CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2311	**Date: September 23, 2011**
	Change Request 7460

NOTE: Transmittal 2262, dated July 29, 2011, is being rescinded and replaced by Transmittal 2311, dated September 23, 2011 to correct the definition of the hemodialysis Kt/V that is used in the calculation of the Kt/V value. All other information remains the same.

SUBJECT: Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims

I. SUMMARY OF CHANGES: 153c of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required The Centers for Medicare and Medicaid Services (CMS) to implement a quality based payment program for dialysis services with payment consequences effective January 1, 2012. MIPPA requires that the Secretary implement an ESRD quality incentive program that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established for certain specified measures.

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
R	4 / 50.1 Outpatient Provider Specific File
R	8 / 20.1 Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate
R	8 / 50.3 Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS
R	8 / 50.9 Coding for Adequacy of Dialysis, Vascular Access and Infection
R	8 / 60.2.3.1 Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)
R	8 / 60.4 Epoetin Alfa (EPO)
R	8 / 60.7 Darbepoetin Alfa (Aranesp) for ESRD Patients

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: 2311	Date: September 23, 2011	Change Request: 7460

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SUBJECT: Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims

Effective Date: January 1, 2012

Implementation Date: January 3, 2012

I. GENERAL INFORMATION

A. Background: 153c of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required The Centers for Medicare & Medicaid Services (CMS) to implement a quality based payment program for dialysis services with payment consequences effective January 1, 2012. MIPPA requires that the Secretary implement an ESRD quality incentive program that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established for certain specified measures. The measures are defined in the annual dialysis facility report (DFR) that each provider receives in addition to the final rule. The payment reductions, which will be up to 2.0 percent of payments otherwise made to ESRD facilities, will apply to payment for renal dialysis services furnished on or after January 1, 2012. The payment reduction will only apply to the year involved for an ESRD facility and will not be taken into account when computing future payment rates for the impacted facility. The ESRD QIP is the first Medicare program that links payments to performance based on outcomes as assessed through specific quality measures.

B. Policy: Contractors will be notified and required to implement the QIP payment reductions for the facilities identified for the payment year.

In addition to implementing the QIP, CMS will require ESRD facilities to submit the following on **ALL** ESRD claims with dates of service on or after January 1, 2012:

- hemoglobin and/or hematocrit values,
- identify the route of administration using the JA or JB modifier code for any claim indicating the administration of erythropoiesis stimulating agents (ESAs),
- use a specified formula to calculate the Kt/V for the measurement of dialysis adequacy.

CMS is making these changes to adequately assess the safety of the administration of ESAs, management of anemia for ESRD patients and to standardize the methodology used for the calculation of Kt/V used to measure the adequacy of the dialysis provided to ESRD patients. These changes will allow CMS to meet the intent of the MIPPA legislation to monitor safety and outcomes delivered by ESRD providers for the entire ESRD population as part of the Quality Incentive Program (QIP).

Reporting Hemoglobin and / or Hematocrit:

CMS will require the submission of the most recent hemoglobin or hematocrit lab value taken prior to the start of the billing period on all ESRD claims irrespective of erythropoiesis stimulating agent (ESA) administration. The blood sample for the hemoglobin or hematocrit lab value must be obtained before the dialysis treatment.

Failure to submit a hemoglobin and/or hematocrit value on all ESRD claims will adversely impact a facility's QIP score and public reporting on Dialysis Facility Compare (DFC).

Required Reporting for ESA Route of Administration:

CMS will require the reporting of modifiers JA (intravenous administration) or JB (subcutaneous administration) indicating the route of administration on all ESRD claims with dates of service on or after January 1, 2012 when reporting the administration of ESAs. ESRD claims that do not contain modifier JA or JB when ESA administration is indicated will be returned to the provider for correction. Patients with end stage renal disease (ESRD) receiving administrations of ESAs, such as epoetin alfa (EPO) and Darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA. Existing instructions require that ESRD facilities submit each administration on a separate line item. Renal dialysis facilities claims including administrations of the ESAs by both methods must report the appropriate route of administration for each line item.

Calculation of the Kt/V Value:

CMS will require the use of the following Kt/V calculations based on the dialytic modality when entering Value Code D5 on ESRD claims.

- **Hemodialysis**: For in-center and home-hemodialysis patients prescribed for three or fewer treatments per week, the last Kt/V obtained during the month must be reported. Facilities must report single pool Kt/V using the preferred National Quality Forum (NQF) endorsed methods for deriving the single pool Kt/V value: Daugirdas II or Urea Kinetic Modeling (UKM). The reported Kt/V should not include residual renal function.

  For patients routinely prescribed four or more hemodialysis treatments per week a value of 8.88 should be entered on the claim. The 8.88 value should not be used for patients who are receiving "extra" treatments for temporary clinical need.

- **Peritoneal Dialysis**: When measured the delivered weekly total Kt/V (dialytic and residual) should be reported.

All other requirements associated with ESRD claims shall remain unchanged.

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	
7460.1	Upon receipt of an annual Technical Direction Letter from CMS identifying ESRD facilities subject to QIP payment reduction, Medicare contractors shall update the outpatient provider specific file (OPSF) as indicated for the payment year specified. OPSF field 74: Redefined as "Quality Indicator Field". Valid values for ESRD facilities: Blank = no reduction 1 = ½ percent payment reduction 2 = 1 percent payment reduction 3 = 1 ½ percent payment reduction 4 = 2 percent payment reduction	X		X							
7460.2	Medicare systems shall default the OPSF field 74 for ESRD facilities to blank each year when creating the new OPSF.						X				
7460.3	Medicare contractors shall send the OPSF field 74 indicators for QIP reduction to the ESRD PRICER.						X				
7460.4	Medicare contractors shall receive and apply the appropriate QIP reduction to the ESRD PPS payment (and composite rate portion of the payment for transitioning providers).										ESRD PRICER
7460.5	Medicare contractors shall apply the QIP reduction to the ESRD related separately billable services for ESRD facilities under the ESRD PPS transitional payment through December 31, 2013.						X				
7460.6	Medicare contractors shall return to provider 72x bill types with dates of service on or after January 1, 2012 that do not contain modifier code JA or JB for ESA route of administration when reporting Q4081 or J0882.						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	
7460.7	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:
7460.2	The OPSF 74 has different indicators and quality rules for hospital provider types. This instruction applies only to ESRD providers and shall not impact other provider files.
7460.3	The field FISS shall send in the input record layout will be called P-QIP-REDUCTION and will be located in column 107. The revised ESRD PPS PRICER will issue for testing this requirement with the annual Recurring ESRD PPS Update issued for January 2012.
7460.5	The value code 79 (Medicare allowed payments for outlier) shall not be reduced for the QIP reduction.

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

V. CONTACTS

Pre-Implementation Contact(s): Policy comments Shannon Kerr 410-786-3039 or Tom Dudley 410-786-1442, Claims processing Wendy Tucker 410-786-3004

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),* and/or *Carriers*:

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 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)

50.1 - Outpatient Provider Specific File
(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

The Outpatient Provider Specific File (OPSF) contains the required information about each provider to enable the pricing software to calculate the payment amount. Data elements and formats are shown below. Contractors must maintain the accuracy of the data, and update the file as changes occur in data element values, e.g., changes in metropolitan statistical area (MSA), bed size, cost to charge ratio. An update is accomplished by preparing and adding an additional complete record showing new current values and the effective date of the change. The old record is retained without change.

Contractors must also furnish CMS a quarterly file in the same format.

NOTE: All data elements, whether required or optional, must have a default value of "0" (zero) if numerical, or blank if alphanumerical.

File Position	Format	Title	Description
1-10	X(10)	National Provider Identifier (NPI)	Alpha-numeric 10 character provider number.
11-16	X(6)	Provider Oscar Number	Alpha-numeric 6 character provider number.
17-24	9(8)	Effective Date	Must be numeric, CCYYMMDD. This is the effective date of the provider's first OPPS period. For subsequent OPPS periods, the effective date is the date of a change to the PROV file. If a termination date is present for this record, the effective date must be equal to or less than the termination date.
25-32	9(8)	Fiscal Year Beginning Date	Must be numeric, CCYYMMDD. Month: 01-12 Day:01-31 The date must be greater than 19990630.

33-40	9(8)	Report Date	Must be numeric, CCYYMMDD. Month: 01-12 Day:01-31 The created/run date of the PROV report for submittal to CO.
41-48	9(8)	Termination Date	Must be numeric, CCYYMMDD. Must be zeros or contain a termination date. (once the official "tie-out" notice from CMS is received). Must be equal to or greater than the effective date. (Termination date is the date on which the reporting intermediary ceased servicing the provider in question).
49	X(1)	Waiver Indicator	Enter a "Y" or "N." Y = waived (provider is not under OPPS) *For End Stage Renal Disease (ESRD) facilities provider waived blended payment, pay full PPS.* N = not waived (provider is under OPPS) *For ESRD facilities provider did not waive blended payment. Pay according to transitional payment method for ESRD PPS through 2013.*
50-54	9(5)	Intermediary Number	Enter the Intermediary #.
55-56	X(2)	Provider Type	This identifies providers that require special handling. Enter one of the following codes as appropriate. 00 or blanks = Short Term Facility 02 Long Term 03 Psychiatric 04 Rehabilitation Facility 05 Pediatric 06 Hospital Distinct Parts (Provider type "06" is effective until July 1, 2006. At that point, provider type "06" will no longer be used. Instead, contractors will assign a hospital distinct part as one of the following

			provider types: 49, 50, 51, 52, 53, or 54) 07 Rural Referral Center 08 Indian Health Service 13 Cancer Facility 14 Medicare Dependent Hospital (during cost reporting periods that began on or after April 1, 1990. 15 Medicare Dependent Hospital/Referral Center (during cost reporting periods that began on or after April 1, 1990. Invalid October 1, 1994 through September 30, 1997). 16 Re-based Sole Community Hospital 17 Re-based Sole Community Hospital /Referral Center 18 Medical Assistance Facility 21 Essential Access Community Hospital 22 Essential Access Community Hospital/Referral Center 23 Rural Primary Care Hospital 32 Nursing Home Case Mix Quality Demonstration Project – Phase II 33 Nursing Home Case Mix Quality Demonstration Project – Phase III – Step 1 34 Reserved 35 Hospice 36 Home Health Agency 37 Critical Access Hospital 38 Skilled Nursing Facility (SNF) – For non-

			demo PPS SNFs – effective for cost reporting periods beginning on or after July 1, 1998 40 Hospital Based ESRD Facility 41 Independent ESRD Facility 42 Federally Qualified Health Centers 43 Religious Non-Medical Health Care Institutions 44 Rural Health Clinics-Free Standing 45 Rural Health Clinics-Provider Based 46 Comprehensive Outpatient Rehab Facilities 47 Community Mental Health Centers 48 Outpatient Physical Therapy Services 49 Psychiatric Distinct Part 50 Rehabilitation Distinct Part 51 Short-Term Hospital – Swing Bed 52 Long-Term Care Hospital – Swing Bed 53 Rehabilitation Facility – Swing Bed 54 Critical Access Hospital – Swing Bed
57	X(1)	Special Locality Indicator	Indicates the type of special locality provision that applies. *For End Stage Renal Disease (ESRD) facilities value "Y" equals low volume adjustment applicable.*
58	X(1)	Change Code For Wage Index Reclassification	Enter "Y" if the hospital's wage index location has been reclassified for the year. Enter "N" if it has not been reclassified for the year. Adjust annually. Does not apply to ESRD Facilities.
59-62	X(4)	Actual Geographic Location—MSA	Enter the appropriate code for MSA, 0040–9965, or the rural area, (blank)(blank) 2-digit numeric State code, such as _ _ 3 6 for Ohio, where the facility is physically located.

63-66	X(4)	Wage Index Location—MSA	The appropriate code for the MSA, 0040-9965, or the rural area, (blank)(blank) (2 digit numeric State code) such as _ _ 3 6 for Ohio, to which a hospital has been reclassified for wage index. Leave blank or enter the actual location MSA if not reclassified. Does not apply to ESRD Facilities.
67-70	9V9(3)	Payment-to-Cost Ratio	Enter the provider's payment-to-cost ratio. Does not apply to ESRD Facilities.
71-72	9(2)	State Code	Enter the 2-digit state where the provider is located. Enter only the first (lowest) code for a given state. For example, effective October 1, 2005, Florida has the following State Codes: 10, 68 and 69. Contractors shall enter a "10" for Florida's State Code. List of valid State Codes is located in Pub. 100-07, Chapter 2, Section 2779A1.
73	X(1)	TOPs Indicator	Enter the code to indicate whether TOPs applies or not. Y = qualifies for TOPs N = does not qualify for TOPs

74	X(1)	Quality Indicator Field	*Hospital:* Enter the code to indicate whether the hospital meets data submission criteria per HOP QDRP requirements. 1 = Hospital quality reporting standards have been met or hospital is not required to submit quality data (e.g., hospitals that are specifically excluded from the IPPS or which are not paid under the OPPS, including psychiatric, rehabilitation, long-term care and children's and cancer hospitals, Maryland hospitals, Indian Health Service hospitals, or hospital units; or hospitals that are located in Puerto Rico or the U.S. territories). The reduction does not apply to hospices, CORFs, HHAs, CMHCs, critical access hospitals or to any other provider type that is not a hospital. Blank = Hospital does not meet criteria. *Independent and Hospital-based End Stage Renal Disease (ESRD) Facilities:* *Enter the code applicable to the ESRD Quality Incentive Program (QIP):* *Blank = no reduction* *1 = ½ percent payment reduction* *2 = 1 percent payment reduction* *3 = 1 ½ percent payment reduction* *4 = 2 percent payment reduction*
75	X(1)	Filler	Blank.
76-79	9V9(3)	Outpatient Cost-to-Charge Ratio	Derived from the latest available cost report data. See §10.11 of this chapter for instructions on how to calculate and report the Cost-to-Charge Ratio. Does not apply to ESRD Facilities.
80-84	X(5)	Actual Geographic Location CBSA	00001-89999, or the rural area, (blank (blank) (blank) 2 digit numeric State code such as _ _ _ 3 6 for Ohio, where the facility is physically located.

85-89	X(5)	Wage Index Location CBSA	Enter the appropriate code for the CBSA, 00001-89999, or the rural area, (blank)(blank)(blank) (2 digit numeric State code) such as _ _ _ 3 6 for Ohio, to which a hospital has been reclassified due to its prevailing wage rates. Leave blank or enter the Actual Geographic Location CBSA, if not reclassified. Pricer will automatically default to the actual location CBSA if this field is left blank. Does not apply to ESRD Facilities.
90-95	9(2) V9(4)	Special Wage Index	Enter the special wage index that certain providers may be assigned. Enter zeroes unless the Special Payment Indicator equals a "1" or "2."
96	X(1)	Special Payment Indicator	The following codes indicate the type of special payment provision that applies. Blank = not applicable Y = reclassified 1 = special wage index indicator 2 = both special wage index indicator and reclassified
97-100	9(4)	Reduced Coinsurance Trailer Count	Enter the number of APCs the provider has elected to reduce coinsurance for. The number cannot be greater than 999.

The contractor enters the number of APCs for which the provider has elected to reduce coinsurance. Cannot be greater than 999. Reduced Coinsurance Trailer Record - Occurs 0-999 times depending on the reduced Coinsurance Trailer Count in positions 97-100. Due to systems capacity limitations the maximum number of reduced coinsurance trailers allowable is 999 at this time.

1-4	9(4)	APC Classification - Enter the 4-digit APC classification for which the provider has elected to reduce coinsurance.
5-10	9(4)V9(2)	Reduced Coinsurance Amount - Enter the reduced coinsurance amount elected by the provider

The Shared system will verify that the last position of the record is equal to the number in file positions 97 through 100 multiplied by 10 plus 100 (last position of record = (# in file position 97-100)(10) + 100).

Future updates will be issued in a Recurring Update Notification.

Medicare Claims Processing Manual

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

20.1 – Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate

(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

A case mix methodology adjusts the composite payment rate based on a limited number of patient characteristics. Variables for which adjustments will be applied to each facility's composite rate include age, body surface area (BSA), and low body mass index (BMI). These variables are determined in the ESRD PRICER to calculate the final composite rate (including all other adjustments).

The following table contains claim data required to calculate a final ESRD composite rate *and the ESRD PPS rate:*

UB-04 Claim Items	**ASC X12N 837i**
Through Date	2300 | DTP segment | 434 qualifier
Date of Birth	2010BA | DMG02
Condition Code (73 or 74)	2300 | HI segment | BG qualifier
Value Codes (A8 and A9) / Amounts	2300 | HI segment | BE qualifier
Revenue Code (0821, 0831, 0841, 0851, 0880, or 0881)	2400 | SV201

For claims with dates of service on or after January 1, 2011, Medicare systems must pass the line item date of service dialysis revenue code lines when the onset of dialysis adjustment is applicable to one or more of the dialysis sessions reported on the claim.

Line Item Date of Service for Revenue Code (0821, 0831, 0841, 0851	2400 | DTP Segment | D8 qualifier

In addition to the above claim data, the following payer only codes are required on claims with dates of service on or after January 1, 2011 to calculate the final ESRD PPS rate:

Payer Only Condition Codes (MA, MB, MC, MD, ME, MF)	2300 | HI segment | BG qualifier
Payer Only Value Code (79)	2300 | HI segment | BE qualifier

Note: These payer only codes above are assigned by the Medicare standard systems and are not submitted on the claim by the provider. Payer only condition codes are only applicable when the appropriate corresponding diagnosis code(s) appears on the claim.

See information below in this section on co-morbidy diagnostic categories. The payer only value code 79 represents the dollar amount for services applicable for the calculation in determining an outlier payment.

The following provider data must also be passed to the ESRD PRICER to make provider-specific calculations that determine the final ESRD rate:

Field	**Format**
Actual Geographic Location MSA	X(4)
Actual Geographic Location CBSA	X(5)
Special Wage Index	9(2)V9(4)
Provider Type	X(2)
Special Payment Indicator	X(1)

In addition to the above provider data, the following is required to calculate the final ESRD PPS rate effective January 1, 2011:

Blended Payment Indicator	X(1)
Low-Volume Indicator	X (1)

Effective January 1, 2012 the following is required to calculate the Quality Incentive Program adjustment for ESRD facilities:

Quality Indicator Field	*X(1)*

ESRD facilities may elect to be reimbursed 100 percent by ESRD PPS no later than November 1, 2010. Facilities that do not elect to be reimbursed 100 percent by the ESRD PPS will be reimbursed by a blended payment rate which is composed of the current basic case-mix adjusted composite rate payment system and the new ESRD PPS.

Blended payment schedule:

Calendar year 2011 – 75 percent of the old payment methodology and 25 percent of new ESRD PPS payment

Calendar year 2012 – 50 percent of the old payment methodology and 50 percent of the new ESRD PPS payment

Calendar year 2013 – 25 percent of the old payment methodology and 75 percent of the new ESRD PPS payment

Calendar year 2014 – 100 percent of the ESRD PPS payment

Based on the claim and provider data shown above, the ESRD PRICER makes adjustments to the facility specific base rate to determine the final composite payment rate. The following factors are used to adjust and make calculations to the final payment rate:

Provider Type	Drug add-on	Budget Neutrality Factor
Patient Age	Patient Height	Patient Weight
Patient BSA	Patient BMI	BSA factor
BMI factor	Condition Code 73 adjustment (if applicable)	Condition Code 74 adjustment (if applicable)

In addition to the above adjustments, the following adjustments may be applicable to the ESRD PPS base rate for **adult** patient claims with dates of service on or after January 1, 2011:

Onset of Dialysis	Patient Co-morbidities	Low-Volume ESRD Facility

Onset of Dialysis:
Providers will receive an adjustment to the ESRD PPS base rate for patients within the first 4 months of dialysis treatment. The provider does not report anything on the claim for this adjustment. The adjustment is determined by the start date of dialysis in the Common Working File as reported on the patient's 2728 form. When the onset of dialysis adjustment is provided, the claim is not entitled to a co-morbidity adjustment or a training add-on adjustment.

Co-morbidity Adjustment Categories
The ESRD PPS will provide adjustments for 6 categories of co-morbidity conditions. Three categories of chronic conditions and 3 categories of acute conditions. **In the event that more**

than one of the co-morbidity categories is present on the claim, the claim will be adjusted for the highest paying co-morbidity category.

Acute Co-morbidity Diagnostic Categories:
The acute co-morbidity categories will be eligible for a payment for the first month reported and the following 3 consecutive months. Acute co-morbidity conditions reported for more than 4 consecutive months will not receive additional payment. In the event that the co-morbidity condition was resolved and later reoccurred, the provider may submit a condition code to indicate the diagnosis is a reoccurrence. The adjustment will be applicable for an additional 4 months.

Acute Categories are:

- Gastro-intestinal tract bleeding
- Bacterial pneumonia
- Pericarditis

Chronic Co-morbidity Diagnostic Categories:
When chronic co-morbidity codes are reported on the claim an adjustment may be made for as long as the chronic condition remains applicable to the patient care provided and is reported on the claim.

Chronic Categories are:

- Hereditary hemolytic or sickle cell anemia
- Monoclonal gammopathy
- Myelodysplastic syndrome

Information related to the comorbid conditions eligible for adjustment can be found at the **following website:**
http://www.cms.gov/ESRDPayment/40_Comorbidity_Conditions.asp#TopOfPage. . This list may be updated as often as quarterly in January, April, July and October of each year.

Low-Volume Facilities:
ESRD facilities will receive an adjustment to their ESRD PPS base 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 open, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. The ESRD facility must notify their Medicare Contractor if they believe they are eligible for the low-volume adjustment. Contractors must validate the eligibility and update the provider specific file. Pediatric patient claims are not eligible for the low-volume adjustment.

In addition to the above adjustments, the following adjustments may be applicable to the ESRD PPS base rate for **adult and pediatric** patient claims with dates of service on or after January 1, 2011:

Training Adjustment: The ESRD PPS provides a training add-on of $33.44 adjusted by the geographic area wage index that accounts for an hour of nursing time for training treatments. The add-on applies to both PD and HD training treatments**.**

ESRD PPS Outlier Payments:
Outlier payments may be applied to the payment. 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 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. ESRD-related oral only drugs are delayed until January 1, 2014. Services not included in the PPS that remain separately payable are not considered outlier services.

When the ESRD PRICER returns an outlier payment, the standard systems shall display the total applicable outlier payment on the claim with value code 17.
Information related to the outlier services eligible for adjustment can be found at the following website: http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage. This list may be updated as often as quarterly in January, April, July and October of each year.

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

(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

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, presence of infection and the vascular access. For information on modifiers required for these quality measures see 50.9 of this chapter.

For information on reporting the GS modifier for reporting a dosage reduction of epoetin alfa or darbepoetin alfa, see sections 60.4 and 60.7 of this chapter.

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.

50.9 - Coding for Adequacy of Dialysis, Vascular Access and Infection

(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

A. Reporting the Urea Reduction Ratio(URR) for ESRD Hemodialysis Claims

All hemodialysis claims must indicate the most recent Urea Reduction Ratio (URR) for the dialysis patient. Code all claims using HCPCS code 90999 along with the appropriate G modifier listed in section B.

Claims for dialysis treatments must include the adequacy of hemodialysis data as measured by URR. Dialysis facilities must monitor the adequacy of dialysis treatments monthly for facility patients. Home hemodialysis and peritoneal dialysis patients may be monitored less frequently, but not less than quarterly. If a home hemodialysis patient is not monitored during a month, the last, most recent URR for the dialysis patient must be reported.

HCPCS code 90999 (unlisted dialysis procedure, inpatient or outpatient) must be reported in field location 44 for all bill types 72X. The appropriate G-modifier in field location 44 (HCPCS/RATES) is used, for patients that received seven or more dialysis treatments in a month. Continue to report revenue codes 0820, 0821, 0825, and 0829 in field location 43.

G1 - Most recent URR of less than 60%
G2 - Most recent URR of 60% to 64.9%
G3 - Most recent URR of 65% to 69.9%
G4 - Most recent URR of 70% to 74.9%
G5 - Most recent URR of 75% or greater

For patients that have received dialysis 6 days or less in a month, facilities use the following modifier:

G6 - ESRD patient for whom less than seven dialysis sessions have been provided in a month.

For services beginning January 1, 2003, and after, if the modifier is not present, FIs must return the claim to the provider for the appropriate modifier. Effective April, 2007 due to the requirement of line item billing, at least one revenue code line for hemodialysis on the claim

must contain one of the URR modifiers shown above. The URR modifier is not required on every hemodialysis line on the claim.

The techniques to be used to draw the pre- and post-dialysis blood urea Nitrogen samples are listed in the National Kidney Foundation Dialysis Outcomes Quality Initiative Clinical Practice Guidelines for Hemodialysis Adequacy, Guideline 8, Acceptable Methods for BUN sampling, New York, National Kidney Foundation, 2000, pp.53-60.

B. Reporting the Vascular Access for ESRD Hemodialysis Claims

ESRD claims for hemodialysis with dates of service on or after July 1, 2010 must indicate the type of vascular access used for the delivery of the hemodialysis at the last hemodialysis session of the month. One of the following codes is required to be reported on the latest line item date of service billing for hemodialysis revenue code 0821. It may be reported on all revenue code 0821 lines at the discretion of the provider.

Modifier V5 - Any Vascular Catheter (alone or with any other vascular access),

Modifier V6 - Arteriovenous Graft (or other Vascular Access not including a vascular catheter)

Modifier V7 - Arteriovenous Fistula Only (in use with two needles)

C. Reporting the Kt/V for ALL ESRD Claims

All ESRD claims with dates of service on or after July 1, 2010 must indicate the applicable Kt/V reading for the dialysis patient. The reading result and the date of the reading must be reported on the claim using the following claim codes:

Value Code 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.

- ***Hemodialysis****: For in-center and home-hemodialysis patients prescribed for three or fewer treatments per week, the last Kt/V obtained during the month must be reported. Facilities must report single pool Kt/V using the preferred National Quality Forum (NQF) endorsed methods for deriving the single pool Kt/V value: Daugirdas II or Urea Kinetic Modeling (UKM). The reported Kt/V should not include residual renal function.*

  For patients routinely prescribed four or more hemodialysis treatments per week a value of 8.88 should be entered on the claim. The 8.88 value should not be used for patients who are receiving "extra" treatments for temporary clinical need.

- ***Peritoneal Dialysis****: When measured the delivered weekly total Kt/V (dialytic and residual) should be reported.*

This code is effective and required on all ESRD claims with dates of service on or after July 1, 2010. In the event that no Kt/V reading was performed providers must report the D5 with a value of 9.99.

Occurrence Code 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. This code is effective for ESRD claims with dates of service on or after July 1, 2010. If no Kt/V reading was performed do not report this code.

D. Reporting of Infection for ALL ESRD Claims

All ESRD claims with dates of service on or after July 1, 2010 must indicate on the claim if an infection was present at the time of treatment. Claims must report on each dialysis revenue code line one of the following codes:

Modifier V8: Dialysis access-related infection present (documented and treated) during the billing month. Reportable dialysis access-related infection is limited to peritonitis for peritoneal dialysis patients or bacteremia for hemodialysis patients. Facilities must report any peritonitis related to a peritoneal dialysis catheter, and any bacteremia related to hemodialysis access (including arteriovenous fistula, arteriovenous graft, or vascular catheter) if identified during the billing month. For individuals that receive different modalities of dialysis during the billing month and an infection is identified, the V8 code should only be indicated on the claim for the patient's primary dialysis modality at the time the infection was first suspected. Non-access related infections should not be coded as V8. If no dialysis-access related infection is present during the billing month by this definition, providers should instead report modifier V9.

Modifier V9: No dialysis-access related infection, as defined for modifier V8, present during the billing month. Dialysis access-related infection, defined as peritonitis for peritoneal dialysis patients or bacteremia for hemodialysis patients must be reported using modifier V8. Providers must report any peritonitis related to a peritoneal dialysis catheter, and any bacteremia related to hemodialysis access (including arteriovenous fistula, arteriovenous graft, or vascular catheter) using modifier V8.

ESRD facilities may report the HCPCS 90999 Unlisted Dialysis Procedure Inpatient or Outpatient to report the above modifiers.

60.2.3.1 - Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA), such as epoetin alfa (EPO) and Darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA.

Effective for claims submitted on or after *January 1, 2012* with dates of services on or after *January 1, 2012*, all providers 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.

60.4 - Epoetin Alfa (EPO)

(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

Coverage rules for Epoetin Alfa (EPO) are explained in the Medicare Benefit Policy Manual, Publication 100-02, chapter 11. For an explanation of Method I and Method II reimbursement for patients dialyzing at home, see §40.1.

Fiscal intermediaries (FIs) pay for EPO to end-stage renal disease (ESRD) facilities as a separately billable drug to the composite rate. No additional payment is made to administer EPO, whether in a facility or a home. Effective January 1, 2005, the cost of supplies to administer EPO may be billed to the FI. HCPCS A4657 and Revenue Code 270 should be used to capture the charges for syringes used in the administration of EPO.

If the beneficiary obtains EPO from a supplier for self-administration, the supplier bills the durable medical equipment regional carrier (DMERC) and the DMERC pays at the rate shown in §60.4.3

Program payment may not be made to a physician for EPO for self-administration. Where EPO is furnished by a physician payable as "incident to services" the carrier processes the claim.

EPO Payment Methodology

Type of Provider	Separately Billable	DMERC Payment	No payment
In-facility freestanding and hospital-based ESRD facility	X		
Self-administer Home Method I	X		
Self-administer Home Method II		X	
Incident to physician in facility or for self-administration *			X

Medicare pays for a drug if self-administered by a dialysis patient. When EPO is administered in a renal facility, the service is not an "incident to" service and not under the "incident to" provision.

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. See §60.4.1.

Effective January 1, 2012, renal dialysis facilities are required to report hematocrit or hemoglobin levels on all ESRD claims irrespective of ESA administration.

Effective for services provided on or after April 1, 2006, Medicare has implemented a national claims monitoring policy for EPO administered in Medicare renal dialysis facilities. This policy does not apply to claims for EPO for patients who receive their dialysis at home and self-administer their EPO.

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to EPO warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services April 1, 2006, and later, the Centers for Medicare & Medicaid Services (CMS) will not initiate monitoring until the hematocrit level exceeds 39.0% or the hemoglobin level exceeds 13.0g/dL. This does not preclude the contractors from performing medical review at lower levels. The Food and Drug Administration (FDA) labeling for EPO notes that as the hematocrit approaches a reading of 36.0 (or hemoglobin 12.0g/dL), the dose of the drug should be reduced by 25%.

Effective for services provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose shall be reduced by 25% over the preceding month. Providers may report that a dose reduction did occur in response to the reported elevated hematocrit or hemoglobin level by adding a GS modifier on the claim. The definition of the GS modifier continues to be defined as: "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." Thus, for claims reporting a hematocrit level or hemoglobin level exceeding the monitoring threshold without the GS modifier, CMS will reduce the dosage reported on the claim by 25%. The excess dosage is considered to be not reasonable and necessary. Providers are reminded that the patient's medical records should reflect hematocrit/hemoglobin levels and any dosage reduction reported on the claim during the same time period for which the claim is submitted.

Effective for dates of service provided on and after January 1, 2008, requests for payments or claims for EPO for ESRD patients receiving dialysis in renal dialysis facilities reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) shall also include modifier ED **or** EE. Claims reporting neither modifier or both modifiers will be returned to the provider for correction.

The definition of modifier ED is "The hematocrit level has exceeded 39.0% (or hemoglobin 1evel has exceeded 13.0g/dL) 3 or more consecutive billing cycles immediately prior to and

including the current billing cycle." The definition of modifier EE is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded 13.0g/dL) less than 3 consecutive billing cycles immediately prior to and including the current billing cycle." The GS modifier continues to be defined as stated above.

Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When both modifiers GS and EE are included, no reduction in the reported dose will occur. Claims reporting a hematocrit or hemoglobin level exceeding the monitoring threshold and the ED modifier shall have an automatic 50% reduction in the reported dose applied, even if the claim also reports the GS modifier.

Below is a chart illustrating the resultant claim actions under all possible reporting scenarios:

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	**ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)**	**EE Modifier? (Hct >39% or Hgb >13g/dL <3 cycles)**	**GS Modifier? (Dosage reduced and maintained)**	**Claim Action**
No	N/A	N/A	N/A	Do not reduce reported dose.
Yes	No	No	No	Return to provider for correction. Claim must report either ED or EE.
Yes	No	No	Yes	Return to provider for correction. Claim must report either ED or EE.
Yes	No	Yes	Yes	Do not reduce reported dose.
Yes	No	Yes	No	Reduce reported dose 25%.
Yes	Yes	No	Yes	Reduce reported dose 50%.
Yes	Yes	No	No	Reduce reported dose 50%.

In addition, for dates of service on and after January 1, 2008, CMS will implement a revised medically unbelievable edit (MUE). For dates of service on and after January 1, 2008, the MUE for claims for Epogen® is reduced to 400,000 units from 500,000. It is likely that claims reporting doses exceeding the new threshold reflect typographical errors and will be returned to providers for correction.

In some cases, physicians may believe there is medical justification to maintain a hematocrit above 39.0% or hemoglobin above 13.0g/dL. Beneficiaries, physicians, and/or renal facilities may submit additional medical documentation to justify this belief under the routine appeal process. You may reinstate any dosage reduction amounts under this first level appeal process when you believe the documentation supports a higher hematocrit/hemoglobin level.

Providers are reminded that, in accordance with FDA labeling, CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction occurs. Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0-12.0g/dL). Hematocrit levels that remain below 30.0% (hemoglobin levels below 10.0g/dL)) despite dosage increases, should have causative factors evaluated. The patient's medical record should reflect the clinical reason for dose changes and hematocrit levels outside the range of 30.0-36.0% (hemoglobin levels 10.0-12.0g/dL). Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.

These hematocrit requirements apply only to EPO furnished as an ESRD benefit under §1881(b) of the Social Security Act. EPO furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for EPO furnished as "incident to service."

60.7 – Darbepoetin Alfa (Aranesp) for ESRD Patients

(Rev.2311, Issued: 09-23-11, Effective: 01-01-12, Implementation: 01-03-12)

Coverage rules for Aranesp® are explained in the Medicare Benefit Policy Manual, Publication 100-02, chapter 11. For an explanation of Method I and Method II reimbursement for patients dialyzing at home see §40.1.

Fiscal intermediaries (FIs) pay for Aranesp® to end-stage renal disease (ESRD) facilities as a separately billable drug to the composite rate. No additional payment is made to administer Aranesp®, whether in a facility or a home. Effective January 1, 2005, the cost of supplies to administer Aranesp® may be billed to the FI. HCPCS A4657 and Revenue Code 270 should be used to capture the charges for syringes used in the administration of Aranesp®.

If the beneficiary obtains Aranesp® from a supplier for self-administration, the supplier bills the durable medical equipment regional carrier (DMERC), and the DMERC pays in accordance with MMA Drug Payment Limits Pricing File.

Program payment may not be made to a physician for self-administration of Aranesp®. When Aranesp® is furnished by a physician as "incident to services," the carrier processes the claim.

For ESRD patients on maintenance dialysis treated in a physician's office, code J0882, "injection, darbepoetin alfa, 1 mcg (for ESRD patients)," should continue to be used with the hematocrit included on the claim. (For ANSI 837 transactions, the hematocrit (HCT) value is reported in 2400 MEA03 with a qualifier of R2 in 2400 MEA02.) Claims without this information will be denied due to lack of documentation. Physicians who provide Aranesp® for ESRD patients on maintenance dialysis must bill using code J0882.

Darbepoetin Alfa Payment Methodology

Type of Provider	Separately Billable	DMERC Payment	No Payment
In-facility freestanding and Hospital-based ESRD facility	X		
Self-administer Home Method I	X		
Self-administer Home Method II		X	
Incident to physician in facility or for self-administration *			X

Medicare pays for a drug if self-administered by a dialysis patient. When Aranesp® is administered in a dialysis facility, the service is not an "incident to" service, and not under the "incident to" provision.

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. See §60.4.1.

Effective January 1, 2012, renal dialysis facilities are required to report hematocrit or hemoglobin levels on all ESRD claims irrespective of ESA administration.

Effective for services provided on or after April 1, 2006, Medicare has implemented a national claims monitoring policy for Aranesp® administered in Medicare renal dialysis facilities. This policy does not apply to claims for Aranesp® for patients who receive their dialysis at home and self-administer their Aranesp®.

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to EPO warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services on and after April 1, 2006, the Centers for Medicare & Medicaid Services (CMS) will not initiate monitoring until the hematocrit level exceeds 39.0% or the hemoglobin level exceeds 13.0g/dL. This does not preclude the contractors from performing medical review at lower levels. The

Food and Drug Administration (FDA) labeling for Aranesp® notes that as the hematocrit approaches a reading of 36.0% (or hemoglobin 12.0g/dL), the dose of the drug should be reduced by 25%.

Effective for dates of service provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose shall be reduced by 25% over the preceding month. Providers may report that a dose reduction did occur in response to the reported elevated hematocrit or hemoglobin level by adding a GS modifier on the claim. The definition of the GS modifier continues to be defined as: "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." Thus, for claims reporting a hematocrit level or hemoglobin level exceeding the monitoring threshold without the GS modifier, CMS shall reduce the dosage reported on the claim by 25%. The excess dosage is considered to be not reasonable and necessary. Providers are reminded that the patient's medical records should reflect hematocrit/hemoglobin levels and any dosage reduction reported on the claim during the same time period for which the claim is submitted.

Effective for dates of service provided on an after January 1, 2008, requests for payments or claims for Aranesp® for ESRD patients receiving dialysis in renal dialysis facilities reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) shall also include modifier ED **or** EE. Claims reporting neither modifier or both modifiers will be returned to the provider for correction.

The definition of modifier ED is "The hematocrit level has exceeded 39.0% (or hemoglobin 1evel has exceeded 13.0g/dL) 3 or more consecutive billing cycles immediately prior to and including the current billing cycle." The definition of modifier EE is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded 13.0g/dL) less than 3 consecutive billing cycles immediately prior to and including the current billing cycle." The GS modifier continues to be defined as stated above.

Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When both modifiers GS and EE are included, no reduction in the reported dose will occur. Claims reporting a hematocrit or hemoglobin level exceeding the monitoring threshold and the ED modifier shall have an automatic 50% reduction in the reported dose applied, even if the claim also reports the GS modifier.

Below is a chart illustrating the resultant claim actions under all possible reporting scenarios.

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	**ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)**	**EE Modifier? (Hct >39% or Hgb >13g/dL <3 cycles)**	**GS Modifier? (Dosage reduced and maintained)**	**Claim Action**

No	N/A	N/A	N/A	Do not reduce reported dose.
Yes	No	No	No	Return to provider for correction. Claim must report either ED or EE.
Yes	No	No	Yes	Return to provider for correction. Claim must report either ED or EE.
Yes	No	Yes	Yes	Do not reduce reported dose.
Yes	No	Yes	No	Reduce reported dose 25%.
Yes	Yes	No	Yes	Reduce reported dose 50%.
Yes	Yes	No	No	Reduce reported dose 50%.

In addition, for dates of service on and after January 1, 2008, CMS will implement a revised medically unbelievable edit (MUE). For dates of service on and after January 1, 2008, the MUE for claims for Aranesp® is reduced to 1200 mcg from 1500 mcg. It is likely that claims reporting doses exceeding the new threshold reflect typographical errors and will be returned to providers for correction.

In some cases, physicians may believe there is medical justification to maintain a hematocrit above 39.0% or hemoglobin above 13.0g/dL. Beneficiaries, physicians, and/or renal facilities may submit additional medical documentation to justify this belief under the routine appeal process. You may reinstate any dosage reduction amounts under this first level appeal process when you believe the documentation supports a higher hematocrit/hemoglobin level.

Providers are reminded that, in accordance with FDA labeling, CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction occurs. Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0-12.0g/dL). Hematocrit levels that remain below 30.0% (hemoglobin levels below10.0g/dL) despite dosage increases, should have causative factors evaluated. The patient's medical record should reflect the clinical reason for dose changes and hematocrit levels outside the range of 30.0-36.0% (hemoglobin levels 10.0-12.0g/dL). Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.

These hematocrit requirements apply only to Aranesp® furnished as an ESRD benefit under §1881(b) of the Social Security Act. Aranesp® furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for Aranesp® furnished as "incident to service."