



The Centers for Medicare & Medicaid Services (CMS) recently issued a final rule that will change how Medicare pays for dialysis services for Medicare beneficiaries who have end-stage renal disease (ESRD). CMS also issued a proposed rule that would establish a new quality incentive program (QIP) to promote high quality services in dialysis facilities by linking a facility's payments to performance standards. The QIP is the first pay-for-performance program in a Medicare fee-for-service payment system. For additional information please see the CMS Fact sheet (7/26) at http://www.cms.gov/apps/media/fact_sheets.asp on the CMS website.

MLN Matters® Number: MM7064

Related Change Request (CR) #: 7064

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Implementation Date: January 3, 2011

End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services

Note: This article was revised on December 5, 2014, to add a reference to MLN Matters® article MM8898 available at (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8898.pdf>) that alerts providers to the clarification of two criteria required for the validation of the ESRD PPS low volume payment adjustment (LVPA). These are the criteria related to: (1) the treatment count requirements for hospital-based ESRD facilities using cost report data and other supporting documents, and (2) when a change of ownership for any ESRD facility does not result in a new provider access transaction number (PTAN) but does result in a new cost reporting period. All other information remains the same.

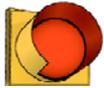
Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, DME Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), and/or A/B Medicare Administrative Contractors (A/B MACs)) for ESRD services provided to Medicare beneficiaries.

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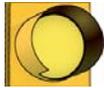
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Provider Action Needed



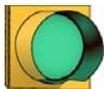
STOP – Impact to You

This article is based on Change Request (CR) 7064 which announces the implementation of an End Stage Renal Disease (ESRD) bundled prospective payment system (PPS) effective January 1, 2011.



CAUTION – What You Need to Know

Once implemented, the ESRD PPS will replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD related items and services. The ESRD PPS will provide a single payment to ESRD facilities, i.e., hospital-based providers of services and renal dialysis facilities, that will cover all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, training, and support services. The ESRD PPS provides ESRD facilities a 4-year phase-in (transition) period under which they would receive a blend of the current payment methodology and the new ESRD PPS payment. In 2014, the payments will be based 100 percent on the ESRD PPS payment.



GO – What You Need to Do

Since the ESRD PPS is effective for services on or after January 1, 2011, it is important that providers not submit claims spanning dates of service in 2010 and 2011. ESRD facilities have the opportunity to make a one time election to be excluded from the transition period and have their payment based entirely on the payment amount under the ESRD PPS as of January 1, 2011. Facilities wishing to exercise this option must do so on or before November 1, 2010. See the Background and Additional Information Sections of this article for further details regarding the ESRD PPS.

Background

The Medicare Improvements for Patients and Providers Act (MIPPA); Section 153(b); see <http://www.govtrack.us/congress/billtext.xpd?bill=h110-6331> on the Internet) requires the Centers for Medicare & Medicaid services (CMS) to implement an End Stage Renal Disease (ESRD) bundled prospective payment system (PPS) effective January 1, 2011. Once implemented, the ESRD PPS will replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD related items and services.

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Specifically, the ESRD PPS combines payments for composite rate and separately billable services into a single base rate. The per dialysis treatment base rate for adult patients is subsequently adjusted to reflect differences in:

- Wage levels among the areas in which ESRD facilities are located;
- Patient-level adjustments for case-mix;
- An outlier adjustment (if applicable);
- Facility-level adjustments;
- A training add-on (if applicable); and
- A budget neutrality adjustment during the transition period through 2013.

Patient-level Adjustments

The patient-level adjustments are patient-specific case-mix adjusters that were developed from a two-equation regression analysis that encompasses composite rate and separately billable items and services. Included in the case-mix adjusters for adults are those variables that are currently used in basic case-mix adjusted composite payment system, that is, age, body surface area (BSA), and low body mass index (BMI). In addition to those adjusters that are currently used, the ESRD PPS will also incorporate adjustments for six co-morbidity categories and an adjustment for the onset of renal dialysis.

Outlier Adjustment

ESRD facilities that are treating patients with unusually high resource requirements, as measured through their utilization of identified services beyond a specified threshold, will be entitled to outlier payments. Such payments are an additional payment beyond the otherwise applicable case-mix adjusted prospective payment amount.

ESRD outlier services are the following items and services that are included in the ESRD PPS bundle:

1. ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
2. ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
3. Medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and
4. Renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, notwithstanding the delayed implementation of ESRD-related oral-only drugs effective January 1, 2014.

Note: Services not included in the PPS that remain separately payable, including blood and blood processing, preventive vaccines, and telehealth services, are not considered outlier services.

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Facility-level Adjustments

The facility-level adjustments include adjusters to reflect urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs). The facility-level adjustments also include an adjuster for facilities treating a low-volume of dialysis treatments.

Training Add-On

Facilities that are certified to furnish training services will receive a **training add-on payment amount of \$33.44**, which is adjusted by the geographic area wage index to account for an hour of nursing time for each training treatment that is furnished. The training add-on applies to both peritoneal dialysis (PD) and hemodialysis (HD) training treatments.

Adjustments Specific to Pediatric Patients

The pediatric model incorporates separate adjusters based on two age groups (<13, 13-17) and dialysis modality (hemodialysis, peritoneal dialysis). The per-treatment base rate as it applies to pediatric patients is the same base rate that applies for adult patients, which is also adjusted by the area wage index. However, due to the lack of statistical robustness, the base rate for pediatric patients is not adjusted by the same patient-level case-mix adjusters as for adult patients. Instead, the pediatric payment adjusters reflect the higher total payments for pediatric composite rate and separately billable services, compared to that of adult patients.

Treatments furnished to pediatric patients:

- Can qualify for a training add-on payment (when applicable), and
- Are eligible for an outlier adjustment.

Note: Pediatric dialysis treatments are not eligible for the low-volume adjustment.

ESRD PPS 4-year Phase-in (Transition) Period

The ESRD PPS provides ESRD facilities with a 4-year transition period under which they would receive a blend of payments under the prior case-mix adjusted composite payment system and the new ESRD PPS as noted in the following table:

The ESRD PPS 4-year Transition Period Blended Rate Determination

Calendar Year	Blended Rate
2011	75 percent of the old payment methodology, and 25 percent of new PPS payment
2012	50 percent of the old payment methodology, and 50 percent of the new PPS payment

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Calendar Year	Blended Rate
2013	25 percent of the old payment methodology, and 75 percent of the new PPS payment
2014	100 percent of the PPS payment

For Calendar Year (CY) 2011, CMS will continue to update the basic case-mix composite payment system for purposes of determining the composite rate portion of the blended payment amount. CMS updated the composite payment rate, the drug add-on adjustment to the composite rate, the wage index adjustment, and the budget neutrality adjustment.

The **ESRD PPS base rate is \$229.63**, which is applicable for both adult and pediatric ESRD patients effective January 1, 2011. This base rate will be wage adjusted as mentioned above where

- The labor-related share of the base rate from the ESRD PPS market basket is 0.41737, and
- The non labor-related share of the base rate is \$133.79 ($(229.63 \times (1 - 0.41737)) = \133.79).

During the transition, the labor-related share of the case-mix adjusted composite payment system will remain 0.53711.

The payment rate for a dialysis treatment is determined by wage adjusting the base rate and then applying any applicable:

- Patient-level adjustments;
- Outlier adjustments;
- Facility-level adjustments; and
- Training add-on payments (adjusted for area wage levels)

Once the payment rate for the dialysis treatment is determined, the last item in the computation to determine the final payment rate is the application of the transition budget neutrality factor of .969, that is, a 3.1 percent reduction.

The ESRD PRICER will provide the payment for existing composite rate, the new ESRD PPS payment rate, and the outlier payment (when applicable). These reimbursement amounts must be blended during a transition period for all ESRD facilities except those facilities opting out of the transition and electing to be paid 100 percent of the payment amount under the new ESRD PPS.

Note: Providers wishing to opt out of the transition period blended rate must notify their Medicare Contractor on or before November 1, 2010. Providers shall not submit claims spanning date of service in 2010 and 2011.

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Three New Adjustments Applicable to the Adult Rate

- 1. Comorbid Adjustments:** The new ESRD PPS provides for **3 categories of chronic comorbid conditions** and **3 categories for acute comorbid conditions**. A single adjustment will be made to claims containing one or more of the comorbid conditions. The highest comorbid adjustment applicable will be applied to the claim. The acute comorbid adjustment may be paid no greater than 4 consecutive months for any reported acute comorbid condition, unless there is a reoccurrence of the condition. **The 3 chronic comorbid categories** eligible for a payment adjustment are:
 - Hereditary hemolytic and sickle cell anemia;
 - Monoclonal gammopathy (in the absence of multiple myeloma); and
 - Myelodysplastic syndrome.The **3 acute comorbid categories** eligible for a payment adjustment are:
 - Bacterial Pneumonia;
 - Gastrointestinal Bleeding; and
 - Pericarditis.
- 2. Onset of Dialysis Adjustment:** An adjustment will be made for patients that have Medicare ESRD coverage during their first 4 months of dialysis. This adjustment will be determined by the dialysis start date in Medicare's Common Working File as provided on the CMS Form 2728, completed by the provider. When the onset of dialysis adjustment is provided, the claim is not entitled to a comorbid adjustment or a training adjustment.
- 3. Low-Volume Facility Adjustment:** Providers will receive an adjustment to their ESRD PPS rate when the facility furnished less than 4,000 treatments in each of the three cost report years preceding the payment year and has not opened, closed, or received a new provider number due to a change in ownership during the three (3) years preceding the payment year. The provider must notify their Medicare Contractor if they believe they are eligible for the low-volume adjustment.

Change in Processing Home Dialysis Claims

For claims with dates of service on or after January 1, 2011, the payment of home dialysis items and services furnished under Method II, regardless of home treatment modality, are included in the ESRD PPS payment rate.

Therefore, all home dialysis claims:

- Must be submitted by a renal dialysis facility and
- Will be processed as Method I claims.

Note: CR 7064 instructs the DME MACs to stop separate payment to suppliers for Method II home dialysis items and services for claims with dates of service on or after January 1, 2011. Medicare will, however, allow separate billing for ESRD supply HCPCS codes (as shown on attachment 4 of CR 7064) by DME suppliers when submitted for services not related to the beneficiary's ESRD dialysis treatment and such services are billed with the AY modifier.

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Consolidated Billing

CR 7064 provides an ESRD consolidated billing requirement for limited Part B services included in the ESRD facility bundled payment. Certain laboratory services and limited drugs and supplies will be subject to Part B consolidated billing and will no longer be separately payable when provided for ESRD beneficiaries by providers other than the renal dialysis facility. Should these lab services, and limited drugs be provided to a beneficiary, but are not related to the treatment for ESRD, the claim lines must be submitted by the laboratory supplier or other provider with the new AY modifier to allow for separate payment outside of ESRD PPS. ESRD facilities billing for any labs or drugs will be considered part of the bundled PPS payment unless billed with the modifier AY. In addition, as noted above, Medicare will, however, allow separate billing for ESRD supply HCPCS codes (as shown on attachment 4 of CR 7064) by DME suppliers when submitted for services not related to the beneficiary's ESRD dialysis treatment and such services are billed with the AY modifier.

Other Billing Reminders

- Note that with the ESRD PPS changes, Medicare systems will also reject any lines reporting revenue code 0880 as of January 1, 2011. These rejections will be made with remittance advice remark code (RARC) M81 (You are required to code to the highest level of specificity), and assign a group code of CO (provider liability) to such lines.
- Medicare will return claims to the provider with dates of service spanning 2010 and 2011.
- Telehealth services billed with HCPCS Q3014, preventive services covered by Medicare, and blood and blood services are exempt from the ESRD PPS and will be paid based on existing payment methodologies.
- When claims are received without the AY modifier for items and services that are not separately payable due to the ESRD PPS consolidated billing process, the claims will be returned with claim adjustment reason code (CARC) 109 (Claim not covered by this payer/contractor. You must send the claim to the correct payer/contractor.), RARC N538 (A facility is responsible for payment to outside providers who furnish these services/supplies/drugs to its patients/residents.), and assign Group code CO.
- All 72X claims from Method II facilities with condition code 74 will be treated as Method I claims as of January 1, 2011. Effective that same date, Medicare will no longer enter Method selection forms data into its systems.
- Services included in the existing composite rate continue to not be reported on the claim unless they are clinical lab services subject to the 50/50 rule. The only additional data that must be reported on or after January 1, 2011 are any oral and other equivalent forms of injectable drugs identified as outlier services. Oral and

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- other equivalent forms of injectable drugs should be reported with the revenue code 0250. The drug NDC code must be reported with quantity field reflecting the smallest available unit.
- Payment for ESRD-related Aranesp and ESRD-related Epoetin Alfa (EPO) is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.
 - Effective January 1, 2011, section 153b of the MIPPA requires that all ESRD-related drugs and biologicals are included in the ESRD PPS and must be billed by the renal dialysis facility.

Additional Information

The official instruction, CR 7064, issued to your carriers, DME MACs, FIs and/or A/B MACs regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf> on the CMS website. Attached to CR 7064, you may find the following documents to be helpful:

- Attachment 3, which is a list of outlier services;
- Attachment 4, which is a list of DME ESRD Supply HCPCS codes used in for ESRD PPS consolidated billing edits;
- Attachment 5, which contains a list of DME ESRD Supply HCPCS codes that are NOT payable to DME suppliers;
- Attachment 6, which is a list of laboratory CPT/HCPCS codes subject to ESRD consolidated billing;
- Attachment 7, which lists the drug codes subject to ESRD consolidated billing; and
- Attachment 8, which lists by ICD-9-CM codes, the comorbid categories and diagnosis codes.

Also see MM7388 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7388.pdf>) for the criteria for a low volume facility and instructions on how to receive the ESRD low volume adjustment for low volume facilities.

You may also want to review the following articles:

- MLN Matters® article MM7476 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7476.pdf>), which alerts providers to changes to Attachments 4, 5 and 8 of CR7064; and
- MM7497 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7497.pdf>), which informs independent

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laboratories (ILs) that effective January 1, 2012, CMS has eliminated the requirement for ILs to bill separately for each individual AMCC laboratory test included in organ disease panel codes for ESRD eligible beneficiaries. It states that organ disease panels will be paid under the Clinical Laboratory Fee Schedule and will not be subject to the 50/50 rule when billed by ILs.

You may want to review MM7869 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7869.pdf>) which alerts providers that, beginning January 1, 2013, ESRD facilities can receive separate payment for Daptomycin injections (J0878). The facility must indicate the diagnosis code for which Daptomycin is indicated.

If you have any questions, please contact your carriers, DME MACs, FIs, and/or A/B MACs at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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