CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2688	**Date: April 26, 2013**
	Change Request 8256

SUBJECT: Reporting End Stage Renal Disease (ESRD) Drugs Administered Through the Dialysate

I. SUMMARY OF CHANGES: This instruction requires ESRD facilities to append a new modifier, JE (Administered via Dialysate) to all ESRD claims where drugs and biologicals are furnished to ESRD beneficiaries via the dialysate solution for claims with dates of service on or after July 1, 2013.

EFFECTIVE DATE: July 1, 2013
IMPLEMENTATION DATE: July 1, 2013

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
R	8/50.3/Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS
R	8/60.2.1.1/Separately Billable ESRD Drugs
R	8/60.4.2/Facility Billing Requirements for ESAs

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 obliged 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: 2688	Date: April 26, 2013	Change Request: 8256

SUBJECT: Reporting End Stage Renal Disease (ESRD) Drugs Administered Through the Dialysate

EFFECTIVE DATE: July 1, 2013

IMPLEMENTATION DATE: July 1, 2013

I. GENERAL INFORMATION

A. Background: This Change Request (CR) requires the use of a new modifier JE defined as Administered via Dialysate and provides supporting instructions for ESRD facilities and FIs or A/B MACs to identify when an ESRD facility furnishes ESRD-related injectable drugs and biologicals to a Medicare beneficiary via the dialysate. Dialysate can be compounded with injectable drugs and biologicals as a way to administer the drug or biological.

Medicare believes that this route of administration (ROA) modifier would prevent inappropriate application of the AY modifier (item or service furnished to an ESRD patient that is not for the treatment of ESRD) because CMS believes that there is confusion in the industry whether a drug or biological is considered ESRD-related when it is added to the dialysate. This modifier would also provide Medicare the ability to monitor which drugs and biologicals are being furnished through the dialysate which would provide us with data that could be used in future refinements of the ESRD PPS.

B. Policy: ESRD facilities shall append the modifier JE to all ESRD claim line items reporting drugs and biologicals that are furnished to ESRD beneficiaries via the dialysate solution for dates of service on or after July 1, 2013. All drugs and biologicals that are furnished to ESRD beneficiaries for the treatment of ESRD are paid under the ESRD PPS base rate regardless of the method of administration. ESRD facilities will continue to have the ability to append the AY modifier when the drug or biological is furnished for reasons other than the treatment of ESRD with the exception of those drugs that are considered to always be ESRD-related. Please go to the CMS website for the list of drugs and biologicals that are included in the ESRD PPS consolidated billing requirements: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8256.1	Medicare contractors shall be aware of the requirement of ESRD facilities to report the route of administration modfier JE when billing for drugs or biologicals administered through the dialysate for claims with	X			X							

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
	dates of service on or after July 1, 2013.											

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Other
		Part A	Part B					
8256.2	MLN Article : 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 sites 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 the contractor's 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.							

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wendy Tucker, wendy.tucker@cms.hhs.gov

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

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 do 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.

50.3 - Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS

(Rev.2688, Issued: 04-26-13, Effective: 07-01-13, Implementation: 07-01-13)

The electronic form required for billing ESRD claims is the ANSI X12N 837 Institutional claim transaction. Since the data structure of the 837 transaction is difficult to express in narrative form and to provide assistance to small providers excepted from the electronic claim requirement, the instructions below are given relative to the UB-04 (Form CMS-1450) hardcopy form. A table to crosswalk UB-04 form locators to the 837 transaction is found in Chapter 25, §100.

Type of Bill

Acceptable codes for Medicare are:

721 - Admit Through Discharge Claim - This code is used for a bill encompassing an entire course of outpatient treatment for which the provider expects payment from the payer.

722 - Interim - First Claim - This code is used for the first of an expected series of payment bills for the same course of treatment.

723 - Interim - Continuing Claim - This code is used when a payment bill for the same course of treatment is submitted and further bills are expected to be submitted later.

724 - Interim - Last Claim - This code is used for a payment bill which is the last of a series for this course of treatment. The “Through” date of this bill (FL 6) is the discharge date for this course of treatment.

727 - Replacement of Prior Claim - This code is used when the provider wants to correct (other than late charges) a previously submitted bill. The previously submitted bill needs to be resubmitted in its entirety, changing only the items that need correction. This is the code used for the corrected or “new” bill.

728 - Void/Cancel of a Prior Claim - This code indicates this bill is a cancel-only adjustment of an incorrect bill previously submitted. Cancel-only adjustments should be used only in cases of incorrect provider identification numbers, incorrect HICNs, duplicate payments and some OIG recoveries. For incorrect provider numbers or HICNs, a corrected bill is also submitted using a code 721.

Statement Covers Period (From-Through) - Hospital-based and independent renal dialysis facilities:

The beginning and ending service dates of the period included on this bill. Note: ESRD services are subject to the monthly billing requirements for repetitive services.

Condition Codes

Hospital-based and independent renal facilities complete these items. Note that one of the codes 71-76 is applicable for every bill. Special Program Indicator codes A0-A9 are not required.

Condition Code Structure (only codes affecting Medicare payment/processing are shown).

02 - Condition is Employment Related - Providers enter this code if the patient alleges that the medical condition causing this episode of care is due to environment/events resulting from employment.

04 – **Information Only Bill**- Providers enter this code to indicate the patient is a member of a Medicare Advantage plan.

59 – Non-Primary ESRD Facility – Providers enter this code to indicate that ESRD beneficiary received non-scheduled or emergency dialysis services at a facility other than his/her primary ESRD dialysis facility.

71 - Full Care in Unit - Providers enter this code to indicate the billing is for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility.

72 - Self-Care in Unit - Providers enter this code to indicate the billing is for a patient who managed his own dialysis in a hospital or renal dialysis facility.

73 - Self-Care in Training - Providers enter this code to indicate the billing is for special dialysis services where a patient and his/her helper (if necessary) were learning to perform dialysis.

76 - Back-up In-facility Dialysis - Providers enter this code to indicate the billing is for a home dialysis patient who received back-up dialysis in a facility.

H3 – Reoccurrence of GI Bleed comorbid category

H4 – Reoccurrence of Pneumonia comorbid category

H5 – Reoccurrence of Pericarditis comorbid Category

Occurrence Codes and Dates

Codes(s) and associated date(s) defining specific events(s) relating to this billing period are shown. Event codes are two alpha-numeric digits, and dates are shown as six numeric digits (MM-DD-YY). When occurrence codes 01-04 and 24 are entered, make sure the entry includes the appropriate value code, if there is another payer involved.

Occurrence and occurrence span codes are mutually exclusive. Occurrence codes have values from 01 through 69 and A0 through L9. Occurrence span codes have values from 70 through 99 and M0 through Z9.

24 - Date Insurance Denied - Code indicates the date of receipt of a denial of coverage by a higher priority payer.

33 - First Day of Medicare Coordination Period for ESRD Beneficiaries Covered by an EGHP - Code indicates the first day of the Medicare coordination period during which Medicare benefits are payable under an EGHP. This is required only for ESRD beneficiaries.

51 – Date of last Kt/V reading. For in-center hemodialysis patients, this is the date of the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis patients, this date may be before the current billing period but should be within 4 months of the claim date of service.

Occurrence Span Code and Dates

Code(s) and associated beginning and ending dates(s) defining a specific event relating to this billing period are shown. Event codes are two alpha-numeric digits and dates are shown numerically as MM-DD-YY.

74 - Noncovered Level of Care - This code is used for repetitive Part B services to show a period of inpatient hospital care or of outpatient surgery during the billing period. Use of this code will not be necessary for ESRD claims with dates of service on or after April 1, 2007 due to the requirement of ESRD line item billing.

Document Control Number (DCN)

Required for all provider types on adjustment requests. (Bill Type/FL=XX7). All providers requesting an adjustment to a previous processed claim insert the DCN of the claims to be adjusted.

Value Codes and Amounts

Code(s) and related dollar amount(s) identify monetary data that are necessary for the processing of this claim. The codes are two alphanumeric digits and each value allows up to nine numeric digits (0000000.00). Negative amounts are not allowed. Whole numbers or non-dollar amounts are right justified to the left of the dollars and cents delimiter. Some values are reported as cents, so refer to specific codes for instructions. If more than one value code is shown for a billing period, show the codes in ascending alphanumeric sequence.

Value Code Structure (Only codes used to bill Medicare are shown.):

06 - Medicare Blood Deductible - Code indicates the amount the patient paid for un-replaced deductible blood.

13 - ESRD Beneficiary in the 30- Month Coordination Period With an EGHP - Code indicates that the amount shown is that portion of a higher priority EGHP payment on behalf of an ESRD beneficiary that applies to covered Medicare charges on this bill. If the provider enters six zeros (0000.00) in the amount field, it is claiming a conditional payment because the EGHP has denied coverage or there has been a substantial delay in its payment. Where the provider received no payment or a reduced payment because of failure to file a proper claim, this is the amount that would have been payable had it filed a proper claim.

17 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim when an outlier payment is being made. The value is the total claim outlier payment.

19 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim for low volume providers to identify the amount of the low volume adjustment being included in the provider’s reimbursement.

37 - Pints of Blood Furnished - Code indicates the total number of pints of blood or units of packed red cells furnished, whether or not replaced. Blood is reported only in terms of complete pints rounded upwards, e.g., 1 1/4 pints is shown as 2 pints. This entry serves a basis for counting pints towards the blood deductible. Hospital-based and independent renal facilities must complete this item.

38 - Blood Deductible Pints - Code indicates the number of un-replaced deductible pints of blood supplied. If all deductible pints furnished have been replaced, no entry is made. Hospital-based and independent renal facilities must complete this item.

39 - Pints of Blood Replaced - Code indicates the total number of pints of blood donated on the patient’s behalf. Where one pint is donated, one pint is replaced. If arrangements have been made for replacement, pints are shown as replaced. Where the provider charges only for the blood processing and administration, i.e., it does not charge a “replacement deposit fee” for un-replaced pints, the blood is considered replaced for purposes of this item. In such cases, all blood charges are shown under the 039x revenue code series, Blood Administration. Hospital-based and independent renal facilities must complete this item.

44 - Amount Provider Agreed To Accept From Primary Payer When This Amount is Less Than Charges But Higher than Payment Received - Code indicates the amount shown is the amount the provider was obligated or required to accept from a primary payer as payment in full when that amount is less than the charges but higher than amount actually received. A Medicare secondary payment is due.

47 - Any Liability Insurance - Code indicates amount shown is that portion from a higher priority liability insurance made on behalf of a Medicare beneficiary that the provider is applying to Medicare covered services on this bill. If six zeros (0000.00) are entered in the amount field, the provider is claiming conditional payment because there has been substantial delay in the other payer’s payment.

48 - Hemoglobin Reading - Code indicates the most recent hemoglobin reading taken before the start of this billing period. This is usually reported in three positions with a decimal. Use the right of the delimiter for the third digit. The blood sample for the hemoglobin reading must be obtained before the dialysis treatment.

49 - Hematocrit Reading - Code indicates the most recent hematocrit reading taken before the start of this billing period. This is usually reported in two positions (a percentage) to the left of the dollar/cents delimiter. If the reading is provided with a decimal, use the position to the right of the delimiter for the third digit. The blood sample for the hemoglobin reading must be obtained before the dialysis treatment.

67 - Peritoneal Dialysis - The number of hours of peritoneal dialysis provided during the billing period. Count only the hours spent in the home. Exclude travel time. Report amount in whole units right-justified to the left of the dollar/cents delimiter. (Round to the nearest whole hour.)

Reporting value code 67 will not be required for claims with dates of service on or after April 1, 2007.

68 - Erythropoietin Units - Code indicates the number of units of administered EPO relating to the billing period and reported in whole units to the left of the dollar/cents delimiter. NOTE: The total amount of EPO injected during the billing period is reported. If there were 12 doses injected, the sum of the units administered for the 12 doses is reported as the value to the left of the dollar/cents delimiter.

Medicare no longer requires value code 68 for claims with dates of service on or after January 1, 2008.

71 - Funding of ESRD Networks - Code indicates the amount of Medicare payment reduction to help fund the ESRD networks. This amount is calculated by the FI and forwarded to CWF. (See §120 for discussion of ESRD networks).

79 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim. The value represents the dollar amount for Medicare allowed payments applicable for the calculation in determining an outlier payment.

A8 – Weight of Patient – Code indicates the weight of the patient in kilograms. The weight of the patient should be measured after the last dialysis session of the month.

A9 – Height of Patient – Code indicates the height of the patient in centimeters. The height of the patient should be measured during the last dialysis session of the month. This height is as the patient presents.

D5 – Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service.

Revenue Codes

The revenue code for the appropriate treatment modality under the composite rate is billed (e.g., 0821 for hemodialysis). Services included in the composite rate and related charges must not be shown on the bill separately. Hospitals must maintain a log of these charges in their records for cost apportionment purposes.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

082X - Hemodialysis - Outpatient or Home Dialysis - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed directly from the blood. Detailed revenue coding is required. Therefore, services may not be summed at the zero level.

0 - General Classification	HEMO/OP OR HOME
1 – Hemodialysis/Composite or other rate	HEMO/COMPOSITE
2 - Home Supplies	HEMO/HOME/SUPPL
3 - Home Equipment	HEMO/HOME/EQUIP
4 - Maintenance 100%	HEMO/HOME/100%
5 - Support Services	HEMO/HOME/SUPSERV
9 - Other Hemodialysis Outpatient	HEMO/HOME/OTHER

083X - Peritoneal Dialysis - Outpatient or Home - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed indirectly by instilling a special solution into the abdomen using the peritoneal membrane as a filter.

0 - General Classification	PERITONEAL/OP OR HOME
1 - Peritoneal/Composite or other rate	PERTNL/COMPOSITE
2 - Home Supplies	PERTNL/HOME/SUPPL
3 - Home Equipment	PERTNL/HOME/EQUIP
4 - Maintenance 100%	PERTNL/HOME/100%
5 - Support Services	PERTNL/HOME/SUPSERV
9 -Other Peritoneal Dialysis	PERTNL/HOME/OTHER

084X - Continuous Ambulatory Peritoneal Dialysis (CAPD) - Outpatient - A continuous dialysis process performed in an outpatient or home setting, which uses the patient's peritoneal membrane as a dialyzer.

0 - General Classification	CAPD/OP OR HOME
1 - CAPD/Composite or other rate	CAPD/COMPOSITE
2 - Home Supplies	CAPD/HOME/SUPPL
3 - Home Equipment	CAPD/HOME/EQUIP
4 - Maintenance 100%	CAPD/HOME/100%
5 - Support Services	CAPD/HOME/SUPSERV
9 -Other CAPD Dialysis	CAPD/HOME/OTHER

085X - Continuous Cycling Peritoneal Dialysis (CCPD) - Outpatient. - A continuous dialysis process performed in an outpatient or home setting, which uses the patient's peritoneal membrane as a dialyzer.

0 - General Classification	CCPD/OP OR HOME
1 - CCPD/Composite or other rate	CCPD/COMPOSITE
2 - Home Supplies	CCPD/HOME/SUPPL
3 - Home Equipment	CCPD/HOME/EQUIP
4 - Maintenance 100%	CCPD/HOME/100%
5 - Support Services	CCPD/HOME/SUPSERV
9 -Other CCPD Dialysis	CCPD/HOME/OTHER

088X – Miscellaneous Dialysis – Charges for Dialysis services not identified elsewhere.

0 - General Classification	DAILY/MISC
1 – Ultrafiltration	DAILY/ULTRAFILT
2 – Home dialysis aid visit	HOME DIALYSIS AID VISIT
9 -Other misc Dialysis	DAILY/MISC/OTHER

HCPCS/Rates

All hemodialysis claims must include HCPCS 90999 on the line reporting revenue code 082x.

Modifiers

Modifiers are required with ESRD Billing for reporting the adequacy of dialysis and the vascular access. For information on modifiers required for these quality measures see 50.9 of this chapter.

For information on reporting modifiers applicable to *the Erythropoietin Stimulating Agents refer to section 60.4 of this chapter*.

Route of administration modifiers required are JA, JB and JE.

For information on reporting the AY modifier for services not related to the treatment of ESRD, see sections 60.2.1.1 – Separately Billable ESRD Drugs and 60.1 - Lab Services.

Service Date

Report the line item date of service for each dialysis session and each separately payable item or service.

Service Units

Hospital-based and independent renal facilities must complete this item. The entries quantify services by revenue category, e.g., number of dialysis treatments. Units are defined as follows:

0634 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of less than 10,000 units of EPO was administered. For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.

0635 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of 10,000 units or more of EPO was administered. For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.

082X - (Hemodialysis) – Sessions

083X - (Peritoneal) – Sessions

084X - (CAPD) - Days covered by the bill

085X - (CCPD) - Days covered by the bill

Effective April 1, 2007, the implementation of ESRD line item billing requires that each dialysis session be billed on a separate line. As a result, claims with dates of service on or after April 1, 2007 should not report units greater than 1 for each dialysis revenue code line billed on the claim.

Total Charges

Hospital-based and independent renal facilities must complete this item. Hospital-based facilities must show their customary charges that correspond to the appropriate revenue code. They must not enter their composite or the EPO` rate as their charge. Independent facilities may enter their composite and/or EPO rates.

Neither revenue codes nor charges for services included in the composite rate may be billed separately (see §90.3 for a description). Hospitals must maintain a log of these charges in their records for cost apportionment purposes.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

The last revenue code entered in as 000l represents the total of all charges billed.

Principal Diagnosis Code

Hospital-based and independent renal facilities must complete this item and it should include a diagnosis of end stage renal disease.

Other Diagnosis Code(s)

For claims with dates of service on or after January 1, 2011 renal dialysis facilities report the appropriate diagnosis code(s) for co-morbidity conditions eligible for an adjustment.

NOTE: Information regarding the form locator numbers that correspond to these data element names and a table to crosswalk UB-04 form locators to the 837 transaction is found in Chapter 25.

60.2.1.1 – Separately Billable ESRD Drugs

(Rev.2688, Issued: 04-26-13, Effective: 07-01-13, Implementation: 07-01-13)

The following categories of drugs (including but not limited to) are separately billable when used to treat the patient's renal condition:

- Antibiotics;
- Analgesics;
- Anabolics;
- Hematinics;
- Muscle relaxants;
- Sedatives;
- Tranquilizers; and
- Thrombolytics: used to declot central venous catheters. *Note: Thrombolytics were removed from the separately billable drugs for claims with dates of service on or after January 1, 2013.*

For claims with dates of service on or after July 1, 2013, when these drugs are administered through the dialysate the provider must append the modifier JE (Administered via Dialysate).

These separately billable drugs may only be billed by an ESRD facility if they are actually administered in the facility by the facility staff. Staff time used to administer separately billable drugs is covered under the composite rate and may not be billed separately. However, the supplies used to administer these drugs may be billed in addition to the composite rate.

Effective January 1, 2011, section 153b of the MIPPA requires that all ESRD-related drugs and biologicals be billed by the renal dialysis facility. When a drug or biological is billed by providers other than the ESRD facility and the drug or biological furnished is designated as a drug or biological that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related drug or biological was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY.

All drugs reported on the renal dialysis facility claim are considered included in the ESRD PPS. The list of drugs and biologicals for consolidated billing are designated as <u>always</u> ESRD-related and therefore not

allowing separate payment to be made to ESRD facilities. However, CMS has determined that some of these drugs may warrant separate payment.

Exceptions to "Always ESRD Related" Drugs:
The following drugs have been approved for separate payment consideration when billed with the AY modifier attesting to the drug not being used for the treatment of ESRD. The ESRD facility is required to indicate (in accordance with ICD-9 guidelines) the diagnosis code for which the drug is indicated.

- Vancomycin, effective January 1, 2012
- Daptomycin, effective January 1, 2013

Items and services subject to the consolidated billing requirements for the ESRD PPS can be found on the CMS website at:
http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage.

Other drugs and biologicals may be considered separately payable to the dialysis facility if the drug was not for the treatment of ESRD. The facility must include the modifier AY to indicate it was not for the treatment of ESRD.

Drugs are assigned HCPCS codes. If no HCPCS code is listed for a drug (e.g., a new drug) the facility bills using HCPCS code J3490, "Unclassified Drugs," and submits documentation identifying the drug. To establish a code for the drug, the FI checks HCPCS to verify that there is no acceptable HCPCS code for billing and if a code is not found checks with the local carrier, which may have a code and price that is appropriate. If no code is found the drug is processed under HCPCS code J3490. See Chapter 17 for a complete description of drug pricing.

60.4.2 - Facility Billing Requirements for ESAs

(Rev.2688, Issued: 04-26-13, Effective: 07-01-13, Implementation: 07-01-13)

Hematocrit and Hemoglobin Levels
Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48.

To report a hemoglobin or hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of epoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.

Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims. Reporting the value 99.99 is not permitted when billing for an ESA.

The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636. The HCPCS code for the ESA must be included:

HCPCS	HCPCS Description	Dates of Service
Q4055	Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0886	Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)	1/1/2006 through 12/31/2006
Q4081	Injection, Epoetin alfa, 100	1/1/2007 to present

	units (for ESRD on Dialysis)	
Q4054	Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0882	Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)	1/1/2006 to present
J0890	Injection, Peginesatide, 0.1 mg (for ESRD on Dialysis)	1/1/2013 to present

Each administration of an ESA is reported on a separate line item with the units reported used as a multiplier by the dosage description in the HCPCS to arrive at the dosage per administration.

Route of Administration Modifiers
Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA. Effective for claims with dates of services on or after January 1, 2012, all facilities billing for injections of ESA for ESRD beneficiaries must include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. ESRD claims containing ESA administrations that are submitted without the route of administration modifiers will be returned to the provider for correction. Renal dialysis facilities claim including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method.

Effective July 1, 2013, providers must identify when a drug is administered via the dialysate by appending the modifier JE (administered via dialysate).

ESA Monitoring Policy Modifiers
Append modifiers ED, EE and GS as applicable, see instructions in section 60.4.1.

Maximum Allowable Administrations
The maximum number of administrations of EPO for a billing cycle is 13 times in 30 days and 14 times in 31 days.

The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/ 31days.

The maximum number of administrations of Peginesatide is 1 time in 30/ 31days.