

Washington Bulletin

Health care legislative and regulatory update



By Larry Goldberg
Senior adviser for health care
legislative and regulatory matters

July 28, 2010

CMS Releases Final 2011 ESRD PPS Bundled Payment System; Rates to be Budget Neutral at 98 Percent

The Centers for Medicare and Medicaid Services (CMS) have issued a final rule that implements a case-mix adjusted bundled prospective payment system for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011 (ESRD PPS). A [copy](#) of the 923 page rule is available on the *Federal Register* web site. Publication is scheduled for August 12. The ESRD PPS is mandated by the *Medicare Improvements for Patients and Providers Act* (MIPPA).

CMS has also issued a proposed rule regarding an ESRD Quality Incentive Program (QIP). The proposed ESRD QIP would reduce ESRD payments by up to 2.0 percent for dialysis providers and facilities that fail to meet or exceed a total performance score for performance standards established with respect to certain specified measures. The QIP would be effective January 1, 2012. A 60-day comment period ending September 24th is provided. A [copy](#) is available on the *Federal Register* web site.

Comment

CMS has responded in great detail to the numerous comments made on moving to the ESRD PPS. One major result is that many proposed values have been recalculated using newer data and many differ significantly from those originally proposed.

ESRD Base Rate

CMS says the final budget-neutral standardized base rate per dialysis treatment for 2011 will be **\$229.63**. The amount represents a single Medicare payment for all services in the PPS bundle prior to adjustments for case-mix and the wage index, including the former composite rate services and services that were previously separately billable, such as non-routine laboratory services and all ESRD-related Part B drugs and their equivalent forms covered under Part D.

The final budget-neutral standardized base rate was computed as follows: The unadjusted cost per treatment in 2011 was estimated to be \$251.60. This amount was reduced by (a) 5.94 percent to standardize the rate to account for the patient and facility adjustments; (b) 1.0 percent to account for the outlier policy, and (c) 2.0 percent to make projected payments in 2011 equal to 98 percent of the estimated total amount of payments that would have been made in 2011 under the previous payment system.

The ESED PPS replaces the current system which pays facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that are not included in the composite rate.

CMS proposed that payments for injectable Erythropoiesis Stimulating Agents (ESAs), (for example, Epoetin® and ARANESP®) would be included in the calculation of the proposed ESRD PPS base rate. CMS has finalized this aspect as proposed. The rule's Table C in the Appendix identifies the Part B injectable drugs that are included in the in the final base rate.

However, CMS is not including oral-only drugs until January 1, 2014. CMS notes that the drugs, biologicals, and procedures that are excluded from the final ESRD PPS base rate represent a very small dollar amount accounting for less than one cent per dialysis treatment and represent less than 0.2 percent of payments made for separately billable drugs and biologicals.

Other major actions include:

- Creates a home or self-care dialysis training payment adjustment specifically directed to patients trained by facilities certified to provide home dialysis training.
- Finalizes payment adjustments for dialysis treatments furnished to adults for patient age, body surface area, and body mass index, onset of dialysis, and certain co-morbidities, but does not finalize adjustments for the patient's sex or the patient's race or ethnicity.
- Finalizes a payment adjustment for dialysis treatments furnished to pediatric patients, based on patient age and dialysis modality, but not co-morbidities.

Laboratory Tests and Blood and Blood Products

Laboratory tests unrelated to the treatment of ESRD will not be included in the payment bundle. CMS says that certain non-ESRD laboratory tests may be ordered in conjunction with ESRD-related laboratory tests, and has developed billing modifiers to provide for separate payment where the testing is not ESRD-related. The ESRD related laboratory tests that will be subject to the ESRD PPS are identified in the rule's Appendix Table F.

CMS does not consider the furnishing of blood and blood products to be renal dialysis services and, therefore, these services are excluded from the ESRD PPS payment bundle.

Payment for Home Dialysis (Method I and Method II)

Effective January 1, 2011, Medicare will pay the ESRD PPS base rate to ESRD facilities for home dialysis services furnished to home dialysis patients under Method I. Under Method I, the incentives will be different because CMS will only pay the ESRD facility the ESRD PPS base rate which includes the costs of all dialysis services such as staff time, equipment, and supplies.

Method II under the ESRD PPS will be eliminated on January 1, 2011.

Self-Dialysis Training

Currently, Medicare makes a separate payment per treatment for home hemodialysis training and two forms of PD training programs. Home dialysis and self-dialysis can only be performed after an ESRD patient has completed an appropriate course of training. The final rule provides a payment adjustment for dialysis training treatments for home or self dialysis for both hemodialysis and peritoneal dialysis modalities. The ESRD training add-on adjustment will target payments for training to those ESRD facilities that actually conduct training treatments rather than including such training in the base rate for all facilities. A home dialysis training adjustment of \$33.38 will be added on to the per treatment ESRD PPS payment each time training is

conducted. The training adjustment will be adjusted by the geographical wage index based on the location of the ESRD facility. The home or self-dialysis training adjustment is not available, however, during the four-month new patient adjustment for the onset of dialysis.

Transition

The law requires CMS to phase in the new bundled payment system over a four-year period. However, facilities will be given the opportunity to choose to be paid entirely under the new payment system beginning on January 1, 2011.

CMS is requiring that ESRD facilities notify their FI/MACs by November 1, 2010 of their decision to opt out of the ESRD PPS transition.

CMS estimates that 43 percent of ESRD facilities will choose to be excluded from the transition and that 57 percent of ESRD facilities will choose to be paid the blended rate during the transition.

CMS is finalizing a reduction of all payments to ESRD facilities in CY 2011 by a factor that is equal to 1 minus the ratio of the estimated payments under the ESRD PPS were there no transition (that is, 98 percent of total estimated payments that would have been made under the current basic case-mix adjusted payment system) to the total estimated payments under the transition, or 3.1 percent.

For 2011, application of this factor will result in a 3.1 percent reduction in all payments to ESRD facilities, that is, CMS intends to apply this adjustment to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS.

Patient-Level Adjustments

MIPPA requires that the bundled payment system “include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors.”

Age

CMS is implementing payment adjustment factors for the same five age groups as proposed.

Patient Age

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

Patient Sex

CMS is *not* finalizing its proposal to include patient sex as a patient-level case-mix adjustment.

Body Surface Area and Body Mass Index

The case-mix patient-level adjustment for BSA (per 0.1m²) is 1.020 and for low BMI (BMI <18.5) is 1.025 effective for renal dialysis services provided on or after January 1, 2011.

Onset of Dialysis (New Patient Adjustment)

CMS says that the onset of dialysis adjustment is applicable only for those patients 18 years or older, during the first 4 months of the onset of dialysis and will not apply to any patient who might receive renal dialysis services by an ESRD facility for subsequent treatments.

CMS is finalizing an adjustment of 1.510 for in-facility and home dialysis patients eligible for the Medicare ESRD benefit for the first 4 months of the initial onset of dialysis. CMS is finalizing the definition of the onset of dialysis as the date reported on the Form 2728 that dialysis begins through the first 4 months a patient is receiving dialysis.

Co-Morbidities

CMS proposed a number of co-morbidities adjustment factors. CMS is eliminating Hepatitis B as a co-morbidity diagnostic category adjustment. CMS is not finalizing cardiac arrest as a co-morbidity diagnostic category. CMS is also not including all infections as proposed co-morbidities recognized for separate payment in the final ESRD PPS. CMS is not finalizing septicemia as part of the infection Comorbidity diagnostic category. CMS is not finalizing other pneumonias/opportunistic infections as part of the infection co-morbidity category. Therefore, CMS is excluding the diagnoses for primary plague pneumonia, unspecified pneumonia, primary coccidiomycosis unspecified, and rare non-bacterial opportunistic infections.

However, CMS is finalizing bacterial pneumonia as an infection co-morbidity diagnostic category eligible for a payment adjustment under the ESRD PPS. The list of bacterial pneumonia ICD-9-CM codes that will be recognized for a payment adjustment to the ESRD PPS base rate appears in Table E of the rule's Appendix.

CMS will limit the diagnoses to gastrointestinal tract bleeding with hemorrhage and have limited the ICD-9-CM codes for luminal ulcers with associated hemorrhage which will be eligible for a payment adjustment. In addition, in order to receive a co-morbidity payment adjustment for this co-morbidity category there must be documentation of an associated hemorrhage with a gastrointestinal tract bleed.

CMS is *not* finalizing HIV/AIDS and Alcohol/Drug Dependence as co-morbidity diagnostic groups and, therefore, HIV/AIDS and Alcohol/Drug Dependence will not be recognized as co-morbidity diagnostic groups for purposes of the co-morbidity payment adjustment under the ESRD PPS.

CMS is finalizing pericarditis as a Comorbidity diagnostic category recognized for the co-morbidity payment adjustment under the ESRD PPS.

CMS is *not* finalizing cancer as a Comorbidity diagnostic category.

CMS is finalizing its proposed co-morbidity diagnostic categories for chronic, long-term conditions of hereditary hemolytic anemia, myelodysplastic syndromes, and monoclonal gammopathy.

Accordingly, the six co-morbidity diagnostic categories and the associated payment adjustment multipliers are shown in the table below.

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

CMS is finalizing in Table E of the rule's Appendix, the ICD-9-CM codes for the six co-morbidity diagnostic categories which would be recognized for an adjustment to the ESRD PPS base rate.

Race/Ethnicity

CMS is *not* implementing case-mix adjustments under the ESRD PPS for race or ethnicity.

Modality

CMS is finalizing the application of the same base rate payment amount under the ESRD PPs for both Hemodialysis (HD) and Peritoneal dialysis (PD) patients in this final rule.

Facility Level Adjustments

Wage Index Adjustment

CMS will finalize its proposal regarding the use of the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values as proposed. Also, although CMS proposed to eliminate the wage index floor under the ESRD PPS, CMS will continue to apply the wage index floor during the transition to the PPS portion of the ESRD PPS payment in 2011. The wage index values will be based on the most current hospital wage data, prior to application of the rural floor and occupational mix adjustments, and geographic reclassifications. The floor wage index will be 0.6000. CMS says it expects to publish the wage index values in the 2011 Final Physician Fee Schedule Update.

Labor Share

The revised final labor-related share is 41.37 percent.

Low-Volume Adjustment

The Act requires a payment adjustment that "reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent."

CMS is defining low-volume to mean 4,000 or less treatments. The low-volume adjustment treatment threshold only pertains to outpatient dialysis and therefore, the treatments counted do not include inpatient dialysis treatments.

CMS says it will use cost reports to confirm facility status as low-volume and recognizes that there is a lag time from when the facility may no longer be eligible for the low-volume adjustment and when the FI/MAC finalizes the cost report. CMS says additional instructions will be issued.

CMS is finalizing a 18.9 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011.

Pediatric Patients

CMS is adding 4 pediatric adjustments that yield a 10.5 percent payment increase. The following table will adjust the base rate of \$229.63 per treatment, depending upon each pediatric patient's classification cell.

Payment Multipliers for Pediatric Patients Based on Adjustments for Age and Modality Base Rate - \$229.63

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

The low-volume payment adjuster of 1.189 will only be applicable to adult patients, and will not be used in calculating the payment rate per treatment for pediatric dialysis patients.

The training add-on amount of \$33.44 per treatment, subsequently adjusted by the area wage index, is applicable to both adult and pediatric patients.

Outlier Policy

MIPPA requires additional payments to ESRD facilities that treat high-cost patients — patients who use more than the predicted amount of services, including variation in the amount of erythropoietin stimulating agents (ESAs) used to manage dialysis-related anemia.

CMS is finalizing the outlier percentage as 1.0 percent. CMS is reducing the standardized base rate payment amount for all dialysis treatments by 1.0 percent, to fund the 1.0 percent outlier policy under the new ESRD PPS. CMS is setting the fixed dollar loss amount at \$155.44 for adult and \$195.02 for pediatric dialysis patients. Once the fixed dollar loss amount is met, CMS will pay 80 percent of the ESRD facility's outlier service costs. CMS projects that approximately 4.7 percent of adult and 2.2 percent of pediatric patient months will qualify for outlier payments.

Comprehensive Payment Model Examples

The rule contains several very helpful examples on how calculations are made in determining payments.

Implementation

Transition Period

CMS is finalizing its proposed four year transition period for adopting the ESRD PPS. For CY 2011, payments will be based on 75 percent of the payment rate under the basic case-mix adjusted composite payment system and 25 percent of the payment rate under the ESRD PPS. For CY 2012, payment will be based on 50 percent of the payment rate under the basic case-mix adjusted composite payment system and 50 percent of the payment rate under the ESRD PPS. For CY 2013, payment will be based on 25 percent of the basic case-mix adjusted composite payment and 75 percent of the payment rate under the ESRD PPS. For renal dialysis services furnished on or after January 1, 2014, payment to ESRD facilities would be based on 100 percent of the payment amount under the ESRD PPS.

The portion of the blended rate based on the payment amount with regard to the basic case-mix adjusted composite payment system will be comprised of the composite payment rate (which is adjusted by the basic case-mix adjustments and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B by Medicare to entities other than the ESRD facility.

CMS will include a \$0.49 adjustment to the portion of the blended payment amount related to the basic case-mix adjusted composite payment system during the transition to account for the ESRD-related drugs and biologicals (currently separately paid under Part D), but effective January 1, 2011, will be bundled under the ESRD PPS.

ESRD facilities electing to be excluded from the transition will receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011

A new ESRD facility that is certified for Medicare participation on or after January 1, 2011 will be paid at 100 percent of the ESRD PPS rate.

Beneficiary Coinsurance

Under the ESRD PPS, the beneficiary coinsurance amount will be 20 percent of the ESRD PPS bundled payment amount, including applicable case-mix and facility-level adjustments and outlier payments. For those beneficiaries served by facilities that are going through the four-year transition period, the coinsurance would be 20 percent of the blended payment amount. Although clinical laboratory services are not currently subject to coinsurance, laboratory services that are bundled would be subject to the 20 percent coinsurance obligation as part of the bundled set of renal dialysis services under the ESRD PPS. Similarly, drugs being bundled that are currently payable under Medicare's prescription drug program and subject to a separate coinsurance structure, would be subject to the 20 percent coinsurance as part of the set of bundled renal dialysis services under the ESRD PPS.

Quality Improvement Program

In a companion rule, CMS proposes to implement a quality incentive program (QIP) for Medicare outpatient end-stage renal disease (ESRD) dialysis providers and facilities with payment consequences beginning January 1, 2012. The proposed ESRD QIP would reduce ESRD payments by up to 2.0 percent for dialysis providers and facilities that fail to meet or exceed a total performance score for performance standards established with respect to certain specified measures.

CMS is adopting the following three measures for use in the QIP for payment consequence year 2012:

- Hemodialysis Adequacy: Achieved urea reduction ratio (URR) of 65 percent or more; and
- Anemia Management: Controlled anemia, as shown in two measures:
 - the percentage of patients at a facility whose hemoglobin levels were less than 10 grams per deciliter (g/dL), and
 - the percentage of patients at a facility whose hemoglobin levels were greater than 12 g/dL.

Data for these measures are collected from ESRD claims submitted to CMS for payment purposes.

The ESRD QIP is the first Medicare program that links any provider or facility payments to performance based on outcomes as assessed through specific quality measures.

CMS proposes to calculate individual total performance scores ranging from 0-30 points for providers and facilities based on the three finalized measures. CMS proposes to weight the total performance score for each provider/facility such that the percentage of Medicare patients with an average Hemoglobin <10g/dL measure makes up 50 percent of the score, and the other hemoglobin measure and the hemodialysis adequacy measure will each be 25 percent of the score.

CMS proposes that the performance standard for each of the three measures for the initial performance period with respect to 2012 payment would be the lesser of (1) the provider/facility-specific rate for each of these measures in 2007, or (2) the 2008 national average rates for each of these measures.

CMS proposes to select all of CY 2010 as the initial performance period for the three finalized measures. CMS proposes to implement a scoring methodology that subtracts 2 points for every 1 percentage point the provider or facility's performance falls below the initial performance standard. For example, if the initial performance standard for a particular provider or facility for the Hemoglobin More Than 12g/dL is set as the 2008 national average rate (26 percent), then if that provider/facility had 28 percent of Medicare patients with hemoglobin levels greater than 12 g/dL during 2010 (the initial performance period), the provider/facility would receive 6 points for its performance on the measure because 28 percent is 2 percentage points below the performance standard.

The following tables reflect the proposed scoring values.

Proposed Scoring Methodology for Anemia Management Measures using National Average Performance Rates in 2008 as the Performance Standard for 2010 Facility-Specific Comparison

	Percentage of Medicare patients whose average hemoglobin levels are less than 10 g/dL	Percentage of Medicare patients whose average hemoglobin levels are greater than 12 g/dL
POINTS	Percentage	Percentage
10 points	2 percent or less	26 percent or less
8 points	3 percent	27 percent
6 points	4 percent	28 percent
4 points	5 percent	29 percent
2 points	6 percent	30 percent
0 point	7 percent or more	31 percent or more

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

Proposed Scoring Methodology for Anemia Management Measures using Facility-Specific Rates in 2007 as the Performance Standard and 2010 Facility-Specific Rate for Comparison

	Percentage of Medicare patients whose average hemoglobin levels are less than 10 g/dL	Percentage of Medicare patients whose average hemoglobin levels are greater than 12 g/dL
POINTS	Percentage	Percentage
	4 percent (Example of a 2007 facility-specific score)	30 percent (Example of a 2007 facility-specific score)
10 points	4 percent or less	30 percent or less
8 points	5 percent	31 percent
6 points	6 percent	32 percent
4 points	7 percent	33 percent
2 points	8 percent	34 percent
0 points	9 percent or more	35 percent or more

Proposed Scoring Methodology for Hemodialysis Adequacy Measure using National Average Performance Rates in 2008 as the Performance Standard for 2010 Facility-Specific Comparison

POINTS	Hemodialysis Adequacy Measure
	Percentage of Medicare patients whose average URR levels are greater than 65 percent
10 points	96 percent or more
8 points	95 percent
6 points	94 percent
4 points	93 percent
2 points	92 percent
0 points	91 percent or less

Proposed Scoring Methodology for Hemodialysis Adequacy Measure using Facility-Specific Rates in 2007 as the Performance Standard and 2010 Facility-Specific Rate for Comparison

POINTS	Hemodialysis Adequacy Measure
	Percentage of Medicare patients whose URR levels are greater than 65 percent
	92 Percent (Example of a 2007 facility-specific score)
10 points	92 percent or more
8 points	91 percent
6 points	90 percent
4 points	89 percent
2 points	88 percent
0 points	87 percent or less

CMS proposes to weight the Hemoglobin Less Than 10g/dL measure as 50 percent of the total performance score. The remaining 50 percent of the total performance score would be divided equally between the Hemoglobin More Than 12g/dL measure and the Hemodialysis Adequacy Measure. When calculating the total performance score for a provider/facility, CMS would first multiply the score achieved by that provider/facility on each measure (0-10 points) by that measure's assigned weight (.50 or .25). Then CMS would add each of the three numbers together, resulting in a number (although not necessarily an integer) between 0-10. Lastly, this

number would be multiplied by the number of measures (three) and rounded to the nearest integer (if necessary). In rounding, any fractional portion 0.5 or greater would be rounded up to the next integer, while fractional portions less than 0.5 are rounded down. Thus, a score of 27.4 would round to 27, while 27.6 would round to 28.

An example of how the proposed scoring methodology would work follows below.

The example assumes that the performance standard for Facility A during the initial performance period is based on the 2008 national average rates (because Facility A's base utilization year results were higher than the 2008 national average) and that Facility A achieves the following results in 2010:

1. Hemoglobin Less Than 10g/dL: 2 percent.
2. Hemoglobin More Than 12g/dL: 26 percent.
3. Hemodialysis Adequacy: 93 percent.

The total performance score for Facility A would be 26 points. Facility A would receive 10 points for achieving the 2008 national average rate for the Hemoglobin Less Than 10g/dL measure; 10 points for achieving the 2008 national average rate for the Hemoglobin More Than 12g/dL measure; and 4 points for performing 3 percentage points below the 2008 national average rate for the Hemodialysis Adequacy Measure in 2010.

Next, CMS would multiply each individual measure's score by its assigned weight: $10 \times .5 = 5$; $10 \times .25 = 2.5$; $4 \times .25 = 1$. Then, all three scores would be added together and multiplied by three: $(5 + 2.5 + 1) \times 3 = 25.5$. Finally, CMS would round Facility A's score to the nearest whole number, resulting in a total performance score of 26 points

CMS proposes to implement a sliding scale of payment reductions for payment consequence year 2012, where the minimum total performance score that providers/facilities would need to achieve in order to avoid a payment reduction would be 26 points. Providers/facilities that score between 21-25 points would receive a 0.5 percent payment reduction, between 16-20 points a 1.0 percent payment reduction, between 11-15 points a 1.5 percent payment reduction, and between 0-10 points the full 2.0 percent payment reduction. Applying this payment reduction scale to the example of Facility A above, Facility A's total performance score of 26 would result in it receiving no payment reduction.

CMS projects the following reductions resulting from QIP:

Estimated Distribution of CY 2012 ESRD QIP Payment Reductions

Payment Reduction	Number of ESRD Facilities
No Payment Reduction	3,205
0.5% Payment Reduction	709
1.0% Payment Reduction	183
1.5% Payment Reduction	184
2.0% Payment Reduction	30

WashingtonBulletin is published by Grant Thornton LLP. It is not intended to answer specific questions or suggest suitability of action in a particular case. For additional information on the issues discussed in the newsletter, consult your Grant Thornton client-service partner.

The people in the independent firms of Grant Thornton International Ltd provide personalized attention and the highest quality service to public and private clients in more than 100 countries. Grant Thornton LLP is the U.S. member firm of Grant Thornton International Ltd, one of the six global audit, tax and advisory organizations. Grant Thornton International Ltd and its member firms are not a worldwide partnership, as each member firm is a separate and distinct legal entity. In the U.S., visit Grant Thornton LLP at www.GrantThornton.com.