

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



MLN Matters® Number: MM9367 **Revised** Related Change Request (CR) #: CR 9367

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Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) For Calendar Year (CY) 2016

Note: This article was revised on December 18, 2015, to reflect the revised CR9367 issued on December 15. In the article, the transmittal number, CR release date, and the Web address for accessing CR9367 were revised. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for End-Stage Renal Disease (ESRD) facilities submitting claims to Medicare Administrative Contractors (MACs) for ESRD services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9367 implements the CY 2016 rate updates for the ESRD PPS. Please make sure your billing staffs are aware of these changes.

Background

Effective January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the ESRD PPS based on the requirements of Section 1881(b)(14) of the Social Security Act (the Act) as added by Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) and amended by Section 3401(h) of the Affordable Care Act established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The ESRD bundled (ESRDB) market basket increase factor minus the productivity adjustment will

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update the ESRD PPS base rate. Section 217(b)(2) of the Protecting Access to Medicare Act of 2014 (PAMA) included a provision that dictated how the market basket should be reduced for CY 2016.

For CY 2016, in accordance with Section 632(c) of the American Taxpayer Relief Act of 2012 (ATRA), CMS conducted an analysis of the case-mix adjustments being used under the ESRD PPS and finalized revisions. Specifically, CMS updated the two-equation regression used to develop the payment adjustments for the CY 2011 ESRD PPS final rule using CY 2012 and 2013 Medicare cost report and claims data.

In addition to case-mix adjustments, CMS also updated the low-volume payment adjustment and is implementing a rural payment adjustment. ESRD facilities that submit an attestation to their respective MACs prior to the payment year and meet the criteria at [42 CFR 413.232\(b\)](#) are eligible to receive the low-volume payment adjustment.

In accordance with Section 217(c) of the Protecting Access to Medicare Act of 2014 (PAMA), CMS implemented a drug designation process for:

- 1) Determining when a product is no longer an oral-only drug; and
- 2) Including new injectable and intravenous products into the ESRD PPS.

CMS is completing a two-year transition to the updated labor-related share and the most recent Core-Based Statistical Area (CBSA) delineations as described in the February 28, 2013 [Office of Management and Budget \(OMB\) Bulletin No. 13-01](#).

In addition, Section 204 of the Achieving a Better Life Experience Act of 2014, provided that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

The ESRD PPS includes Consolidated Billing (CB) requirements for limited Part B services included in the ESRD facility's bundled payment. CMS periodically updates the list of items and services that are subject to Part B CB and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

Effective January 1, 2016, Healthcare Common Procedure Coding System (HCPCS) Code J0886 (Injection, epoetin alfa, 1000 units (for esrd on dialysis)) will be terminated. All drugs and biologicals used for the treatment of ESRD are the responsibility of the ESRD facility. Practitioners treating Medicare ESRD beneficiaries with erythropoiesis stimulating agents (ESAs) for reasons other than the beneficiary's ESRD must use the appropriate HCPCS code. Specifically, practitioners should use HCPCS code J0885 (Injection, epoetin alfa, (for non-esrd use), 1000 units).

CY 2016 ESRD PPS Updates – ESRD PPS Base Rate:

- A 0.15 percent update to the CY 2015 payment rate. ($\$239.43 \times 1.0015 = \239.79)
- A wage index budget-neutrality adjustment factor of 1.000495.
- A refinement budget-neutrality adjustment factor of 0.960319. Therefore, the CY 2016 ESRD PPS base rate is $\$230.39$ ($\$239.43 \times 1.0015 \times 0.960319 = \230.39).

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Wage Index:

- The wage index adjustment will be updated to reflect the latest available wage data.
- The most recent OMB CBSA delineations is fully implemented; therefore, CMS is no longer transitioning the wage index and use of the special wage indicator is no longer necessary for those ESRD facilities that experienced a change in CBSA.
- The wage index floor will remain at 0.4000.

Labor-related Share:

The revised labor-related share of 50.673 is fully implemented.

Update to the Patient-Level and Facility-Level Payment Adjustments:

For the CY 2016 ESRD PPS refinement, CMS is changing the adjustment payment amounts to reflect the updated regression analysis that was completed using CY 2012 and 2013 ESRD claims and cost report data for adult and pediatric patients.

In addition, for adult beneficiaries, CMS has removed two comorbidity categories (bacterial pneumonia and monoclonal gammopathy) from being eligible for a payment adjustment and is implementing a rural payment adjustment for those ESRD facilities that are located in a rural CBSA (that is, a non-urban CBSA).

The patient-level and facility-level payment adjustments are available in Tables 1 (adult) and 2 (pediatric) below.

Table 1: Adult ESRD Beneficiaries

Variable	Separately Billable Multipliers for PY 2016	Expanded Bundle Multipliers for PY 2016
Age		
18-44	1.044	1.257
45-59	1.000	1.068
60-69	1.005	1.070
70-79	1.000	1.000
80+	0.961	1.109
Body surface area (per 0.1 m ²)	1.000	1.032
Underweight (BMI < 18.5)	1.090	1.017
Time since onset of renal dialysis < 4 months	1.409	1.327

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Variable	Separately Billable Multipliers for PY 2016	Expanded Bundle Multipliers for PY 2016
Facility low volume status	0.955	1.239
Comorbidities		
Pericarditis (acute)	1.209	1.040
Gastro-intestinal tract bleeding (acute)	1.426	1.082
Hereditary hemolytic or sickle cell anemia (chronic)	1.999	1.192
Myelodysplastic syndrome (chronic)	1.494	1.095
Rural	0.978	1.008

Table 2: Pediatric ESRD Beneficiaries

Cell	Patient Characteristics		PY 2016 Final Rule	
	Age	Modality	Separately Billable Multipliers	Expanded Bundle Multipliers
1	<13	PD	0.410	1.063
2	<13	HD	1.406	1.306
3	13-17	PD	0.569	1.102
4	13-17	HD	1.494	1.327

Outlier Policy:

As a result of the CY 2016 ESRD PPS refinement, CMS is also changing the adjusters used for determining the Medicare Allowable Payment (MAP) amount in the outlier calculation. These values are available in Tables 1 and 2 above in the separately billable multipliers column.

CMS made the following updates to the adjusted average outlier service MAP amount per treatment:

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1. For adult patients, the adjusted average outlier service MAP amount per treatment is \$50.81.
2. For pediatric patients, the adjusted average outlier service MAP amount per treatment is \$39.20.

CMS made the following updates to the fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold:

1. The fixed dollar loss amount is \$86.97 for adult patients.
2. The fixed dollar loss amount is \$62.19 for pediatric patients.

CMS made the following changes to the list of outlier services:

1. Renal dialysis drugs that are oral equivalents to injectable drugs are based on the most recent prices retrieved from the Medicare Prescription Drug Plan Finder, are updated to reflect the most recent mean unit cost. In addition, CMS will add or remove any renal dialysis items and services that are eligible for outlier payment. See Attachment B of [CR9367](#).
2. The mean dispensing fee of the National Drug Codes (NDC) qualifying for outlier consideration is revised to \$0.97 per NDC per month for claims with dates of service on or after January 1, 2016. See Attachment B of [CR9367](#).

Consolidated Billing Requirements:

1. The consolidated billing requirements for drugs and biologicals included in the ESRD PPS is updated by:
 - a. Removing Current Procedural Terminology code 80061 (Lipid Panel) as it has been determined that this laboratory test is routinely furnished for reasons other than for the treatment of ESRD. Therefore, for dates of service on or after January 1, 2016, the Lipid Panel is no longer subject to the ESRD PPS consolidated billing requirements.
 - b. Removing HCPCS J0886 injection, epoetin alfa, 1000 units (for esrd on dialysis) since the code will be terminated effective December 31, 2015.
 - c. Removing HCPCS Q9976 – Injection, Ferric Pyrophosphate Citrate Solution; 0.1 mg of iron since this code will be terminated effective December 31, 2015.
 - d. Adding HCPCS J1443 - Injection, Ferric Pyrophosphate Citrate Solution; 0.1 mg of iron since this code will be replacing Q9976 and is effective January 1, 2016.
 - i. J1443 is a drug that is used for anemia management. Anemia management is an ESRD PPS functional category where drugs and biologicals that fall in this category are always considered to be used for the treatment of ESRD. ESRD facilities will not receive separate payment for J1443 with or without the AY modifier and the claims shall process the line item as covered with no separate payment under the ESRD PPS.

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- ii. J1443 is administered via dialysate. Therefore, when billing for J1443, it should be accompanied by the JE modifier as discussed in CR 8256 issued April 26, 2013.
- iii. In accordance with 42 CFR 413.237(a)(1), HCPCS J1443 is considered to be eligible outlier services and will be included in the outlier calculation when CMS provides a fee amount on the Average Sales Price fee schedule.

Attachment C of [CR9367](#) reflects the items and services that are subject to the ESRD PPS consolidated billing requirements.

Additional Information

The official instruction, CR9367 issued to your MAC regarding this change is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R214BP.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

Document History

Date	Description
December 18, 2015	This article was revised on December 18, 2015, to reflect the revised CR9352 issued on December 15, 2015. In the article, the transmittal number, CR release date, and the Web address for accessing CR9367 were revised.

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