CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal: 2281	**Date: August 19, 2011**
	Change Request 7471

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 3, 2011. The Transmittal Number, Date Issued and all other information remain the same. This instruction may now be posted to Internet.

SUBJECT: Implementation of Changes to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Outlier Payment Policy and Changes to the ESRD PPS Consolidated Billing Requirements for Laboratory Services Furnished in a Hospital Emergency Room or Department

I. SUMMARY OF CHANGES: Revisions to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) outlier services and a consolidated billing bypass for laboratory services billed with an emergency room service.

EFFECTIVE DATE: January 1, 2012
IMPLEMENTATION DATE: January 3, 2012

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	8 / 50.1.5/Lab Services Included in the Prospective Payment System
N	8 / 50.1.6/Laboratory Services Performed During Emergency Room Service
N	8 / 50.2.5/Drugs and Biologicals Included in the PPS
D	8/50.15/Laboratory Services Included in the ESRD PPS
D	8/50.25/Drugs and Biologicals Included in the ESRD PPS

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Business Requirements

Pub. 100-04	Transmittal: 2281	Date: August 19, 2011	Change Request: 7471

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SUBJECT: Implementation of Changes to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Outlier Payment Policy and Changes to the ESRD PPS Consolidated Billing Requirements for Laboratory Services Furnished in a Hospital Emergency Room or Department

Effective Date: January 1, 2012

Implementation Date: January 3, 2012

I. GENERAL INFORMATION

A. Background: Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) amends section 1881(b)(12) of the Act by requiring the implementation of an End Stage Renal Disease (ESRD) bundled prospective payment system (PPS) effective January 1, 2011. Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care. Medicare regulation §413.237(a)(1) provides that ESRD outlier services are those ESRD-related services that were or would have been considered separately billable under Medicare Part B, or would have been separately payable drugs under Medicare Part D (excluding ESRD-related oral-only drugs), for renal dialysis services furnished prior to January 1, 2011. Change Request (CR) 7064, Transmittal 2134, entitled "End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services" implemented the ESRD PPS.

In addition, CR 7064 provided ESRD consolidated billing requirements for limited Part B services included in the ESRD facility bundled payment. CR 7064 instructed contractors that certain renal dialysis services are subject to Part B consolidated billing and are no longer separately payable when provided to ESRD beneficiaries by providers other than the ESRD facilities. Included in the consolidated billing requirements are edits for ESRD related laboratory services (ESRD-related laboratory services can be found on attachment 6 of CR 7064). All outpatient claims are subject to these edits.

B. Policy: Subsequent to the publication of the ESRD PPS final rule, we have concluded that any CMS prepared lists of drugs and biologicals recognized as outlier services may be difficult to keep up-to-date. Because of the number of Part B drugs and biologicals that may be considered ESRD-related eligible outlier service drugs, effective January 1, 2012, CMS is eliminating the issuance of a list of former Part B drugs and biologicals that would be eligible for outlier payments. As a result, all ESRD-related Part B drugs and biologicals reported with a Healthcare Common Procedure Coding System (HCPCS) code that is on the Average Sales Price List will be included for outlier payments (with the exception of composite rate drugs).

In an emergency room or emergency department, diagnostic laboratory testing is ordered according to the illness the patient is presenting, and it may not be feasible for the ordering physician to know at the time the laboratory test is being ordered if it is being ordered for reasons of treating the patient's ESRD. Emergency rooms or emergency departments will not be required to append an AY modifier to these laboratory tests when submitting claims with dates of service on or after January 1, 2012. Allowing laboratory testing to bypass consolidated billing edits in the emergency room or department does not mean that ESRD facilities should send

patients to the emergency room or department for routine laboratory testing or for the provision of renal dialysis services that should be provided by ESRD facilities.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7471.1	For 72x bill type with dates of service on or after January 1, 2012, Medicare contractors shall apply to the value code 79 for outlier consideration, all drugs reported on a covered line item with revenue codes 0634, 0635 and 0636 and a HCPCS with a rate available on the ASP pricing file when the modifier AY is not present on the line.						X				
7471.1.1	Deductible and coinsurance shall not be taken from the ASP drug payment amounts being added to the value code 79 for outlier consideration.						X				
7471.2	Medicare systems shall bypass the ESRD PPS consolidated billing edit for labs on hospital claims (13x and 85x) when the hospital claim contains a 045x revenue code.						X			X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7471.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X							

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
7471.1	A revised ESRD PRICER will be issued for testing this instruction with the annual Recurring ESRD PPS Update issued for January 2012.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Claims Processing Wendy.Tucker@cms.hhs.gov 410-786-3004, Policy Michelle.Cruse@cms.hhs.gov 410-786-7540.

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual

Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

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(Rev.2281, Issued: 08-19-11)

50.1.5 - Laboratory Services Included in the ESRD PPS

(Rev. 2281, Issued: 08-19-11, Effective: 01-01-12, Implementation: 01-03-12)

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.

If the renal dialysis facility needs to report a lab service that was not related to the treatment of ESRD, they must include the modifier AY to indicate the item or service is not for the treatment of ESRD.

ESRD-related lab services that were separately paid under the basic case-mix composite rate payment system are considered in the calculation of any applicable outlier payment under the ESRD PPS.

50.1.6 - Laboratory Services Performed During Emergency Room Service

(Rev. 2281, Issued: 08-19-11, Effective: 01-01-12, Implementation: 01-03-12)

For claims with dates of service on or after January 1, 2012, the consolidated billing edit for laboratory services will be bypassed when billed in conjunction with an emergency room service on a hospital outpatient claim and the AY modifier will not be necessary. Allowing laboratory testing to bypass consolidated billing edits in the emergency room or department does not mean that ESRD facilities should send patients to the emergency room or department for routine laboratory testing or for the provision of renal dialysis services that should be provided by ESRD facilities. The intent of the bypass is to acknowledge that there are emergency circumstances where the reason for the patient's illness is unknown and the determination of a laboratory test as being ESRD-related is not known.

50.2.5 - Drugs and Biologicals Included in the ESRD PPS

(Rev. 2281, Issued: 08-19-11, Effective: 01-01-12, Implementation: 01-03-12)

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related injectable drugs and biologicals and oral equivalents of those injectable drugs and biologicals are included in the ESRD PPS.

If the renal dialysis facility needs to report a drug that was furnished to an ESRD beneficiary that was not related to the treatment of ESRD, they must include the modifier AY to indicate the item or service is not for the treatment of ESRD.

ESRD-related drugs and biologicals that were separately paid under the basic case-mix composite rate payment system are considered in the calculation of any applicable outlier payment under the ESRD PPS.