	19.86%
	Yes	45,764	11,340	--	--	--
Hereditary hemolytic or sickle cell anemia (chronic)	No	3,714,869	601	2.16%	0.15%	6.19%
	Yes	77,049	5,086	--	--	--
Myelodysplastic syndrome (chronic)	No	3,712,432	102	2.24%	0.28%	12.40%
	Yes	74,523	10,548	--	--	--
Monoclonal gammopathy (chronic)	No	3,705,259	151	2.43%	0.47%	19.20%
	Yes	74,491	17,704	--	--	--

[1] Condition appears on general Medicare claims; denominator is total number of claims.
[2] Condition appears on Type 72x claim; denominator is total number of claims.
[3] This is the ratio of presence of comorbidity on Type 72x divided by presence of comorbidity on Medicare claims. For example, for pericarditis: 2,304 / (13,755+2,304) = 14.35%. This shows the rate of the presence of the comorbidity as indicated on the Type 72x in comparison to the presence of the comorbidity on the Medicare claims. The rate does not include the negligible number of claims that indicated the presence of the comorbidity on the Type 72x claim but not identified with comorbidity in the Medicare claims.
-- Indicates "not applicable."

Notably, for all six comorbidities, the frequency of reporting the presence of a comorbidity on the dialysis facility claims was a small fraction (ranging from approximately 7% to 20%, as noted in the far right column of Table 3.1) of the presence of a comorbidity based on all Medicare claims types. This result was unexpected, given the substantial increase in payment associated with reporting the comorbidities. Indeed, a rate of comorbidity reporting on Type 72x claims that was equal or even higher than all Medicare claims would not have been surprising, given the financial incentives. Comments from dialysis providers indicated that the low frequency of comorbidity identification on the dialysis facility claims was due to (1) facility difficulty in determining the comorbidities of its patients, and (2) difficulties in documenting the presence of a comorbidity due to CMS requirements (e.g., bacteriologic diagnosis for pneumonia, or anatomic location for gastrointestinal (GI) bleeding.

Table 3.7 also indicates that very rarely (<.02% for all comorbidities) was a comorbidity reported on a Type 72x dialysis facility claim but not reported on other Medicare claims. For example, out of 3,797,605 claims for 2014, there were only seven claims that indicated the presence of pericarditis in the Type 72x claims without an indication of the comorbidity in the other Medicare claims. This finding supports the conclusion that dialysis facilities were not reporting unsubstantiated (or nonexistent) comorbidities.

Statistical Relationships between Comorbidities and SB Costs

UM-KECC conducted several analyses of the relations between comorbidities as reported on dialysis facility claims and SB costs under the ESRD PPS. The first set of analyses applied a modified version of the 2011 SB cost model to updated claims and other data from 2013 (using the June 2014 claims file). These initial analyses compared a model that included all six comorbidities to models having fewer comorbidities. In these initial models, facility control variables were excluded because these variables were not available at the time the analyses were conducted. Because the control variables have little effect on the payment multipliers in the SB model (they have substantial impact in the CR model), their exclusion from these initial models did not meaningfully affect the conclusions. Results of the modified SB model with 2013 data are presented in Table 3.8.

Table 3.8 Separately Billable Case-Mix Multipliers for ESRD PPS Models with Modified Comorbidity Variable Inclusion All SB models exclude facility controls

Payment variables	1 2006-2008 CY 2011 Final Rule SB model without facility control variables[1]	2 2013 All Medicare claims-based identified comorbidities[2] R^2= .0170	3 2013 Type 72x dialysis claims paid comorbidities[3] R^2 = .0084	4 2013 No adjustments for comorbidities[3] R^2 = .0062	5 2013 Type 72x paid comorbidities - chronic only[3] R^2 = .0078	6 2013 Type 72x paid comorbidities w/out pneum and monoclonal gammopathy[3] R^2 = .0083
Age						
18-44	0.993	1.053	1.049	1.049	1.049	1.049
45-59	0.991	1.003	1.000	1.000	1.000	1.000
60-69	1.000	1.000	1.000	1.000	1.000	1.000
70-79	0.962	0.985	0.990	0.991	0.990	0.990
80+	0.910	0.938	0.946	0.948	0.946	0.947
Body surface area (per 0.1 m^2)	1.014	0.993	0.992	0.992	0.992	0.992
Underweight (BMI < 18.5)	1.076	1.054	1.067	1.069	1.067	1.067
Time since onset of renal dialysis < 4 months	1.448	1.367	1.389	1.386	1.387	1.388
Pericarditis (acute)	1.351	1.296	1.131	--	--	1.138
Bacterial pneumonia (acute)	1.422	1.372	1.179	--	--	--
Gastrointestinal tract bleeding (acute)	1.571	1.524	1.384	--	--	1.389
Hereditary hemolytic or sickle cell anemia (chronic)	1.213	1.277	1.982	--	1.987	1.985
Myelodysplastic syndrome (chronic)	1.305	1.324	1.525	--	1.537	1.529
Monoclonal gammopathy (chronic)	1.074	1.050	1.067	--	1.069	--
Facility low-volume status						
<4,000 treatments, low-volume eligible [4]	0.971	0.946	0.946	0.946	0.946	0.946

[1] Based on log-linear regression models of the average Medicare Allowable Payment per treatment for separately billable services. Includes n=8,603,325 Medicare dialysis patient months during 2006-08.

[2] Based on log-linear regression models of the average Medicare Allowable Payment per treatment for separately billable services. Includes n= 3,564,436 Medicare dialysis patient months during 2013. R^2 at patient month level.

[3] The age category 44-59 does not differ statistically different than age category 60-69.

[4] For 2013 data, low-volume is based on Type 72x PRICER return code identification.

-- Indicates "not applicable."

Column 1 shows the payment multipliers from the re-estimated SB model that excludes facility control variables; this model applies the same 2006-2008 data used in the CY 2011 ESRD PPS final payment rule. Here, comorbidities were identified using all types of Medicare claims except laboratory claims. These payment multipliers are included here for comparison to the models that have updated models but lack facility controls. Column 2 shows a model using the same set of variables as seen in column 1. Here, payment multipliers based on Medicare claims for 2013 and the presence of a comorbidity are similarly based on identification in all non-laboratory Medicare claims. Comparison of column 1 (2006-2008 data) and column 2 (2013 data) offers an important initial result: using the same type of data and the same set of model variables, all six comorbidities continue to exhibit significant relationships to higher SB costs after the institution of the ESRD PPS. The multipliers for each of the three acute conditions were slightly lower using the 2013 data, while the multipliers for two of the three chronic conditions were slightly larger. Overall, the comparison of the payment multipliers in columns 1 and 2 indicates that the relationships between comorbidities and SB costs remained quite stable over time and across payment systems.

Column 3 shows a model using the same set of variables, but estimated using only the dialysis facility claims (Type 72x claims), as opposed to all types of Medicare claims, for 2013. Here, using a restricted claims type but the same set of model variables, all six comorbidities continue to exhibit significant relationships to higher SB costs. However, the implied payment multipliers differ from those presented in Column 2. This result suggests that the data on the Type 72x claims are not a purely random subset of the larger number of comorbidities identified on all non-laboratory claims. Further, as indicated in Column 3, the resultant payment multipliers for the three acute comorbidities would be somewhat smaller than in the SB model estimated for the 2011 Final Rule (using all Medicare claims types as shown in column 1). The resultant payment multipliers for two of the three chronic comorbidities (hereditary hemolytic or sickle cell anemia and myelodysplastic syndrome) would be higher. The exception is for monoclonal gammopathy, where the multiplier would be slightly lower. Larger multipliers in column 3 relative to column 2 would be consistent with dialysis facilities identifying and reporting relatively severe cases, but this pattern was only seen for two of the comorbidities (hereditary hemolytic or sickle cell anemia and myelodysplastic syndrome).

Several model configurations with restricted sets of comorbidities were estimated using the dialysis facility claims. These are also reported in Table 3.8. Column 4 presents an SB payment model that eliminates all comorbidities as payment adjusters. Note that the associated payment multipliers on the remaining patient characteristics (age, body size, and time since onset of dialysis) are quite similar to those associated with the model with the full set of six comorbidities shown in Column 3. In the models presented in columns 5 and 6, the presence of a comorbidity is based on dialysis facility claims. Column 5 presents a payment model using only chronic comorbidities as payment adjusters. Again, we see no notable changes in other multipliers.

Further, the chronic comorbidities multipliers in Column 5 are very close to those in Column 3. This result suggests little correlation between the existence of the three acute and three chronic comorbidities. In consideration of stakeholder concerns about the variation in patient assessment and burden of documentation requirements for both monoclonal gammopathy and bacterial pneumonia, we were asked to consider an SB payment model that excluded these two comorbidities. Column 6 presents an SB payment model with four comorbidities, excluding bacterial pneumonia and monoclonal gammopathy. These two comorbidities were chosen for potential exclusion by CMS. Exclusion of these two comorbidities has almost no effect on the other multipliers.

In all of these model configurations, the payment multipliers on patient characteristics other than comorbidities were essentially unchanged as a result of restricting the set of comorbidities used as payment adjusters. Hence, the selection of the set of comorbidities for the CY 2016 ESRD PPS Proposed and Final Rules could be made on other bases.

C. Body Size

Two measures based on patient height and weight have been included as case-mix adjusters since the implementation of the Basic Case-Mix Adjustment (BCMA) for Composite Rate (CR) services in 2005. Those measures are intended to reflect two related, but distinct, concepts: patient size and frailty. Size might be related to costs because larger patients would be expected to require more dialysis resources (e.g., more time on machine, larger membrane, more dialysate) to achieve a comparable "dose" of dialysis for smaller patients. Larger patients may also require greater dosages of injectable medications than smaller patients to achieve the same clinical outcomes. In contrast, it may be more costly to care for frail patients, who may be malnourished and have multiple comorbidities and increased dependence on others. Therefore, adjusting payments and only for larger body size might underestimate the costliness of caring for frail (underweight) patients who might require extra resources, such as staff attention.

The size measure, body surface area (BSA), is calculated as a function of height (H) and weight (W) using the following formula (Dubois and Dubois 1916): $BSA = 0.007184 \times H^{0.0725} \times W^{0.0425}$. Body mass index (BMI) values below 18.5 kg/m^2 are used to identify underweight/frail patients (CDC, 2004; NIH, 2004). For example, using pounds and inches, a person who is 5 feet 6 inches tall would be considered underweight if they weighed 114 pounds or less. Section IV, C of our 2015 report describes alternative measures of patient size that were analyzed before selecting these specific measures (Hirth et al, 2015: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-Analysis.pdf

Although continuous measures of BSA and BMI are correlated (r=0.685 based on 2013 data), the correlation between the actual payment variables (continuous BSA and dichotomous indicator of low BMI) is low (r=-0.257 based on 2013 data). Therefore, multi-collinearity is not so strong as to make it impossible, *a priori*, to identify the separate effects of the continuous measure of BSA and the dichotomous indicator of low BMI on costs. In fact, the analyses underlying the BCMA were able to identify independent, statistically significant positive associations with CR costs for both variables (Table 3.9).

Table 3.9 The Basic Case-Mix Adjustments for the Composite Rate, 2000-2002[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/m2	1.112	0.043	(1.003, 1.232)
>18.5 kg/m2	1.000	Reference	--

[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.
*R^2 for all covariates: case-mix and control variables = 0.3595; R^2 for all control variables only = 0.3488.
-- Indicates "not applicable."

The analyses underlying the CY 2011 ESRD PPS Final Rule were able to identify independent, statistically significant positive associations with separately billable (SB) costs for both variables, but identified a significant association with CR costs only for the continuous BSA measure (Table 3.10)

Table 3.10 Payment multipliers for an expanded bundle of services, ages 18 and older, 2006-2008 Estimated payment multipliers based on a two-equation model (Base Rate - $229.63)

Adjustments for patient characteristics	Composite rate services[1] multiplier -- $PmtMult_{CR}$	Separately billable services[2] multiplier -- $PmtMult_{SB}$	Modeled case-mix adjustment[3,4] multiplier -- $PmtMult_{EB}$
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
Gastrointestinal 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 (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 (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 (Medicare Allowable Payment) 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 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.

[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.

By way of contrast, the CY 2016 ESRD PPS Final Rule only identified statistically significant increases in costs between BSA and CR and between low BMI and SB (Table 3.3). The overall pattern for the combined multiplier applied as a payment adjuster remained the same (higher costs with higher BSA and with low BMI). As in the CY 2011 model, the CY 2016 low BMI adjustment was derived solely from the SB model. The magnitudes of the SB multiplier were similar in both years, but the EB multiplier for low BMI was lower for CY 2016 due to the lower weight placed on SB services as a share of the whole bundle. See Section VI for a detailed description of the change in weighting resulting from the reductions in the use of SB services following implementation of the ESRD PPS. Thus, the updated CY 2016 analyses support the continued use of both BSA and BMI in the ESRD PPS. Future analyses beyond the CY 2016 refinement could again consider alternative size measures or alternative methods of combining the size and frailty adjusters.

Table 3.11 CY 2016 ESRD PPS Comorbidity Payment Adjustments for Adult Patients

Patient or facility characteristic	% of Medicare dialysis treatments or average	CR Multipliers for PY2016	SB Multipliers for PY2016	ESRD PPS Payment Multipliers for PY2016
Age				
18-44	12.8%	1.308	1.044	1.257
45-59	27.8%	1.084	1.000	1.068
60-69	25.8%	1.086	1.005	1.070
70-79	21.1%	1.000	1.000	1.000
80+	12.4%	1.145	0.961	1.109
Body surface area (per 0.1 m^2)	1.90	1.039	1.000	1.032
Underweight (BMI < 18.5)	3.3%	1.000	1.090	1.017
Time since onset of renal dialysis < 4 months	4.0%	1.307	1.409	1.327
Facility low-volume status	1.7%	1.368	0.955	1.239

D. Onset of Dialysis

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 (CKD) identified until very late in the progression toward ESRD. This contributes to a high prevalence of patients who have received inadequate modality education, have not established permanent vascular access (potentially exposing them to greater infection risks from catheters), and have not had 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. The adjustment for onset continues to be a component of the ESRD PPS.

The onset of ESRD is determined from the date of first dialysis reported on CMS Form 2728 and the onset period continues through the first four months a patient is receiving dialysis (74 FR 49952). As described in earlier work, month-by-month analyses demonstrated that costs were highest in the first four months of dialysis, with a significant decline and stabilization thereafter (Hirth, et al, 2008; Hirth, et al, 2015 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-Analysis.pdf. The single onset 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.

The cost analyses for patients receiving dialysis were based on Medicare claims data and cost reports. 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 data.

The model appearing in the CY 2011 ESRD PPS Final Rule included a payment multiplier of 1.510 for patients in the first four months of dialysis. Details are available in our 2015 report (Hirth et al., 2015 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-Analysis.pdf. For the CY 2016 ESRD PPS refinement model, the expanded bundle (EB) onset multiplier

decreased to 1.327. This decrease was due to three factors. First, for the CY 2011 Final Rule, the composite rate (CR) model the onset multiplier equaled 1.539, and this CR multiplier decreased to 1.307 in the CY 2016 Final Rule. Second, because the weight attached to CR model increased in the CY 2016 Final Rule (as discussed in Section VI), the effect of the decrease in the multiplier was magnified. Third, the separately billable (SB) multiplier declined slightly from 1.450 to 1.409. For the CY 2016 refinement, the onset multiplier was fairly robust across tested modifications in age categorizations, comorbidity inclusion / exclusion, and control variables inclusion. While we cannot directly assess the clinical and practice factors that might have contributed to the decline, changing practices such as improved access to pre-ESRD care or timing of dialysis initiation might have contributed.

IV. Refinement of Case-Mix Adjustments for Pediatric Patients

Due to the small number of pediatric patients in the dialysis population and clinical differences between pediatric and adult patients (e.g., body size, comorbidities, distribution of treatment modalities), a pediatric case-mix model was developed separately from the adult model for the end stage renal disease prospective payment system (ESRD PPS). Details for the methodology used to calculate the base rate for pediatric patients, including the final pediatric payment adjusters, can be found in the calendar year (CY) 2011 ESRD PPS Final Rule at 75 FR 49131 through 49134 (Federal Register. 2011;76:70228-70316: https://www.gpo.gov/fdsys/pkg/FR-2011-11-10/pdf/2011-28606.pdf). Briefly, the methodology for calculating the pediatric payment adjusters reflects case-mix adjustments for age and modality. Age categories were defined as either less than 13 years, or 13 through 17 years and modality was either peritoneal dialysis (PD) or hemodialysis (HD). The final pediatric payment adjusters in the CY 2011 ESRD PPS reflected the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate (CR) services and separately billable (SB) items in CY 2007 based on the 872 pediatric dialysis patients reflected in the data.

For the purpose of updating the pediatric payment model for the CY 2016 ESRD PPS, the same methodology that was used in the CY 2011 ESRD PPS Final Rule was employed, except for the use of more recent data (2012 through 2013), and in the method of obtaining payment data. Specifically, University of Michigan Kidney Epidemiology & Cost Center (UM-KECC) used the projected total expanded bundle Medicare Allowable Payments (MAP) based on 2013 claims to calculate the ratio of pediatric total MAP per session to adult total MAP per session. The projected MAP was calculated by pricing current utilization of SBs based on line items in the claims, rather than using actual payments from the claims that had been available in the data used for the CY 2011 ESRD PPS Final Rule, which was pre-bundling.

Specifically, the pricing for these services was based on Centers for Medicare and Medicaid Services (CMS) payments under the fee-for-service system, updated on a quarterly basis. The payment amounts for drugs are 106 percent of the Average Sales Price (ASP) calculated from data submitted by drug manufacturers. The quarter to quarter price changes are generally the result of updated data from the manufacturers of these medications. The change in data source from actual payments to line item utilization necessitated by the implementation of the ESRD PPS is described in more detail in Section II, D of this report. The same log-linear regression model was used to develop the separately billable (SB) model multipliers with the average SB MAP payment per session during 2012 through 2013 for each pediatric patient as the independent variable.

There is no change in the formula used to establish the pediatric expanded bundle payment multiplier (MultEB):

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

where P is the ratio of the average MAP per session for pediatric patients to the average MAP per session for adult patients, C is the average payment multiplier for adult patients (1.1151), WCR (0.798) and WSB (0.202) are the proportion of MAP for CR and SB services, respectively, among pediatric patients, and MultSB represents the SB model multipliers. Updated values for P, C, WCR, and WSB were used along with the updated SB multipliers to calculate the updated EB multipliers. The overall difference in the CY 2013 MAP between adult and pediatric dialysis patients was 8.2 percent (P = $283.42/$ 261.91= 1.082) higher for pediatric patients, accounting for the overall difference in average payments per treatment.

Table 4.1 Final updated pediatric case-mix payment adjustments (CY 2016 Final Rule, based on 2012 and 2013 data)[1]

Cell	Age	Modality	Population %	Separately Billable Multiplier[1]	Expanded Bundle Payment Multiplier
1	<13	PD	27.62%	0.410	1.063
2	<13	HD	19.23%	1.406	1.306
3	13-17	PD	20.19%	0.569	1.102
4	13-17	HD	32.96%	1.494	1.327

1. Based on log-linear regression models of the average Medicare Allowable Payment per treatment for separately billable services. Includes n=13,113 (0.185% of total Medicare patient months) Medicare dialysis pediatric patient months during 2012 and 2013.

V. Facility-Level Adjustments: Low-Volume and Rural

Background/Rationale: Low-Volume Facility Payment Adjustment

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. Initial work on the development of a low-volume payment adjustment (LVPA) was presented in the report, "End-Stage Renal Disease Payment System: Results of Research on Case-mix Adjustment for an Expanded Bundle," University of Michigan Kidney Epidemiology and Cost Center, ((UM-KECC) 2008, pp. 37-39). Consistent with the statute to reimburse facilities operating on a smaller scale, initial research 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).

Further research that informed the development of the calendar year (CY) 2011 ESRD PPS Final Rule was reviewed in the second ESRD PPS methodology report entitled "Analyses to Inform the Design and Implementation of the End-Stage Renal Disease Prospective Payment System," (UM-KECC 2015, pp. 93-103). That report presented key analyses related to the size threshold for identifying low-volume facilities and resulting number of eligible low-volume facilities, the magnitude of the low- volume payment adjustment (LVPA) for the potential thresholds being considered, and other inclusion criteria to identify facilities operating at a consistently smaller scale. Research presented in the UM-KECC 2015 report demonstrated how the low-volume size threshold being considered was related to both the magnitude of the resulting LVPA and the number of facilities deemed eligible for the LVPA.

As discussed in the CY 2011 ESRD PPS Final Rule, the facility low-volume threshold was determined to be 4,000 treatments per year. This resulted in a projected application of the LVPA to 1.9 percent of Medicare dialysis claims (CY 2011 ESRD PPS Final Rule 75 FR 49030). As summarized in the UM-KECC 2015 report, results from analyses using 2006-2008 data and a low-volume threshold of 4,000 treatments showed that low-volume facilities were more likely than other facilities to be located in a rural area, less likely to be owned by a large dialysis organization (LDO), more likely to be hospital-based facilities, and more likely to be pediatric facilities. Low-volume facilities were also more likely to treat a higher percentage of Medicare patients, and to have been eligible for a composite rate payment exception as an Isolated Essential Facility. When using the 4,000 treatment threshold, the empirical cost models indicated a per treatment 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 facilities identified as eligible for the LVPA based on available data, and satisfied the MIPPA requirement that the adjustment being finalized for CY 2011 be at least 10 percent.

The CY 2011 ESRD PPS Final Rule also specified that for dialysis facilities opening after January 1, 2011, eligibility for the LVPA based on the 4,000 treatment threshold would be determined by summing the facility's number of treatments with the number of treatments reported for any other facility (1) under common ownership, and (2) geographically located within 25 road miles of the facility in question. As noted in the Final Rule, this provision was intended to avoid creating an incentive for dialysis companies to open small facilities within close geographic proximity to existing facilities. Given the other criterion for organizational stability (facilities in operation for three full years using the same provider number), the soonest that a newly opened facility would be eligible for the LVPA (given that it does not violate this geographical proximity clause) was CY 2015. Facilities that had opened and were certified for Medicare participation prior to January 1, 2011, were grandfathered and exempt from this geographic proximity clause. For these grandfathered facilities, the number of treatments used to determine eligibility for the LVPA was based only on treatments reported for the facility in question.

Further details regarding eligibility for the low-volume adjustment were described in the CY 2011 ESRD PPS Final Rule (pp. 49117-49125).

Identification of Low-Volume Facilities for the CY 2012-CY 2015 ESRD PPS Final Rules

In the initial years following the implementation of the CY 2011 ESRD PPS, the methods used to identify low-volume facilities for the ESRD PPS impact analyses underwent two refinements. The first refinement involved a change in the data source that was used to determine eligibility for the LVPA. For both the CY 2011 and CY 2012 ESRD PPS Final Rules, Standard Information Managements System (SIMS) data were used to identify projected low-volume eligible facilities for the impact analyses. At the time these analyses were performed, SIMS data were the most current data available for ascertaining facility low-volume eligibility (due to the lag in available cost report data). For subsequent ESRD PPS Final Rules, it was possible to identify facilities that received the LVPA under the ESRD PPS using pricer return codes in the claims data. For the CY 2013 ESRD PPS Final Rule, claims data for 2011 were available for analysis. The facilities identified as receiving the LVPA in the 2011 claims (based on the June 2012 claims file) are described in Table 5.1. Similar to the analyses completed for the CY 2011 ESRD PPS Final Rule (which used 2006-2008 SIMS data for LVPA eligibility), low-volume facilities identified using pricer return codes in the 2011 claims were less likely to be owned by an LDO, more likely to be hospital-based facilities, and more likely to be located in a rural area.

Table 5.1 shows the frequency of the projected LVPA corresponding to the impact analyses for the CY 2011 through CY 2015 ESRD PPS Final Rules. Based on the 2011 claims data used for the CY 2013 Final Rule, fewer facilities were identified as being eligible for the LVPA than what had been originally expected based on the SIMS data that were used for the CY 2011 Final Rule (5.8% vs. 7.1% of facilities). For the CY 2014 and CY 2015 Final Rules, the number of facilities determined to be eligible for the LVPA increased to 6.2% and 6.7% of facilities, respectively.

Table 5.1 Comparison of Facility Attributes by Low-Volume Status in the 2011 claims (June 2012 claims file)[1]

Facility attributes	Count of low-volume facilities: Yes	% Low-volume facilities: Yes	Count of low-volume facilities: No	% Low-volume facilities: No	Total facilities count
All facilities	**332**	**5.80%**	**5,394**	**94.20%**	**5,726**
Ownership					
1) LDO	173	4.65%	3546	95.35%	3,719
2) Regional	47	5.08%	879	94.92%	926
3) Independent	48	7.55%	588	92.45%	636
4) Hospital	64	14.75%	370	85.25%	434
5) Unknown	--	--	11	100.00%	11
Pediatric					
1) <2%	323	5.75%	5293	94.25%	5,616
2) 2-19%	3	6.82%	41	93.18%	44
3) 20-49%	1	12.50%	7	87.50%	8
4) >=50%	5	8.62%	53	91.38%	58
Hospital Based					
1) Yes – Hospital-Based	88	16.00%	462	84.00%	550
2) No – Hospital-Based	244	4.71%	4932	95.29%	5,176
Rural					
1) Yes - Rural	174	13.73%	1093	86.27%	1,267
2) No - Rural	158	3.54%	4301	96.46%	4,459

[1.] Low-volume attestation based on pricer return codes.
-- Indicates "not applicable."

Table 5.2 Number and percent of dialysis facilities projected to be eligible for the low-volume payment adjustment (LVPA), based on analyses for the PY2011 - PY2015 ESRD PPS Final Rules

Data source for determining facility eligibility for the LVPA	Final rule	Total number of dialysis facilities	Total[1]	Freestanding[1]	Total hospital-based[1]	Hospital-based satellite: yes[1]	Hospital-based satellite: no[1]
2009 SIMS/Annual Facility Survey*	PY 2011	4,951	351 (7.1%)	249 (5.0%)	102 (2.1%)	18 (0.4%)	84 (1.7%)
2010 SIMS/Annual Facility Survey	PY 2012	5,503	378 (6.9%)	288 (5.2%)	90 (1.6%)	8 (0.1%)	82 (1.5%)
2011 claims (based on pricer return codes)	PY 2013	5,726	332 (5.8%)	244 (4.3%)	88 (1.5%)	44 (0.8%)	44 (0.8%)
2012 claims (based on pricer return codes)	PY 2014	5,873	362 (6.2%)	295 (5.0%)	67 (1.1%)	28 (0.5%)	39 (0.7%)
2013 claims (based on pricer return codes)	PY 2015	6,096	407 (6.7%)	328 (5.4%)	79 (1.3%)	42 (0.7%)	37(0.6%)

*Used in calculating the original base rate amount for the PPS in FY2011.

[1] Dialysis facilities projected to be eligible for the LVPA (n, %)

A second refinement to the methodology that was used to identify projected low-volume eligible facilities was incorporated in the impact analyses for the CY 2015 ESRD PPS Final Rule. This refinement involved the reclassification of low-volume status for a relatively small number of hospital satellite facilities. As noted in the CY 2015 Final Rule, CMS was made aware of concerns that certain low-volume eligible hospital satellite facilities were not receiving the LVPA because they were not permitted by their Medicare Administrative Contractor to submit supporting data to demonstrate eligibility for the LVPA, given that hospital cost reports that combine data for facilities affiliated with a hospital do not by themselves provide the information needed to make this determination. The CY 2015 Final Rule clarified that in addition to cost report data and the facility attestation, MACs could accept supporting data demonstrating facility eligibility for the LVPA. Using the most recent claims data available (for 2013), UM-KECC considered the potential for this clarification to lead additional hospital satellite facilities to be identified as eligible for the LVPA. Based on a comparison of the facilities receiving the LVPA in the 2013 claims with facilities deemed to be eligible for the LVPA according to Standard Information Management System (SIMS) and Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) data for the preceding three years, UM-KECC identified an additional 10 hospital satellite facilities as likely eligible for the LVPA beyond those already receiving the LVPA in the existing claims data. These 10 additional hospital satellite facilities were included among the projected low-volume eligible facilities in both the impact analyses for the CY 2015 Final Rule and in the last row of Table 5.2.

Low-Volume Facility Designation for CY 2016

For the LVPA that was implemented in the CY 2016 ESRD PPS Final Rule, CMS modified the geographical proximity mileage provision to include commonly owned facilities located within five road miles of a facility in question. As stated in the CY 2016 Final Rule (80 p 68994-69001), low-volume eligibility for a facility was ascertained by aggregating treatments for commonly owned CMS Medicare certified dialysis facilities located within five road miles and under common ownership. In addition, the CY 2016 Final Rule eliminated grandfathering for facilities that opened prior to January 1, 2011 (80 p. 68995). The low-volume size threshold remained at <4,000 treatments for the prior three years in addition to the criterion for organizational stability.

To determine the LVPA for the CY 2016 Final Rule, CMS provided UM-KECC with a list of freestanding facilities that were deemed eligible for the LVPA based on their revised methodology. This list was based on work done by Acumen, another CMS contractor. UM-KECC included a corresponding low-volume facility indicator in both facility-level analyses of the estimated costs for services previously covered under the composite rate system (i.e., CR services) and patient-month level analyses of Medicare Allowable Payments

for those services that were previously separately billable (i.e., SB services). As in Table 5.3, these analyses resulted in an estimated low-volume payment multiplier of 1.239 for the ESRD PPS.

Table 5.3 CY 2016 ESRD Low-Volume Payment Adjustments for Adult Patients

Patient or facility characteristic	% of Medicare dialysis treatments or average	CR Multipliers for CY 2016	SB Multipliers for CY 2016	ESRD PPS Payment Multipliers for CY 2016
Facility low-volume status	1.7%	1.368	0.955	1.239

Background/Motivation: Rural Facility Payment Adjustment

One option that was considered for the CY 2011 ESRD PPS was a payment adjustment for facilities located in rural areas, was a type of adjustment that was authorized by the Medicare Improvements for Patients and Providers Act.(MIPPA). As discussed in the CY 2011 ESRD PPS Final Rule, a separate payment adjustment for rural facilities was not established as part of the initial implementation of the expanded PPS. As one of the determining factors, it was noted that a smaller decrease in payments was projected under the ESRD PPS in CY 2011 for rural facilities than for urban facilities (with an overall 2 percent reduction required by MIPPA), which was due in part to the greater likelihood that rural facilities would be eligible for the low-volume payment adjustment that was being implemented. In addition, the regression analyses that UM-KECC performed for the CY 2011 Final Rule did not indicate that rural facilities have higher costs per treatment for composite rate services that were independent of the higher costs observed for low-volume facilities.

For the CY 2016 ESRD PPS Final Rule, the possibility of a rural payment adjustment was revisited as a way to protect beneficiary access to care in the context of concerns that rural facilities may be experiencing financial difficulties under the ESRD PPS. To inform a decision regarding a potential rural payment adjustment for CY 2016, UM-KECC performed analyses to assess whether treatment costs were higher for rural facilities when accounting for other factors such as facility low-volume status that were being used to adjust payments. UM-KECC also tested whether the increment in costs for low-volume facilities differed for those in rural and urban areas.

Rural Designation

The designation of rural dialysis facilities in analyses performed by UM-KECC for the CY 2016 ESRD PPS Final Rule corresponded to that used in applying wage index adjustments for rural facilities. To have a rural designation, a facility must be located in an area that is not part of a Core-Based Statistical Area (CBSA); the CBSA is a geographical area defined by the Office of Management and Budget (OMB) with a core

socioeconomic center that exceeds a population of 10,000 (https://www.census.gov/geo/reference/gtc/gtc_cbsa.html). Facilities located within a CBSA are designated as urban. To ascertain if a facility is located within a CBSA, the facility postal ZIP code is identified for each freestanding hospital and satellite facility using data from CROWNWeb. On occasion, when facility ZIP code information was missing in CROWNWeb, the Quality Improvement Evaluation System (QIES) was used as a secondary data source. CMS provided a crosswalk that converts ZIP codes to the Federal Information Processing Standard (FIPS) county code. For the FIPS code, the first two digits are the state code and the last three are the county code within the state. CMS provided an additional file that links the FIPS code to CBSA codes and to the corresponding wage index adjustment.

New CBSA delineations began January 1, 2015, with a two-year transition period, as described in the ESRD Final Rule for CY 2015 (FR 79 p. 66123). A complete explanation of the change in CBSAs and the two-year transition period was included in the CY 2015 Final Rule (FR79, p. 66137- 66142). Changes in the wage indices with the new CBSA delineations were also noted for the 100 facilities moving from rural to urban status; for 30 facilities moving from urban to rural status; for facilities in urban areas that changed to new urban CBSAs; and for rural facilities based on new state wage indices.

Rural Payment Adjustment for CY 2016

Using an indicator of rural location that was based on the new CBSA delineations, UM-KECC assessed whether estimated treatment costs for CR and SB services differed between facilities in rural and urban areas. This was accomplished using facility-level analyses of wage-adjusted costs per treatment for CR services and patient-month level analyses of estimated Medicare Allowable Payments per treatment for SB services. These analyses controlled for facility eligibility for the LVPA, patient characteristics used to adjust payments, and facility control variables. These analyses indicated that estimated treatment costs for services covered under the ESRD PPS were 0.8 percent higher for rural facilities. This result corresponded to a rural payment multiplier of 1.008, which was implemented in the CY 2016 ESRD PPS Final Rule (see Table 5.3).

Rural and Low-Volume Facilities

In response to the CY 2016 ESRD PPS proposed rule, which proposed separate payment adjustments based on facility low-volume status and rural location, there were public comments suggesting that these facility characteristics were intertwined and were not independent variables warranting separate adjustments. In analyses that were performed for both the Proposed and Final Rules, there was evidence that the effects of these characteristics may be differentiated. For example, as seen in Table 5.4, while many low-volume facilities (identified using claims pricer return codes) are located in rural areas, only 13.9 percent of rural facilities were considered to be low-volume. With many facilities potentially eligible for one but not both of

the rural and low-volume payment adjustments, there is sufficient information available to determine whether separate adjustments for these characteristics are warranted. Based on facility-level regression analyses for composite rate services, UM-KECC found evidence of statistically independent relationships of both low-volume status and rural location with higher treatment costs.

UM-KECC also tested whether the higher costs observed for low-volume facilities vary based on rural/urban location. This possibility was raised in public comments suggesting that costs associated with low-volume status may be highest for facilities in rural areas. However, past and current research do not support this conclusion. As noted in the methodology section of the UM-KECC 2015 ESRD PPS report (pp. 96-99), prior to implementation of the ESRD expanded-bundle PPS, "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, the increment in costs associated with smaller facility size was found to be relatively similar for facilities in both urban and rural areas. That is, there were similar additional costs being incurred by smaller facilities regardless of whether they were located in urban or rural areas. "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 just because 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).

In preliminary regression analyses that UM-KECC performed for the CY 2016 ESRD PPS Proposed Rule, the inclusion of an interaction term for rural location and low-volume status (based on claims pricer return codes) was not found to have a statistically significant association with CR costs, with an estimated CR multiplier close to 1.00 (see Table 5.5). In other words, the multiplicative effect of low-volume status on costs in rural facilities was comparable to that in urban facilities. Controlling for other potential facility payment variables and control variables, both rural and low-volume designations were, as independent variables, statistically significant and associated with higher costs. The finding that similarly elevated costs were observed for low-volume facilities in rural and urban areas is consistent with earlier work that informed the development of the CY 2011 ESRD PPS. In the CY 2016 ESRD PPS Final Rule, CMS implemented a low-volume payment adjustment that applied to both urban and rural facilities as well as a separate payment adjustment for facilities located in rural areas.

Table 5.4 Low-volume and Rural Designation in 2014 claims data ^

	Low-volume		
Rural	**Yes**	**No**	**Total**
1) Yes	172	1,067	1,239
2) No	222	4,803	5,025
Total	**394**	**5,870**	**6,264**

^ 2014 claims from the December 2014 file with low-volume based on pricer return codes and rural location based on new CBSA designations.

1. 43.7% of low-volume facilities were located in rural areas (172 of 394) using the new CBSA designation, while the remaining 56.3% of low-volume facilities were in urban areas.

2. 13.9% of rural facilities received the LVPA (172 of 1239) while the remaining 86.1% of rural facilities did not receive the LVPA.

Table 5.5 Preliminary (CR) Model with rural and low-volume interaction (freestanding only^, Adj R^2=0.280)

Payment Variables	CR multiplier	Pr > |t|
Age		
18-44	1.2295	<.0001
45-59	1.0811	0.0077
60-69	1.0848	0.0134
70-79	1.0000	--
80+	1.1274	0.002
Body surface area (per 0.1 m^2)	1.0377	<.0001
Time since onset of renal dialysis < 4 months	1.4021	<.0001
Facility low-volume status (based on claims)	1.3654	<.0001
Control Variables		
Facility size - Treatment Count (tmtot)		
<4,000 treatments, not low-volume eligible	1.4578	<.0001
4,000 to 5,000 treatments	1.3096	<.0001
5,000 to 9,999 treatments	1.1374	<.0001
>10,000 treatments (ref)	1.0000	--
Facility ownership		
Large dialysis organization (chain1-chain6)	1.0635	<.0001
Regional chain	1.0953	<.0001
Independent (ref)	1.0000	--
Unknown	1.0867	0.5401
Rural	1.0184	0.0003
Rural * Low-volume	0.9947	0.8436
Year 2012 (reference year)	1.0000	--
Year 2013	1.0243	<.0001
Age less than 18 years	1.8156	0.0002

^ Based on log-linear regression models of the average composite rate cost per treatment from CMS cost reports. Includes n=10,094 dialysis facilities during 2012-2013. Excludes hospital-based facilities. Low-volume based on pricer return codes; rural based on new CBSA designations.

VI. Weighting of Composite Rate and Separately Billable Models

The final payment adjustments for the calendar year (CY) 2016 End-Stage Renal Disease Prospective Payment System (ESRD PPS) were determined using the refined case-mix adjustment models discussed in Section III. These models reflected separate analyses of the estimated costs for services previously covered under the composite rate system (i.e., (CR) services) and for those services that were previously separately billable (i.e., denoted below for simplicity as (SB) services). As discussed in the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) December 2015 report, "Analyses to Inform the Design and Implementation of the End-Stage Renal Disease Prospective Payment System", a two-equation modeling approach was used to establish the payment adjustments for the CY 2011 ESRD PPS. This modeling approach used available facility-level data on composite rate costs and patient-month level data on Medicare Allowable Payments for separately billable services for the CR and SB models, respectively. The results of these two separate models were combined by weighting the estimated payment multipliers for CR and SB services according to their respective proportions of the total estimated costs for services included in the PPS. For the CY 2011 ESRD PPS, the weights were calculated to be 0.6791 for CR services and 0.3209 for SB services based on Medicare cost report and claims data for 2006-08 (ESRD PPS Final Rule, Federal Register 2010).

In refining the payment adjustments for the CY 2016 ESRD PPS, the same approach for weighting the CR and SB multipliers was used. To account for changes in the relative costs of CR and SB services since the CY 2011 ESRD PPS was developed, the CR and SB weights were recalculated using updated data. In particular, the updated weights would account for the substantial declines in the utilization of ESAs and other SB services, which have been observed following the implementation of the ESRD PPS and the FDA-approved label change for ESAs in 2011 (Hirth et al., 2013; Brunelli et al., 2013; Fuller et al., 2013). To the extent that SB services accounted for a smaller share of overall resource use for dialysis-related services due to changes in practice, the relationship of patient and facility characteristics with the estimated costs for SB services would be given less weight in determining the refined payment adjustments for the CY 2016 ESRD PPS.

The average treatment costs for CR and SB services that were used to determine the weighting of the CR and SB models were estimated using the same general approach that was used for the CY 2011 ESRD PPS Final Rule and described in the December 2015 UM-KECC report, "Analyses to Inform the Design and Implementation of the End-Stage Renal Disease Prospective Payment System." As noted in Section III of this report, Medicare prices were applied to the SB utilization amounts reported on claims to estimate SB Medicare Allowable Payments. The updated estimates were based on cost report and claims data for 2012-2013 as the latest available data for determining the relative costs of CR and SB services. Based on cost report data for n=10,094 freestanding and hospital-based facility records for 2012-2013, the average estimated cost

per hemodialysis-equivalent treatment for CR services in 2013 was $208.45. Based on claims data representing n=6,967,110 dialysis patient months during 2012-2013, the average estimated Medicare Allowable Payment per hemodialysis-equivalent treatment for SB services was $49.68. With the CR and SB cost estimates summing to a total estimated average cost of $258.13 per treatment for CR and SB services ($208.45+$49.68), the relative weights were calculated as $Weight_{CR}$=0.8075 for CR services ($208.45/$258.13) and $Weight_{SB}$=0.1925 for SB services ($49.68/$258.13). That is, CR services accounted for 80.8 percent of the total estimated cost of services included in the ESRD PPS, with SB services accounting for the remaining 19.2 percent of the total estimated cost. The updated SB costs and weights were substantially lower than the corresponding estimates used for the CY 2011 ESRD PPS (see Table 6.1).

Table 6.1 Estimated average costs for composite rate and separately billable services

Service category	Average estimated cost per treatment(1)*	Percent of total average cost per treatment(1)	Average estimated cost per treatment(2)*	Percent of total average cost per treatment(2)
Composite rate services	$177.72	67.91%	$208.45	80.75%
Separately billable services	$83.97	32.09%	$49.68	19.25%
Total	$261.69	--	$258.13	--

*For CR services, the average composite rate cost per treatment was calculated using Medicare cost reports for freestanding and hospital-based dialysis facilities. For SB services, the average Medicare Allowable Payment per treatment was calculated using Medicare claims.
(1) CY 2011 ESRD PPS Final Rule (based on 2006-2008 data)
(2) CY 2016 ESRD PPS Final Rule (based on 2012-2013 data)
-- Indicates "not applicable."

The weights in Table 6.1 were then used to calculate the combined payment multipliers for the CY 2016 ESRD PPS as the weighted average of the estimated CR and SB multipliers. For patient and facility characteristics included in the CR and SB models, the combined payment multipliers were calculated as

$$PmtMult_{PPS} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB},$$

where PmtMultCR is the estimated multiplier from the facility year level composite rate model and PmtMultSB is the estimated multiplier from the patient month level SB model, as shown in the first two columns of Table 3 D 2. This is the same approach that was used to calculate the payment multipliers for the CY 2011 ESRD PPS, using updated estimates for both the payment multipliers and the weights. For example, the ESRD PPS payment multiplier for ages 18-44 years was calculated as ((0.8075*1.308)+(0.1925*1.044)) = 1.257. Factors that were not included in either the CR model or SB model were assigned a payment multiplier

of 1.000. For example, for the four patient comorbidities that were included in the SB model but not in the CR model, a value of 1.000 for PmtMultCR was used in the calculation.

As with the CY 2011 ESRD PPS Final Rule, an additional step was needed to determine the low-volume facility payment multiplier so that it would be calculated relative to all other facilities combined. The estimated low- volume coefficients from the CR and SB regression models, which correspond to the CR and SB multipliers of 1.368 and 0.955, respectively, in Table 6.2, were divided by the weighted average of the other facility size coefficients in the models. The weighting procedure described above was then applied in calculating the low- volume payment multiplier of 1.239.

The resulting payment multipliers that were finalized for the CY 2016 ESRD PPS (ESRD PPS Final Rule, Federal Register 2015) are shown in the last column of Table 6.2.

Table 6.2 CY 2016 ESRD PPS Payment Adjustments for Adult Patients

Patient or facility characteristic	% of Medicare dialysis treatments or average	CR Multipliers for CY 2016 ($PmtMult_{CR}$)	SB Multipliers for CY 2016 ($PmtMult_{SB}$)	ESRD PPS Payment Multipliers for CY 2016 ($PmtMult_{PPS}$)
Age				
18-44	12.8%	1.308	1.044	1.257
45-59	27.8%	1.084	1.000	1.068
60-69	25.8%	1.086	1.005	1.070
70-79	21.1%	1.000	1.000	1.000
80+	12.4%	1.145	0.961	1.109
Body surface area (per 0.1 m^2)	1.90	1.039	1.000	1.032
Underweight (BMI < 18.5)	3.3%	1.000	1.090	1.017
Time since onset of renal dialysis < 4 months	4.0%	1.307	1.409	1.327
Facility low-volume status	1.7%	1.368	0.955	1.239
Comorbidities				
Pericarditis (acute)	0.1%	1.000	1.209	1.040
Gastrointestinal tract bleeding (acute)	0.5%	1.000	1.426	1.082
Hereditary hemolytic or sickle cell anemia (chronic)	0.1%	1.000	1.999	1.192
Myelodysplastic syndrome (chronic)	0.3%	1.000	1.494	1.095
Rural	15.0%	1.015	0.978	1.008

VII. Conclusion

The update to the end-stage renal disease prospective payment system (ESRD PPS) that became effective on January 1, 2016, was the most significant since the system's initial implementation on January 1, 2011. Prior to the current revisions, annual updates primarily focused on routine issues such as updating wage indices and outlier thresholds. In addition to those routine updates, the CY 2016 payment year featured a number of significant changes informed by analyses done by UM-KECC and several policy decisions made by the Centers for Medicare & Medicaid Services (CMS).

Most significantly, the updates to the adult payment model (ages 18+years) involved the first re-estimation of the case-mix adjustment model, which resulted in revised payment multipliers. Other changes to the case-mix model included the CMS decision to eliminate two of the six comorbidities (bacterial pneumonia and monoclonal gammopathy) that were included in the original model and the addition of a payment adjustment for rural location. As the original case-mix adjustment model was based on data from 2006-2008, updating the analyses to use data from 2012-2013 would ensure that the payment adjusters reflect any changes in practice that occurred for clinical reasons or due to the change in incentives under the ESRD PPS. Due to the lack of data measuring costs at the individual level, for those services formerly paid for under the Composite Rate (CR) for dialysis, the updated analyses continued to generate payment multipliers on the basis of a weighted average of the multipliers from the facility level CR model and the patient level model for services that were formerly billed on a fee-for-service basis separately from the CR (primarily injectable medications and laboratory tests), where the weights represent the share of total dialysis-related costs from each source. As the use of injectable medications was substantially lower in 2012-2013 than it was in 2006-2008, the weight placed on the formerly separately billable items declined in the 2016 update. As a result, the new weighting and the resulting payment multipliers better reflect practices under the ESRD PPS.

Overall, the characteristics that predicted higher costs in the models based on 2006-2008 data continued to predict higher costs in the models based on 2012-2013 data. While the basic patterns of the relationships largely persisted, the magnitudes of the multipliers changed to some extent. There continued to be a U-shaped relationship between age and cost per treatment, but the lowest cost age group shifted from 60-69 years to 70-79 years , and the extent to which costs were higher for the youngest and oldest age groups (18-44 years and 80+ years) was accentuated in the newer data. Larger patients (proxied by higher body surface area) and frail patients (proxied by low body mass index) continued to have higher costs than smaller and non-frail patients. Recent onset of ESRD (within 4 months) continued to be associated with substantially higher costs, but the relationship was somewhat smaller in the new analyses (the payment multiplier fell from 1.510 to 1.327). Each of the four comorbidities retained by CMS in the payment model continued to predict higher costs, but the payment multipliers associated with the two chronic comorbidities rose while the multipliers

associated with the two acute comorbidities declined compared to their previous values. Additionally, facility low-volume status (facilities that consistently furnish < 4,000 annual treatments) continued to predict higher cost per treatment. CMS made a decision to refine the criteria used to define eligibility for the low-volume adjuster. Previously, a facility otherwise eligible for the low-volume adjuster would lose its eligibility if there were commonly owned facilities within 25 road miles of each other that had a summed volume of treatments exceeding 4,000. Facilities that were in operation prior to the implementation of the ESRD PPS on January 1, 2011, were exempted (grandfathered) from this new requirement. For the CY 2016 payment year, CMS changed the criteria for loss of eligibility by eliminating the grandfathering of older facilities and changing the summed volume test to be greater than 4,000 treatments provided by commonly owned facilities within five road miles of the given facility. Finally, a small rural adjustment (payment multiplier of 1.008) was added to the payment system to reflect slightly higher costs experienced by rural providers independent of low-volume status. Prior analyses of data from 2006-2008 did not indicate that such a relationship existed at that time.

Another important change reflected in the new analyses affects the estimated prevalence of comorbidities. Because comorbidities were rarely reported on dialysis claims prior to the ESRD PPS, the original analyses based on 2006-2008 data had to estimate the prevalence of comorbidities based on diagnoses reported on other types of Medicare claims (e.g., inpatient, physician/supplier). In 2011, actual reporting of comorbidities by dialysis providers for payment adjustment was substantially lower than what would have been expected on the basis of the frequency of diagnoses reported on other types of claims. These lower than expected rates of reporting continued in subsequent years. Therefore, the amount of money held back from the base rate for dialysis in order to fund the comorbidity adjusters consistently exceeded the amount actually paid out for those adjusters. Because the updated analysis is based on diagnoses reported for payment by dialysis facilities rather than diagnoses appearing on other claim types, the reduction in the base rate to fund those adjusters should align much more closely to actual payments for comorbidity adjusters going forward.

Finally, the pediatric case-mix adjustment model was also updated to reflect 2012-2013 data. The same factors remained predictive of differences in costs (age <13 years vs. 13-17 years, and hemodialysis vs. peritoneal dialysis).

In conclusion, the new analyses and policy decisions have served to update the dialysis payment system to reflect recent practices. Such an update should help ensure continued access to care for patients for whom the cost of care is predictably higher and ensure equitable payment to the providers caring for them.

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