Medicare Claims Processing Manual

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

---

Table of Contents
(Rev. 1364, 11-02-07)
(Rev. 1412, 01-11-08)
(Rev. 1472, 03-06-08)

10 - General Description of ESRD Payment

(Rev. 1, 10-01-03)

PRM-1-2702, RDF-206

See the Medicare Benefit Policy Manual, Chapter 11, for a general description of coverage policies relating to the ESRD benefit.

ESRD benefits may be paid in several ways at several sites, either in a hospital setting, an independent facility or at home. Depending on the location or the type of dialysis performed, rates may differ. ESRD facilities are paid at a composite rate and for beneficiaries dialyzing at home benefits may be paid under a composite rate (Method I) or as a series of separately billable services (Method II). Home dialysis patients choose between the two methods.

Renal dialysis facilities develop a unit charge for the range of services normally provided, taking into account variations among patients (complicated and uncomplicated situations) since it is the overall dialysis service that is covered. Any auxiliary service that cannot be included in the single unit charge for dialysis services as an integral part of a maintenance dialysis must be includable under another specific coverage provision of the Medicare law, or be denied. For example, the Medicare law excludes from coverage out of hospital drugs except when specified conditions are met with respect to the physician's involvement. Furthermore, when the conditions are met, the drug and injection charges must be billed to the carrier by the physician. Medicare benefits are secondary, during a coordination period, to benefits payable under a Group Health Plan (GHP) in the case of individuals entitled to benefits on the basis of ESRD. See the Medicare Secondary Payer (MSP) Manual, Chapter 2, for further information on the coordination period and when Medicare would pay secondary to GHP insurance.

10.1 - General Description of ESRD Facility Composite Rates

(Rev. 1, 10-01-03)

PRM-1-2702, A3-3166, RDF-245, RDF-245.2

The composite rate payment system is a prospective, incentive system for the payment of outpatient maintenance dialysis services to Medicare beneficiaries. All maintenance dialysis treatments furnished to Medicare beneficiaries in an approved end stage renal disease (ESRD) facility are covered by this system. The composite rate system also is used to determine payment for home dialysis services for beneficiaries who select Method I for home dialysis payments. See §70 for a description of Method I and Method II for home dialysis.

There are two base composite rates: one for hospital-based ESRD facilities and a separate lower rate for independent facilities. Each of these base rates is composed of a labor and a nonlabor portion. To determine a facility's actual payment rate, the labor portion of the appropriate base rate is first adjusted by an area wage index and then added to the nonlabor portion. (See §30 for the base composite payment rate.)

The facility's composite rate is a comprehensive payment for all modes of in-facility dialysis, hemofiltration, and home dialysis except for bad debts, physicians' patient care

services, and certain laboratory services and drugs that are separately billable. This payment is subject to the normal Part B deductible and coinsurance requirements and it must be accepted as payment in full for all items and services covered by the composite rate. The program's portion of the payment and the portion for which the beneficiary is liable are both based on the composite rate, regardless of the facility's charge schedule.

Under the composite rate payment system, the patient's ESRD facility must furnish all of the necessary dialysis services, equipment, and supplies. (Beneficiaries dialyzing at home may elect to be excluded from the composite rate payment system and deal directly with a supplier per §90.) If the facility fails to furnish (either directly or under arrangements) any part of the items and services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that it furnishes. Therefore, if the intermediary (FI) determines that the facility has not furnished all of the items and services covered under the composite rate, the FI does not reimburse the facility any amount for the incomplete dialysis treatments.

Services that are considered included in the composite rate are described in the Medicare Benefit Policy Manual, Chapter 11.

10.2 - Uncompleted Treatments

(Rev. 1, 10-01-03)

PRM-1-2702.1

If a dialysis treatment is started, i.e., a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, e.g., a medical emergency when the patient must be rushed to an emergency room, the facility is paid based on the full composite rate. This is a rare occurrence and must be fully documented to the FI's satisfaction.

10.3 - No-Shows

(Rev. 1, 10-01-03)

PRM-1-2702.1

If a facility sets up in preparation for a dialysis treatment, but the treatment is never started, e.g., the patient never arrives, no payment is made. In this case, no service has been furnished to a Medicare beneficiary even though staff time and supplies may have been used. Furthermore, the facility may not bill the patient or the patient's private insurance for these services. This is because the program is already paying the cost of pre-dialysis services through the facility's per treatment composite rate. In setting that rate, CMS has included the salaries of facility personnel and the cost of supplies used for furnishing pre-dialysis services.

Therefore, these costs (e.g., salaries for staff time, overhead, supply costs) are included in the facility's costs and reported on its cost report, and they are included in the allowable costs used to set future reimbursement rates under the composite rate system for ESRD facilities. However, these costs may not be used as the basis for a facility to request a reimbursement exception to its composite rate, nor may they be reimbursed as Medicare bad debts.

10.4 - Deductible and Coinsurance

(Rev. 1, 10-01-03)

RDF-112, RDF-114

The beneficiary is responsible for any unmet deductible and for coinsurance. For services in independent facilities and hospitals the coinsurance is based on the composite rate, or other payment rate for services paid in addition to the composite rate, except for Erythropoietin (EPO) where coinsurance is based on the payment rate.

10.5 - Hospital Services

(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)

Outpatient dialysis services for a patient with acute kidney failure or chronic kidney failure but not eligible for Medicare under the ESRD provisions at the time services are rendered must be billed by the hospital and cannot be billed by a Medicare certified renal dialysis facility on bill type 72x.

Hospitals with a Medicare certified renal dialysis facility should have outpatient ESRD related services billed by the hospital-based renal dialysis facility on bill type 72x. Hospitals that do not have a Medicare certified renal dialysis facility may bill for outpatient emergency or unscheduled dialysis services. The composite rate is not paid. For more information regarding the outpatient hospital billing policy for ESRD related services, see chapter 4 section 210 of this manual.

When an individual is furnished outpatient hospital services and is thereafter admitted as an inpatient of the same hospital due to renal failure - within 24 hours for non PPS hospitals and within 72 hours for PPS hospitals - the outpatient hospital services furnished are treated as inpatient services unless the patient does not have Part A coverage. Charges are reported on Form CMS-1450. The day on which the patient is formally admitted as an inpatient is counted as the first inpatient day. The composite rate is not paid.

10.6 - Amount of Payment

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

After the beneficiary's Part B deductible is met, FIs pay 80 percent of the facility composite payment rate for each in-facility outpatient maintenance dialysis treatment and 80 percent of this same amount for all home dialysis patients who elect to have their dialysis care reimbursed under Method I. (See the Medicare Benefit Policy Manual, Chapter 11.

10.7 - ESRD Services Not Provided Within the United States

(Rev. 1, 10-01-03)

RDF-221

Services (except for certain inpatient hospital services and related physicians and ambulance services in specified situations) that are not provided within the United States are not covered. United States includes the 50 States, the District of Columbia, the

Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa. See Chapter 1 for additional information concerning specified situations that may be covered, billing and payment procedures and jurisdiction for payment.

10.8 - Transportation Services

(Rev. 1, 10-01-03)

RDF-207.4

In general, transportation services to obtain ESRD services are not covered. However, see the Medicare Benefit Policy Manual, Chapter 10, for coverage of ambulance services to renal dialysis facilities located on hospital premises and for coverage of ambulance services to nonhospital based dialysis facilities. Billing and payment instructions are provided in Chapter 15 of this manual.

10.9 – Dialysis Provider Number Series

(Rev. 771, Issued: 12-02-05, Effective: 01-03-06, Implementation: 01-03-06)

There are multiple facilities that provide dialysis services to ESRD beneficiaries. To ensure that provider data is correct, facilities are required to use a Provider Number based on facility type issued by CMS.

The Provider Number Series for Dialysis Providers are as follows (for CMS use only, effective May 23, 2007, providers are required to submit only their National Provider Identifier (NPI). The dialysis provider numbers will be mapped to the NPI):

2300-2499	Chronic Renal Dialysis Facilities (Hospital – Based)
2500-2899	Non – Hospital Renal Facilities
2900-2999	Independent Special Purpose Renal Dialysis Facility
3300-3399	Children's Hospitals (Excluded from PPS)
3500-3699	Renal Disease Treatment Centers (Hospital Satellites)
3700-3799	Hospital Based Special Purpose Renal Dialysis Facilities

All facilities should use their appropriately assigned provider numbers on the 72x type of bill. In the event that a facility changes from one type to another, the provider number must reflect the facility's present provider type.

20 - Definitions Related to Calculating Composite Rate

(Rev. 1, 10-01-03)

See Chapter 11 of the Medicare Benefit Policy Manual for definitions relating to ESRD and the composite rate.

20.1 – Calculation of Case Mix Adjusted Composite Rate

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

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:

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

The following provider data must also be passed to the ESRD PRICER to make provider-specific calculations that determine the final ESRD composite 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)
ESRD Rate from FISS Map 1105 or 105A or B	9(7)V9(2)

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)

20.1.1 – Calculation for Double Amputee Dialysis Patients

(Rev. 1389; Issued: 12-07-07; Effective: 01-01-08; Implementation: 01-07-08)

For dialysis treatments on or after January 1, 2006, we are revising the reporting requirements for value codes A8 and A9 for double amputee dialysis patients.

Weight should be calculated based on pre-amputation weight using the following formula: Pre-amputation weight = Actual weight x 1.15

Example: Current weight for double amputee patient = 75.5 kg.

Pre-Amputation weight = 75.5 x 1.15 = 89kg.

The results should be reported under value code A8.

Height should be reported under value code A9 as pre-amputation height. Where feasible this measurement may be obtained from Form 2728.

30 - Determination and Publication of Composite Rate

(Rev. 1, 10-01-03)

30.1 - Publication of Composite Rates

(Rev. 373, Issued: 11-19-04, Effective: 01-01-05, Implementation: 01-03-05)

The composite rate regulations require CMS to publish composite payment rates in a "Federal Register" notice when CMS incorporates new cost data or wage index. These rates are updated using new program data or revising the payment methodology. Each base rate consists of a labor portion and a nonlabor portion for both hospital and independent renal facilities. When the composite payment rates are updated, a listing of the new composite payment rates is published. These rates are updated and published as needed and are used when issuing a composite payment rate to a new facility or an existing facility.

The CMS notifies FIs when new composite payment rates are issued. An FI, before the effective date of new composite payment rates, is responsible for notifying each ESRD

facility of its composite payment rate in writing. At the same time, the FI sends a copy of the notification to CMS Central Office at the following address:

Centers for Medicare & Medicaid Services
Center for Medicare Management
Chronic Care Policy Group
Room: C5-05-27
7500 Security Boulevard
Baltimore, MD 21244-1850

The FI must notify the facility of its payment rate even if the facility's payment rate (i.e. the composite cap of $159.08) does not change. Published composite payment rates stay in effect until CMS announces new payment rates. The issuing of new payment rates includes an effective date for these rates, and the procedures for determining an individual facility's payment rates are in the Medicare Provider Reimbursement Manual (PRM), Part I, §2706.1.

30.2 - Determining Individual Facility Composite Rate

(Rev. 373, Issued: 11-19-04, Effective: 01-01-05, Implementation: 01-03-05)

To determine a facility's composite rate payment, use the following procedures:

A. Determine Whether Facility Is Classified as Hospital-Based or Independent Facility

To receive the higher hospital composite rate payment, a facility must be approved by an RO as hospital-based. The RO approves a facility as hospital-based, if it determines that the requirements are met. If these requirements are met, the RO assigns a hospital or hospital-based satellite identification number. If the RO determines that the requirements are not met, it may approve the facility as independent and assign an identification number in the 2000 series. Intermediaries and facilities may assume that existing classifications are proper unless they are changed under the usual annual survey or, at some other time, at the special request of the facility or CMS.

If any ESRD facility is under the Initial Method (IM), add the IM add-on amount to the labor portion of the base composite rate before applying the facility's wage index in calculating the facility's composite rate. (See §2715 of PRM, Part 1 for the IM.)

B. Determine Facility's Wage Index

1. General

Each facility is classified as either urban or rural. Urban facilities use the wage index for the Metropolitan Statistical Area (MSA) in which the facility is located and rural facilities use the rural wage index. The ESRD composite rate payment system utilizes its own wage index that is different from the hospital PPS systems wage index.

2. Application of Wage Index to Hospital-Based Satellite

In some instances, a facility, which is assigned a hospital-based satellite identification number, is located in a different geographical area than the main hospital complex. As a result of its location, the satellite facility is assigned a wage index that is different from the wage index assigned to the hospital. For example, the hospital is classified as urban

and uses the wage index for the MSA in which the facility is located, while the hospital-based satellite is classified as rural and uses the rural wage index for that State. The wage index applicable to the hospital also applies to the satellite if the actual wage scales are identical in both the hospital and satellite facility. The provider must furnish auditable financial data to the FI who demonstrates that the wage scales are identical; e.g., the wages and benefits paid to the employees of the satellite are identical to the wages and benefits paid to the employees of the hospital. The FI reviews the facility's documentation to verify that the wage index for the hospital is also appropriate for the satellite facility, and then submits the notification of the facility's revised rate to CMS. If the wage scales are not identical, the wage indexes are based on each facility's geographical location.

C. New ESRD Composite Payment Rates Effective January 1, 2005 Include a 1.6% Increase and a Drug Add-On Adjustment

In accordance with the appropriate provisions of §623 of the MMA, the new rates will be calculated as follows: (a) the wage adjusted composite payment rates in effect on December 31, 2004 will be increased by 1.6 percent as required by §623(a)(3); (b) these new rates will be further increased by a drug add-on adjustment (or multiplier), in the amount of 8.7 percent. This drug add-on adjustment represents the difference between our current payment of 95% of AWP for separately billed drugs and biologicals, and $10.00 per 1,000 units for EPO, and the acquisition costs of such drugs and biologicals, as determined by Inspector General reports to the Secretary as required by §623(c) and §623(d)(1)(B) of the MMA.

30.3 - Transition Period

(Rev. 1, 10-01-03)

PRM-1-2705

At the time that the composite payment rates were established, the wage index was modified on a transition period basis pending possible development of an alternative wage index based on ESRD-specific salary data. This action was taken because of concern over whether the current wage index is completely valid for ESRD outpatient facilities. Since there is no specific ESRD wage index, the transition continues as follows:

There is a wage index floor of .9; that is, during the transition period, no composite rate is computed with a wage index of less than .9.

30.4 - Record-Keeping and Reporting Requirements Under Composite Rate System

(Rev. 1, 10-01-03)

PRM-1-2717

Each approved ESRD facility must keep adequate records and submit the CMS-approved cost report. Independent facilities are required to submit a completed Form CMS-265 in accordance with CMS Pub. 15-II, Chapter 9. Hospital-based facilities are required to complete Form CMS-2552, the hospital cost report, in accordance with CMS Pub. 15-II.

Failure to submit a timely cost report could result in suspending composite rate payments or revocation of the facility's approval to participate in the program.

Except as noted, the Medicare reasonable cost principles apply in the determination and reporting of the allowable cost incurred by a facility in furnishing outpatient dialysis treatments (in-facility and home).

Reasonable costs under the composite rate do not include:

- Return on equity capital for proprietary providers;
- Reimbursement of organ procurement agencies (OPAs) and histocompatibility laboratories; and
- The cost of providing paid aides for home dialysis patients.

30.5 - Facility Preparation and Intermediary Review of Cost Reports

(Rev. 1, 10-01-03)

PRM-1-2728

ESRD facilities use Form CMS-265 cost report for independent facilities. Form CMS-2552, Supplemental Worksheets I, is used for hospital-based renal facilities.

A - Guidelines for Intermediaries in Processing Cost Reports

It is necessary for the FI to perform a limited review of the cost reports prior to submittal to CMS, focusing on the accuracy and completion of the cost reporting forms. Accurate cost data is required since it is used to establish a computerized renal cost database. The compiled renal cost data is utilized for accumulation of data for overall program evaluation, review of exception requests to the composite rate and for the determination of future composite rates. The FI:

1. Reviews all the information submitted, according to cost reporting instructions contained in CMS Pub. 15-II, for Form CMS-2552 and Form CMS-265 to ensure that all the applicable items have been properly completed. Annotates those items not applicable. Completes all applicable cost reporting forms.
2. Determines that the facilities have utilized the Medicare principles of reimbursement to ensure that only reasonable and allowable costs for furnishing covered services to Medicare beneficiaries are reimbursed. (See PRM §2718 for exceptions to Medicare ESRD costs.)
3. Verifies that the cost for the varying modality of treatments, i.e., peritoneal, hemodialysis, etc., listed on one schedule is also listed on the corresponding schedule on the appropriate lines. ESRD facilities are to report hemofiltration cost and treatment data under the hemodialysis modality.
4. Performs a clerical review by cross-footing and footing cost item columns.

The following procedures outline the type of data that must accompany the appropriate cost reporting forms submitted to CMS for each ESRD facility.

B - Cost Reports

For cost reporting periods beginning on or after October 1, 1987, the ESRD facility cost reports are electronically transmitted to CMS. The hospital-based facilities utilize the Hospital Cost Report Information System (HCRIS) and the independent facilities use the Independent Renal Dialysis Information System (IRDIS). In both HCRIS and IRDIS, edits are included for both accuracy and timeliness under the Contractor Performance Evaluation (CPE). This is a continuation of the CPE review previously performed by CMS.

Hospital-Based ESRD Facilities - A hospital must submit the following worksheets from the cost report Form CMS-2552: Supplemental Worksheets S-5, I-2 (Parts I and II), I-3, and I-4.

The cost of the approved drug epoetin (EPO) furnished to ESRD patients must be listed on Supplemental Worksheet I-2, Parts I and II, line 31. Do not transfer the total cost of furnishing EPO on these supplemental worksheets to Supplemental Worksheet I-3, column 2.

Independent ESRD Facilities - An independent facility must submit the entire cost report Form CMS-265. The facility must continue to submit a copy of its audited financial statement (if available) or unaudited for the accounting period as specified to its servicing FI.

The cost of the approved drug epoetin (EPO) furnished to ESRD patients must be listed on Schedule A, line 25 and Schedules B and B-1, line 18. Do not transfer the total cost of furnishing EPO on these schedules to Worksheet C, column 2.

C - Submission of Cost Reports

An ESRD facility must submit an annual cost report (Form CMS-265) or Supplemental Worksheets (Form CMS-2552, Worksheets I-1, 2, and 3) and other worksheets as stated.

Cost reports are due on or before the last day of the third month following the close of the period covered by the report. Any ESRD facility failing to submit the cost reporting form to the FI within the specified time periods is subject to a suspension of its Medicare reimbursement.

All FIs must submit the unaudited cost report for each renal dialysis facility to CMS after completion of the FI's review. The independent facility's cost report is primarily filed as unaudited, unless CMS requests an audit of the cost report to substantiate a facility's exception request. The unaudited cost report for each individual ESRD facility must be provided to CMS within 180 days of the facility's fiscal year end or 60 days after FI receipt, whichever is later.

In order for CMS to maintain accurate cost data in the renal dialysis cost system, the FI after completion of final settlement (Notice of Provider Reimbursement has been issued), submits a copy of the finalized hospital-based cost report with all adjustments. This submission must be sent to CMS within 30 days after issuance of the Notice of Final Settlement. If the final settlement is made with no changes to the unaudited cost report for the renal dialysis department (as previously sent to CMS), the FI must notify CMS that there are no changes. Subsequent submissions are required each time a settled cost report is reopened and the renal dialysis costs are adjusted. These submissions are due within 30 days after the date of each final settlement.

The ESRD facility must submit Forms CMS-265 and CMS-2552, Supplemental Worksheets Is to its FI which, in turn, must review and electronically transmit the cost reporting forms to CMS.

Incomplete cost reporting forms are returned to the FI for transmittal to the facility for completion.

30.6 - Issuance of Notice of Program Reimbursement

(Rev. 1, 10-01-03)

PRM-1-2719

Upon completion of the desk review and/or audit of the ESRD facility's cost report, the FI issues a notice of program reimbursement (NPR). The NPR is prepared using the guidelines in §2906 (PRM, Part 1). An NPR issued for an ESRD facility must include reimbursement for bad debts. All adjustments made by the FI need to be explained in the NPR. The provider appeal rights are explained in the NPR. In addition, to protect the facility's appeal rights under Subpart R, an NPR is issued even though the provider is not claiming reimbursement, or the FI has not changed the requested amount.

A separate NPR need not be issued for a hospital-based ESRD facility. Instead, the facility's activities are combined with the other hospital activities on a single NPR.

40 - Processing Requests for Composite Rate Exceptions

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

40.1 – General Instructions for Processing Exceptions Under the Composite Rate Reimbursement System

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A hospital-based or independent renal dialysis facility may request CMS to approve an exception to the composite payment rate and set a higher payment rate, if the facility has an estimated allowable cost per treatment higher than its composite rate, and if the higher costs relate to the exception criteria referenced below. The costs in excess of the composite rate must be attributable to items and services provided to Medicare patients for maintenance dialysis, whether furnished at home or in a hospital-based or independent facility. All of the facility's costs with respect to all modes of outpatient maintenance dialysis (exclusive of self-dialysis training costs), for both in-facility and home dialysis patients are considered in an exception request for any mode of dialysis. For example, if the facility's peritoneal dialysis cost per treatment exceeds its composite rate payment, no exception is granted if the facility's total maintenance dialysis revenues exceed its total maintenance dialysis costs. In considering exception requests for self-dialysis training, only the costs relating to self-dialysis training are considered.

Section 623(b)(1)(D) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173 provides only for the submission of new pediatric facility exception requests in the case of a pediatric facility that did not have an approved exception rate as of October 1, 2002. The statute defines the term "pediatric facility" to mean a renal facility with at least 50 percent of whose patients are individuals under 18 years of age.

A pediatric ESRD facility can file an exception request at any time it is in operation for at least 12 consecutive months. The facility must submit its ESRD exception request in duplicate to its servicing intermediary. Upon completion of its review, the servicing intermediary can either deny the facility's exception request and furnish a copy of its denial letter to CMS, or the intermediary furnishes one copy of the facility's request together with its recommendation and original workpapers to CMS for adjudication. Upon adjudicating the documentation submitted by the facility and the intermediary, CMS will send its decision letter to the servicing intermediary, which will notify the facility of CMS's decision.

An exception request is deemed approved unless CMS disapproves a composite rate exception request within 60 working days after it is filed with the intermediary. To meet the 60 working days deadline required by law, the first day for counting is the date that the exception request is filed with all required documentation with the intermediary. Facilities are advised to send their requests by a method which documents the date of receipt during the intermediary's regular business hours.

Delivery of pediatric exception requests to intermediaries must be accomplished through a method which documents the date of receipt. A postmark or other similar date does not serve as documentation of the date of receipt.

40.2 - Criteria for Approval of ESRD Exception Requests

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant Medicare cost reimbursement principles and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

A. Pediatric patient mix, as specified in section 40.7, and

B. Self-dialysis training costs in pediatric facilities, as specified in 40.8.

40.3 - Procedures for Requesting Exceptions to ESRD Payment Rates

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

The pediatric ESRD facility is responsible for justifying and demonstrating to CMS's satisfaction that the requirements of this section and the exception criteria listed in this chapter are met in full. The burden of proof is on the facility to show that one or more of the criteria are met and that the facility's costs in excess of its composite payment rate are justifiable under the Medicare reasonable cost principles.

A. A pediatric facility filing a request for an exception must meet the following conditions:

1. Submittal of written justification.

The pediatric facility must provide written justification for supporting the facility's higher cost. The fact that the facility projects costs higher than its composite payment rate is not adequate documentation for granting an exception. The facility must provide

CMS with supporting material documenting the reasons that may justify its costs in excess of its composite payment rate(s).

2. Amount requested.

The pediatric facility must list its current composite payment rates and the requested composite payment rate for each modality of treatment, i.e., outpatient maintenance (including the home program) and home training. The amount requested must be identified by specific cost component(s), for example, salaries, supplies, overhead, and laboratory with a cross reference to the narrative explanation and the work papers supporting the exception request.

3. Cost per treatment.

A pediatric renal facility must submit a schedule showing the cost per treatment (CPT) for each component cost by mode of dialysis treatment. The cost components (i.e., salaries, supplies, depreciation) are those reported by a facility on its cost report. The CPT for each component cost must reconcile with reported costs. In addition, a facility must submit a schedule combining total outpatient and home maintenance dialysis costs, since the composite rate system is based on a single payment for all outpatient maintenance dialysis treatments (infacility and home). This schedule combines the facility's infacility outpatient maintenance costs with its home dialysis maintenance costs and computes a CPT for these combined costs. This schedule is required for both actual and budgeted costs.

4. Budget estimate.

A pediatric facility must submit a projected budget estimate and utilization trend through the period for which the exception rate is to apply, showing that its allowable CPT is higher than its composite rate, and that the costs in excess of the composite rate are attributable to factors related to one of the below stated exception criteria. Any significant variance between budgeted treatments and actual treatments furnished in the prior year must be addressed in the supporting documentation. The documentation to support the projected budget estimate must be submitted in the following format:

- Appropriate completed cost reporting schedules; i.e., Worksheets I-1, 2, and 3 of Form CMS-2552 (hospital-based facilities) or Form CMS-265 (independent facilities) full cost report listing the projected budget costs; and
- Documentation supporting any significant increases in budgeted costs over actual costs reported for prior reporting period.

5. Reporting actual costs and cost reporting requirements.

A pediatric renal facility must submit a copy of its most recently filed cost report. When the facility submits a revised cost report, it must have received prior intermediary approval to change its cost allocation methodology in accordance with cost reporting instructions contained in CMS Pub. 15-II. No intermediary approval is needed if the facility is changing to the recommended statistics, as described in the cost report instructions. However, the facility must submit a copy of the revised cost report to its intermediary who must accept it. In addition, the facility must state that it has auditable documentation to support its statistical basis for the reallocation and must explain the

reason for any shifting of costs. If the revised cost allocation is for the purpose of shifting costs to meet the exception criterion or in less costs being allocated to inpatient treatments than outpatient treatments, CMS disregards the revised cost report and uses the latest actual cost report received by the intermediary.

The facility must submit the following cost reports:

A - Provider-based facilities—The provider must submit the previous year's complete cost report Form CMS-2552 and Worksheets I-1, 2, and 3 (with the attached analysis of other expenses in the renal department as shown on Worksheet A, line 41 and line 59, column 2). A provider may not revise Worksheet I merely to reflect a more favorable historic financial position when filing an exception request.

B - Independent facilities—The independent facilities must submit the full cost report Form CMS-265 and a copy of the facility's audited financial statement (if available) or unaudited for the accounting period specified on the cost report. An independent facility may not revise the Form CMS-265 merely to reflect a more favorable historic financial position when filing an exception request.

6. Laboratory.

The facility must submit a list of the laboratory tests used routinely in the dialysis procedure. Laboratory tests are defined in:

- §50-17 of the Coverage Issues Manual for hospital-based facilities; and
- §207.1 of the Renal Dialysis Facility Manual for independent facilities.

7. Drugs/Medications.

The facility must submit a list of the drugs/medications covered under the composite rate (see §2710.2) that the facility furnishes to its dialysis patients.

8. Routine ancillary cost.

Routine items include laboratory, oxygen therapy, drugs/medications and supplies, and services which are commonly furnished as part of a typical dialysis service. These costs are reimbursed through the facility's dialysis composite payment rate and may not be billed separately. Also included are procedures such as the hemodialysis flow study and Doppler flow study when such procedures are used to monitor the access site.

9. Nonroutine ancillary cost.

The facility must exclude nonroutine items and services from its allowable cost because they are not considered part of the dialysis service costs that are used in computing its composite payment rate. Additional ancillary items and services that are not routinely furnished, but medically necessary for some patients, must be separately billed, justified for medical necessity, and verified by the intermediary. Nonroutine items and services such as drugs/medications, supplies, and laboratory tests are not part of the normal dialysis and are not reimbursed through the facility's rate and may therefore be billed separately.

10. Satellite facilities.

Although satellite facilities are separate facilities and receive a separate provider number for certification purposes, they are still considered to be part of the hospital complex. Their costs flow through the hospital and are reported on the hospital's cost report. Therefore, when CMS processes an exception request from a hospital-based facility that has one or more satellite facilities associated with it, CMS reviews the costs and circumstances of the entire facility including all satellites, to see if the exception criteria are met.

11. Inpatient treatments.

A hospital renal facility must submit with its current cost report the number of inpatient dialysis treatments it furnished. The hospital computes a CPT and provides an explanation if its inpatient CPT is equal to or less than the provider's outpatient CPT. An independent renal facility also provides similar information if it is furnishing inpatient treatments under arrangement.

12. Onsite review.

Any facility that requests an exception to its composite payment rate is required to maintain records and furnish information to substantiate the costs incurred and that its costs are in excess of the composite rate and are attributable to one or more of the exception criteria. CMS may determine that an onsite review of the facility is necessary to aid CMS in its review of the exception request by evaluating the efficiency and the economy of the facility's operation. The findings resulting from the onsite review are used as a basis for adjudicating the facility's exception request. The onsite review is performed by the area servicing intermediary.

13. Materials submitted to CMS must also include the following:

(a) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate,

(b) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the Medicare reimbursement cost principles,

(c) Show that the elements of excessive cost are specifically attributable to one or more of the exception criteria (specified in section 40.2),

(d) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(e) Specify that the facility has compared its most recently completed and filed cost report with cost reports from at least 2 prior years, if available. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request, and

(f) Remove costs associated with separately billable items.

40.4 - Period of approval: Payment exception request.

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its intermediary until thirty days after the intermediary's receipt of the facility's letter notifying the intermediary of the facility's request to give up its exception rate and be subject to the basic case-mix adjusted composite payment rate methodology. An ESRD facility that has an existing exception rate may give up that rate if it determines that it will be paid a higher composite payment rate under the new case-mix adjusted composite rate methodology. Each ESRD facility must notify its fiscal intermediary (in writing) if it wishes to give up its existing exception rate(s) or its pediatric facility's exception rate(s). The facility will be paid based on its case-mix adjusted composite payment rate beginning thirty days after the intermediary's receipt of written notification that the facility wishes to give up its exception rate. Once a facility notifies its fiscal intermediary that it wishes to give up its exception rate, that decision cannot be subsequently rescinded or reversed. ESRD facilities that retain their existing exception rates do not need to notify their intermediaries.

40.5 - Criteria for Refiling a Denied Exception Request.

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

CMS denies exception requests submitted without the general documentation specified in section 40.2 and the documentation specified in the applicable exception criteria (sections 40.8 and 40.9). A pediatric ESRD facility that has been denied an exception request may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

40.6 - Responsibility of Intermediaries

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

All pediatric composite rate exception requests are to be reviewed and processed within 15 working days from the date that the exception is filed. The intermediary must verify that the exception request contains documentation to support the renal facility's position. When the renal facility fails to submit the required documentation, the exception request is returned to the facility. The 60 working days start when a pediatric renal facility files an exception request with all required documentation with the intermediary during the intermediary's regular business hours.

A - Inform CMS central office of pediatric composite rate exception requests

To track the start of the 60 working day requirement, intermediaries must call CMS central office the day a pediatric composite rate exception is received. The contact person is listed on telephone number (410) 786-5472. The following information is provided:

- The name and provider number of the pediatric renal facility;
- The date the exception is received;
- The type of exception, e.g., pediatric patient mix;
- The amount requested;

- A phone number and contact person at the intermediary.

B – Composite rate exception log

- The intermediary maintains a composite rate exception log. The purpose of this log is to monitor the 15 working days and to ensure the timely processing of all pediatric composite rate exceptions. In addition, the log documents the starting date for processing composite rate exceptions. This is in case a renal pediatric facility alleges that its composite rate exception was not processed within 60 working days. The following information is included in the log:
- The date the exception is received by the intermediary. (The intermediary date stamps each request.);
- The renal pediatric facility's reason for requesting the exception;
- The intermediary's reason for returning the exception;
- The intermediary's recommendation to either approve or deny the facility's request. (All workpapers supporting the intermediary's decision must accompany the facility's exception request when mailed to CMS central office.); and
- The date the exception is mailed to CMS central office.

C – Intermediary review

The following procedures are applied after receiving a facility's pediatric composite rate exception request:

- The intermediary reviews the exception request, the cost report, the facility's projected costs, and any other documentation submitted by the facility to assure that it is complete and accurate. If the renal facility fails to submit the required documentation, the exception request is returned to the facility.
- Mailing of the exception request. After completing its review of the renal facility's exception request, the intermediary mails the facility's exception request plus its recommendation with all its supporting work papers to CMS central office. To expedite the exception process, the intermediary mails all exception requests using an overnight delivery service. In its cover letter, the intermediary must state the date the exception request was received in its office.
- Determination of reasonable and allowable costs. The intermediary determines that Medicare principles of reimbursement were used to ensure that only reasonable and allowable costs are included in the facility's costs. The facility reviews the following reimbursement areas:

    1. Bad Debts--Facilities are not to include an allowance for doubtful accounts in reported costs but submit separately the total dollar amount of bad debts actually incurred. Allowable bad debts include only uncollectible deductibles and coinsurance related to covered composite rate services furnished to Part B beneficiaries. Renal facilities may not claim the 50 cents reduction required by §9335(j) of OBRA 1986 as an expense on their Medicare cost reports. The intermediary verifies that renal facilities have properly treated this 50 cents

reduction before the facility calculates it reimbursable bad debts or files for an exception request. (See §§300 and 2714.)

2. Allowable Compensation for Physician Owners and Medical Directors—Compensation, including fringe benefits, paid to a physician owner or medical director may not exceed the reasonable compensation equivalent (RCE) limits currently in effect for a specialty of internal medicine for a metropolitan area of greater than one million people. See §2182 for a description of the RCE limits and §2182.6 for the current salary limit for a specialty of internal medicine. The physician's salary reported as a Medicare allowable cost for administrative services may not exceed the RCE limit. Furthermore, the facility must adjust the RCE limit by the time spent by the physician as owner or medical director performing administrative services for the facility. Based on Medicare program statistics, the median amount of time spent by physicians in ESRD facilities on administrative duties is 25 percent. If a facility reports that a physician spends more than 25 percent of his or her time performing administrative type services, the facility must document its claim. If no documentation is furnished and the facility is reporting physicians' time in excess of 25 percent, the intermediary limits the physician's compensation to the lower of the amount claimed or 25 percent of the RCE limit in effect. If the physician as owner or medical director furnishes services to more than one facility, his or her total time may not exceed 25 percent unless the facility has documentation to support its claim. A renal facility may adjust the 25 percent limit to reflect special facts or circumstances, e.g., a medical director may spend more time at a renal facility that furnishes a large number of treatments and other medical services than most renal facilities. If a renal facility claims a higher percentage of time, it must be able to document the medical director's actual time spent performing administrative duties.

3. Allowable Compensation for Owners, Administrators, and Assistant Administrators—-Reasonable compensation, including fringe benefits, paid to owners, administrators, and assistant administrators is an allowable cost. (See §904.) In most instances, compensation paid to these individuals may not exceed $120,000. When these individuals spend less than 100 percent of their time performing services, adjust the $120,000 to reflect the actual time spent at the facility. If an individual provides services to more than one renal facility, the individual's time must be prorated among the different entities and may not exceed 100 percent. In certain circumstances, a renal facility could claim more than the $120,000 limit, e.g., it may be reasonable for a renal facility furnishing a large volume of dialysis treatments and other medical services to pay an individual in excess of $90,000. In these circumstances, an intermediary may survey other renal facilities to determine if the higher amount is reasonable.

4. Depreciation--An appropriate allowance for depreciation on building and equipment is an allowable cost. Payment for services includes depreciation on all depreciable type assets that are used to provide covered services to beneficiaries. (See §104.)

5. Start-up and/or Organizational Costs--Start-up and organizational costs are allowable costs under the program. The start-up and organizational costs incurred must be amortized over an appropriate period of time. (See §2132.)
6. Interns and Residents--Reasonable costs for an approved intern and resident teaching program, if comparable to the costs of other similar facilities that have educational programs, are reimbursable to the hospital under the program. (See §404.)
7. Nursing School--An approved nursing education program must be operated by a provider (or jointly by a group of providers) for students of the provider(s) for Medicare to recognize the costs of the program as allowable costs of the provider(s). (See §404.)
8. Medical Records--The reasonable cost of medical records is reimbursable under the program.
9. Cost to Related Organizations--This cost represents the cost applicable to services, facilities, and supplies furnished to the facility by organizations related to the facility by common ownership or control and is included in the allowable cost of the facility at the cost to the related organization. (See §1005).
10. Home Office Costs—These costs directly related to those services performed for individual facilities which relate to patient care plus an appropriate share of indirect costs (overhead, rent, administrative salaries, etc.) are allowable to the extent they are reasonable. (See §2150.)
11. Prudent Buyer--Facilities are to utilize the prudent buyer concept by refusing to pay more than the going price for an item or service. This is especially so when the buyer is an institution or organization which makes bulk purchases and can, therefore, often obtain discounts because of the size of its purchases. (See §2103.)
12. Dietary--Facilities are not to include the cost of meals served to patients in the outpatient renal department in their reported total costs. However, the reasonable cost of dieticians' salaries is reimbursable under the program.

- Cost Report Review--The intermediary performs a limited review of the cost reports prior to submitting to CMS.

    1. The intermediary reviews all the cost reporting forms and information submitted in accordance with CMS Pub.15-II to ensure that all the applicable items have been properly completed. All cost reporting forms must be completed. Those items not applicable are submitted and annotated as N/A (not applicable).

    2. The intermediary identifies changes in the CPT, lists the requested CPT by modality (i.e., hemodialysis, peritoneal dialysis, and home program), and compares this data with the CPT in the most current cost report. Then, the intermediary determines whether the facility has adequately explained any variances in its narrative documentation.

3. The intermediary performs a clerical review by cross footing cost item columns.

- Submission of Documentation--The intermediary submits the exception request, a preliminary recommendation, including appropriate workpapers and the reason for the decision, and the cost report and supporting documentation to the following address:

  Centers for Medicare and Medicaid Services
  Centers for Medicare Management
  Chronic Care Policy Group
  Division of Chronic Care Management
  7500 Security Boulevard
  Baltimore, Maryland 21244-1850

  To provide that all filings by the provider are handled by the intermediary, the intermediary instructs the provider to:

- Mail all exceptions separately from any other material, e.g., Medicare cost reports that are not related to exception requests, and
- Use specially marked envelopes to forward the exception to the intermediary.

40.7 - Payment exception: Pediatric patient mix.

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A. General

An exception to the composite payment rate for pediatric patient mix is allowed under specific circumstances. This exception is limited to those situations where the facility can demonstrate that it expects to incur higher than average per treatment costs which are directly related to at least 50 percent of its patients (individuals under 18 years of age), and because of their complex medical needs require more intense care, special dialysis procedures or supplies during an outpatient maintenance dialysis session.

B. Criteria

To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate the following--

(1) The provider must document that for the most recently completed and filed cost reporting year that at least 50 percent of its dialysis outpatients (including home patients) are individuals under 18 years of age;

(2) The provider must submit data which demonstrates that its pediatric patients will receive significantly more nursing (refers to RNs, LPNs, technicians and aides) hours per treatment than patients receive in other facilities. The increased hours of nursing service must be justified by data that demonstrate that the higher hours per treatment and thus the higher per treatment costs are necessitated by the special needs of the pediatric patients.

(3) Data must be submitted that show that higher staff-to-patient ratios represent nursing assessment/intervention based upon the pediatric patient acuity levels. The provider must demonstrate that its nursing personnel costs are allocated properly between each mode of care and that the additional nursing hours per treatment are not the result of an excess number of employees in the outpatient maintenance renal area, compared to facilities treating a similar patient mix;

(4) The provider must also show that excess supply cost per treatment is related to the special needs of the pediatric patients and not the result of inefficiency. CMS uses, as a guideline, manufacturer and supplier price lists, and cost reporting information from other facilities.

(5) There are infrequent instances when higher overhead costs may be justifiable, such as when an isolated area is required for a hepatitis patient. General statements regarding a facility's higher overhead costs are not acceptable in meeting the criteria.

(6) A listing of patients by diagnosis and general statements submitted regarding the medical conditions of a facility's pediatric patient population without showing the adverse effects of patient mix on facility costs are unacceptable in meeting this exception criteria. Therefore, documentation that does not identify both the specific additional items and/or services to be rendered which are in addition to a routine dialysis service and the incremental costs of these items and/or services do not qualify for an exception under this section. Also, a one-month time sampling is not sufficient documentation to verify the acuity of a facility's ESRD patient population nor to justify increased salary costs. In the event that a time study is used, the general Medicare principles regarding the adequacy of periodic time sampling as described in §2313 must be followed.

C. Documentation

(1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report showing--

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must-

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed and filed fiscal year cost report showing-

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing-

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing:

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

40.8 - Payment Exception: Self-dialysis Training Costs in Pediatric Facilities

(Rev. 781, Issued: 12-16-05, Effective: 01-01-06, Implementation: 01-17-06)

A General

Self dialysis and home dialysis training are programs that train ESRD patients to perform self dialysis in the facility or home dialysis (including CAPD and CCPD) with little or no professional assistance. They also train other individuals to assist patients in performing self dialysis or home dialysis. A facility that has training costs greater than its composite training rate may apply for an exception to its training rate. However, the burden of proof is on the facility and it is responsible to demonstrate to CMS that its per treatment costs are reasonable and allowable. Further, the facility must train an average of three patients over a two year period (if 2 years are available.)

B. Criteria

To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for the training sessions.

To justify its exception request, a facility must--

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

C.Criteria for determining proper cost reporting. CMS considers the pediatric ESRD facility's total costs, cost finding and apportionment, including its allocation of costs, to

determine if costs are properly reported by treatment modality. Under the composite rate, the cost of the home program is reimbursed at the same rate as infacility dialysis. Therefore, it is important that the pediatric ESRD facility keep its home program and home dialysis training cost separated.

D Limitation of exception requests. Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

E Documentation. The pediatric ESRD facility must provide the following information to support its exception request:

(1) A copy of the facility's training manual and training program. The training manual must be submitted with the first training request. Thereafter, the facility submits only the changes to the training manual. The training program must be submitted with each training request.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients and the length of time required for each session.

(5) List of patients trained for the current year and the prior 2 years (except for a newly certified provider which submits only 12 months of data) on a monthly basis by modality, number of treatments, completed training, retrained or cross-trained. The number of training treatments must reconcile with the number of training treatments reported on the latest completed and filed cost report.

(6) Projection for the next 12 months of future training candidates and the number of training sessions required by treatment modality to train them and the length of time for each session.

(7) The number and qualifications of staff at training sessions and the rationale in allocating staff time to home training, home support and other duties.

(8) Supplies – A higher composite training rate is granted if the ESRD pediatric facility is able to document that its cost in excess of the composite training rate is attributable to supplies required to train patients. For example, an ESRD pediatric facility may incur higher supply costs to train its patients because of wastage. To justify supply cost, the facility must submit the following information:

- A list of supplies used during a training and maintenance dialysis session;
- A cost per treatment computation for supplies listed above;
- An explanation of any difference in cost and type of supplies between maintenance and training dialysis session; and

- A comparison and projection of the five most expensive supply costs with the catalog list price or notification of higher charges by its suppliers.

(9) Special education costs – An ESRD pediatric facility which incurs costs in excess of its composite training rate and which are attributable to educational materials or equipment used to train patients, may be granted an increase to its composite training rate. For cost in excess of the composite training rate to be reimbursed, the ESRD facility needs to document its cost per treatment for these special education items and it projected costs. To justify its request for exception, a facility needs to provide the following information:

- A description of the educational item;
- Its costs (number purchased and unit cost);
- Its useful life, if it is reusable; and
- A projection of training sessions and patients to be trained.

F Accelerated training exception. (1) A pediatric ESRD facility may only bill Medicare for a dialysis training session when a patient receives a dialysis treatment (normally three times a week for hemodialysis). If a pediatric ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the--

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility receives in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(2) Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities, and ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided. An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training. In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(3) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period. The facility must submit with the exception request a list of patients, by modality, trained during the most recently completed and filed cost report. The list must include each beneficiary's--

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

The total treatments from the above patient list must be the same as the total treatments reported on the cost report filed with the request. Further, retraining sessions are not considered in determining the minimum number of training sessions because retraining sessions are only for patients that have previously been trained and are completed in one or two days.

50 - In-Facility Dialysis Bill Processing Procedures

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

General instructions for billing via UB-*04* or ANSI X12N formats are in Chapter 25. The following instructions apply to facility reporting of ESRD services and to FI processing of in-facility dialysis claims.

The shared system checks the Common Working File (CWF) to determine if there is Employer Group Health Plan (EGHP) insurance. Where the beneficiary is covered under the EGHP insurance, see the Medicare Secondary Payer Manual.

50.1 - Laboratory Services Included in the Composite Rate

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

The costs of certain ESRD laboratory services performed by either the ESRD facility or an independent laboratory are included in the composite rate calculations. Therefore, payment for all of these tests is included in the composite rate and may NOT be billed separately to the Medicare program. For an exception, see the discussion of ESRD related laboratory tests in Chapter 16 of this manual.

These tests are either performed by the facility, in which case payment is included in the composite rate, or by an outside laboratory for the facility, in which case the laboratory bills the facility, which is paid only under the composite rate.

For the laboratory tests and the frequency of coverage included in the composite rate for hemodialysis, intermittent peritoneal dialysis and continuous cycling peritoneal dialysis see the Medicare Benefit Policy Manual (100-02, Chapter 11, Section 30.2).

For the laboratory tests and the frequency of coverage included in the composite rate for continuous ambulatory peritoneal. See the Medicare Benefit Policy Manual (100-02, Chapter 11, Section 70.2).

50.2 - Drugs and Biologicals Included in the Composite Rate

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

Certain drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items or are used to accomplish the same effect are also included in the composite rate.

The administration of these items (both staff time and supplies) is covered under the composite rate and may not be billed separately. Self-administered items are not covered under the Medicare program with the exception of EPO. For a list of the drugs included in the composite rate see the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 11, Section 30.4.1).

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

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

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.

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.

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.

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 hemoglobin reading taken before the last administration of Erythropoietin (EPO) during this billing cycle. This is usually reported in three positions with a decimal. Use the right of the delimiter for the third digit.

Effective January 1, 2006 the definition of value code 48 is changed to indicate the patient's most recent hemoglobin reading taken before the start of the billing period.

49 - Hematocrit Reading - Code indicates the hematocrit reading taken before the last administration of EPO during this billing cycle. 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.

Effective January 1, 2006 the definition of value code 49 is changed to indicate the patient's most recent hematocrit reading taken before the start of the billing period.

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).

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.

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 are required for ESRD Billing for Adequacy of Hemodialysis. For information on reporting the urea reduction ratio with modifiers G1 through G6, see section 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.

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.

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.*

50.3.1 - Submitting Corrected Bills

(Rev. 1, 10-01-03)

RDF-320.1

Claimants must submit a corrected Form CMS-1450 if any of the following apply to a previously processed claim:

- A change in provider number;
- A change in coinsurance involves an amount greater than $1.99; or
- A change in visits (decrease or increase).

Claimants must follow procedures for submitting corrected bills in Chapter 26.

50.4 – Line Item Detail Billing and Automated Claim Adjustments

(Rev. 1364, Issued: 11-02-07: Effective: 04-01-08; Implantation: 04-07-08)

The implementation of line item detail billing for ESRD claims effective on April 1, 2007 requires that each service be submitted on a separate line with the appropriate line item date of service. The Medicare standard systems perform line item date of service compare for RDFs claims with statement billing periods overlapping the statement billing period of another processed claim. This prevents monthly claims from receiving overlapping edits based on the statement billing period dates but rather, only when the RDF claim has a line item that duplicates another processed claim or falls within the dates of an inpatient hospital stay. Standard systems reject only those overlapping line items while any line items not overlapping another claim continue to process for payment. As a result of this logic, the RDFs no longer have to submit the occurrence span code 74 on the monthly dialysis claim when an inpatient stay occurred during the same month.

The initial line item detail billing instruction did not implement a process for rejecting services on the RDF claim overlapping an inpatient stay when the RDF claim is received before the inpatient hospital claim. A subsequent instruction implemented for April 1, 2008 requires the Medicare Common Working File (CWF) to create an informational unsolicited response prompting the standard system to perform an automated adjustment of the processed 72x claim that contains line item dates of service that are overlapping dates of an incoming inpatient hospital claim. The admission and discharge dates of an inpatient stay are not considered overlapping dates and may be payable to the RDF.

50.5 - IPD in the Facility

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

Payment for IPD in the facility is subject to the same payment rules as hemodialysis.

50.6 - In-Facility Back-Up Dialysis

(Rev. 1, 10-01-03)

RDF-245.2.D

Back-up dialysis is an in-facility dialysis treatment furnished to a home dialysis patient. Condition code 76 must appear as one entry in FLs 24-30. The facility must explain why any in-facility backup dialysis sessions (furnished on either an inpatient or outpatient basis) are furnished to home dialysis patients who are covered under the composite rate. If a backup session is furnished because of a failure to furnish any of the required items or services, then it will be covered only to the extent of a home dialysis session and reimbursed at the facility's composite rate. If the backup dialysis is furnished by an institution other than the home patient's composite rate facility, then the composite rate facility must assume financial liability for any cost or charge in excess of the facility's composite rate except where the patient is traveling away from home.

50.6.1 - Payment for In-Facility Maintenance Dialysis Sessions Furnished to CAPD/CCPD Home Dialysis Patients

(Rev. 1, 10-01-03)

A3-3644.1, 3171.1

Although CAPD and CCPD patients are home dialysis patients, it may be necessary at times to dialyze them in-facility as a substitute. In this case, the total weekly reimbursement to the facility remains the same regardless of the type and frequency of in-facility dialysis involved.

In order to furnish covered CAPD services, a facility must be a Medicare approved ESRD facility and must meet additional standards established by CMS.

However, in rare instances an ESRD patient may require a combination of dialysis techniques, on the same day, in order to achieve satisfactory results. In these situations, Medicare pays for both types of dialysis services furnished on the same day. Medicare FIs determine the medical necessity. In each case the FI obtains medical documentation from the facility that supports the use of back-up dialysis with another treatment

modality. If a CAPD patient frequently requires back-up sessions, the FI's medical staff may request medical records to determine if this is the appropriate mode of treatment to meet medical necessity requirement for payment purposes and/or whether a different mode of treatment is more advantageous to the beneficiary.

50.6.2 - Payment for Hemodialysis Sessions

(Rev. 1, 10-01-03)

A3-3644.1

Hemodialysis is typically furnished three times per week in sessions of three to five hours duration. Each hemodialysis session equals one composite rate payment. Therefore, three sessions per week is three composite rate payments. Dialysis furnished at this frequency is paid without medical justification in the ICD-9 field of the claim (FL-68-75). The justification must support the medical necessity of the service(s) being rendered.

50.7 - Ultrafiltration

(Rev. 1, 10-01-03)

PRM-1-2702.2

Ultrafiltration (revenue code 0881) is a process for removing excess fluid from the blood through the dialysis membrane by means of pressure. It is not a substitute for dialysis. Ultrafiltration is used in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. It is commonly done during the first hour or two of hemodialysis on patients who, for example, have refractory edema.

Pre-dialysis Ultrafiltration - While the need, if any, for pre-dialysis ultrafiltration varies from patient to patient, the facility's composite rate covers the full range of complicated and uncomplicated outpatient dialysis treatments. Therefore, no additional charge is recognized for pre-dialysis ultrafiltration.

Separate Ultrafiltration - Occasionally, medical complications require that ultrafiltration be performed at a time other than when a dialysis treatment is given, and in these cases an additional payment may be made. However, the claim must be documented in the medical record and included on the billing form in the ICD-9 field (FL-68-75) as to why the ultrafiltration could not have been performed at the time of the dialysis treatment. The FI determines the payment based on the facility's cost of furnishing the ultrafiltration, not to exceed the facility's composite rate.

50.8 - Training and Retraining

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

See the Medicare Benefit Policy Manual, Chapter 11, for coverage rules for dialysis training.

Training services and supplies that are covered under the composite rate include personnel services, dialysis supplies and parenteral items used in dialysis, written training manuals, material and laboratory tests. The facility is reimbursed an add-on amount to their composite rate and the amount is dependent on the type of dialysis, as shown below:

0821	Composite Rate	Plus	$20.00
0831	Composite Rate	Plus	$20.00
0841	Composite Rate	Plus	$12.00
0851	Composite Rate	Plus	$20.00

Training

For intermittent peritoneal dialysis (IPD), continuous cycling peritoneal dialysis (CCPD) and hemodialysis training:

> The facility's composite rate (exclusive of any approved exception amount) plus $20 per training session, furnished up to three times per week. A facility is not reimbursed for more than three IPD or for hemodialysis training treatments in a single week, of for a total duration longer than 3 months, unless it has received an exception in accordance with §40 of this chapter. A maximum of 15 CCPD training sessions are reimbursable.

For continuous ambulatory peritoneal dialysis (CAPD):

> The facility's composite rate (exclusive of any approved exception amount) plus $12 per training session. Only one CAPD training session per day is reimbursable, up to a maximum of 15.

Retraining

A. General - Occasionally, it is necessary to furnish additional training to an ESRD self-dialysis beneficiary after the initial training course is completed. Retraining sessions are paid under the following conditions:

- The patient changes from one mode of dialysis to another, e.g., from hemodialysis to CAPD;
- The patient's home dialysis equipment changes;
- The patient's dialysis setting changes;
- The patient's dialysis partner changes; or
- The patient's medical condition changes e.g., temporary memory loss due to stroke, physical impairment.

The patient must continue to be an appropriate patient for self-dialysis.

B. Payment Rates - Retraining sessions are reimbursed at the same rate as the facility's training rate.

C. Duplicate Payments **-** No composite rate payment is made for a home dialysis treatment furnished on the same day as a retraining session. In the case of a CAPD patient, the facility's equivalent CAPD daily rate is not paid on the day(s) of retraining.

EXAMPLE: A CAPD patient dialyzes at home Monday and Tuesday. On Wednesday he attends a retraining session at his facility. Thursday through Sunday he dialyzes at home. The facility's composite rate is $130 per treatment. The Part B deductible is met. For that week the facility's payment is:

80 percent of:

CAPD weekly rate = 3 X 130 = $390

CAPD daily rate = $390 ÷ 7 = $55.71

CAPD training rate = $130 + $12 = $142

6 X 55.71 = $334.26

+ $142

$476.26

Therefore, for the week Monday - Sunday, payment is 80 percent X $476.26 = $381.01

NOTE: Often, services furnished to a CAPD patient who has already completed a course of training are home support services, and not retraining services. Reviewing the CAPD patient's technique and instructing him/her in any corrections or refinements in technique is a support service; and, therefore, is not covered as a retraining service.

50.9 - Coding for Adequacy of Hemodialysis

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

A. General

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.

B. Billing Requirements

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.

60 - Separately Billable ESRD Items and Services

(Rev. 1, 10-01-03)

PRM-1-2711

An item or service is separately billable if its cost was specifically excluded from cost data used to calculate the composite rate. This determination is not dependent on the frequency that dialysis patients require the item or service during dialysis. All claims for separately billable items/services must indicate why the items/services were medically necessary. ESRD facilities must accept the Medicare allowance as the full payment for any items and services they furnish.

60.1 - Lab Services

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of lab services included in the composite rate.

Independent laboratories and independent dialysis facilities with the appropriate clinical laboratory certification in accordance with CLIA may be paid for ESRD clinical laboratory tests that are separately billable. The laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare laboratory fee schedule for independent laboratories. Independent dialysis facilities billing for separately billable laboratory tests that they perform must submit claims to the FI. Independent laboratories must bill the carrier.

Hospital-based laboratories providing separately billable laboratory services to hospital dialysis patients of the hospital's dialysis facility bill separately and are paid in accordance with the outpatient lab provisions. However, where the hospital lab does tests for an independent dialysis facility or for another hospital's facility, the non-patient billing provisions apply.

Clinical laboratory tests are performed individually. Automated profiles and application of the "50 percent rule" can be found in Chapter 16 of this manual.

A specimen collection fee determined by CMS (as of this writing, up to $3.00) will be allowed for ESRD Method II billing only in the following circumstances:

- Drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with a syringe or vacutainer to draw the specimen).
- Collecting a urine sample by catheterization.

  Laboratory tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration (as specified in the Medicare Benefit Policy Manual Pub. 100-02, Chapter 11, Section 30.2) are usually performed for dialysis patients and are routinely covered at the frequency specified in the absence of indications to the contrary, i.e., no documentation of medical necessity is required other than knowledge of the patient's status as an ESRD beneficiary. When any of these tests is performed at a frequency greater than that specified, the additional tests are separately billable and are covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using the ICD-9-CM coding system.

60.2 - Drugs Furnished in Dialysis Facilities

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

There are some drugs that are not covered under the composite rate, but that may be medically necessary for some patients receiving dialysis. See the Medicare Benefit Policy Manual, Pub.100-02, Chapter 11, Section 30.4.1 for a description of drugs that are part of the composite rate and when other drugs may be covered.

Except for EPO and Darbepoetin Alfa (Aranesp), (see §60.4), drugs and biologicals, such as blood, may be covered in the home dialysis setting only if the "incident to a physician's services" criteria are met (i.e., it is not covered under the composite rate). Normally, a physician is not in the patient's home when the drugs or biologicals are administered, and therefore, drugs and biologicals generally are not paid in the home setting.

60.2.1 - Billing Procedures for Drugs for Facilities

(Rev. 1364: Issued: 11-02-07: Effective: 04-01-08; Implantation: 04-07-08)

The following billing procedures apply to independent and hospital based facilities.

Facilities identify and bill for drugs by HCPCS code, along with revenue code 0636, "Drugs Requiring Specific Information." Example below includes the HCPCS code and indicates the dosage amount specified in the descriptor of that code. Facilities use the units field as a multiplier to arrive at the dosage amount.

EXAMPLE:

HCPCS	Drug	Dosage (lowest denominator)	Amount
J3360	Valium	5 mg	$2.00

Actual dosage, 10 mg

On the bill, the facility shows J3360 and 2 in the units field (2 x 5 mg = 10 mg). For independent facilities, FIs compare the price of $4.00 (2 x $2.00) to the billed charge and pay the lower, subject to coinsurance and deductible. Effective January 1, 2006 payment is not subject to the lower of charges or fee. All separately payable drugs for both hospital-based and independent facilities are paid at ASP+6% except vaccines. For information on billing and payment for vaccines see section 60.6 of this chapter.

NOTE: When the dosage amount is greater than the amount indicated for the HCPCS code, the facility rounds up to determine units. When the dosage amount is less than the amount indicated for the HCPCS code, use one as the unit of measure. In the example above, if the dosage were 7 mg, the facility would show 2 in the unit field, if the dosage were 3 mg, the facility would show 1 in the unit field.

Facilities bill for supplies used to administer drugs with revenue code 0270, "Medical/Surgical Supplies." The number of administrations is shown in the units field.

EXAMPLE:

Revenue Code	Units
0270	3

The number of units for supply codes billed should match the number of injections billed on the claim form.

Appropriate HCPCS codes for administration-supply of separately billable drugs would include:

A4657: Injection Administration-supply Charge: include the cost of alcohol swab, syringe, and gloves. *Reimbursement for all RDFs is based on a fee of $0.50 per unit billed for A4657.*

A4913: IV Administration-supply Charge: include the cost of IV solution administration set, alcohol swab, syringe, and gloves. This code should only be used when an IV solution set is required for a drug to be given. This rate will not be paid for drugs that only require a syringe for administration. *Hospital based dialysis facilities are paid on a cost basis utilizing the base providers cost report with cost settlement. Contractors gap fill to determine payment to independent dialysis facilities for A4913. Acceptable methods include consulting with other contractors in the area, use of the Drug Topics Red Book, Med-Span, or First Data Bank. Contacting other providers in the area is allowed where costs are not*

readily available. Contractors must ensure the payment for this supply does not include any labor costs. The payment for this supply is the only allowable basis for determining this payment.

60.2.1.1 – Separately Billable ESRD Drugs

(Rev. 146, 04-23-04)

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: Erythropoietin replacement therapies are separately billable and paid at established rates through appropriate billing methodology: Epotein Alfa (EPO) §60.4 and Darbepoetin Alfa (Aranesp) §60.7.

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.

60.2.2 - Drug Payment Amounts for Facilities

(Rev. 849, Issued: 02-10-06; Effective: 01-01-06; Implementation: 02-13-06)

Hospital-based facilities are paid at cost with applicable coinsurance and deductibles. Independent facilities are paid based on the lower of billed charges or 95 percent AWP for the calendar year 2004: coinsurance and deductibles are applied to billed charges. Effective January 1, 2006, both hospital-based and independent ESRD facilities will be paid ASP+6% for all separately billable drugs except vaccines. See Chapter 17 for a complete description of drug pricing.

60.2.3 - Use of Additional Codes by Facilities to Report Drugs

(Rev. 1, 10-01-03)

AB-02-005

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.

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

(Rev. 1212; Issued: 03-30-07; Effective: 01-01-07; Implementation: 06-29-07)

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 February 1, 2007 with dates of services on or after January 1, 2007, all providers billing for injections of ESA for ESRD beneficiaries are encouraged to include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. All providers billing for injections of ESAs for ESRD beneficiaries will be required to include route of administration when claims processing system changes are completed. 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.

60.2.4 - Intravenous Iron Therapy

(Rev. 1, 10-01-03)

RDF-319.4, A3-3644.E

Iron deficiency is a common condition in ESRD patients undergoing dialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBC (hematocrit) levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis.

60.2.4.1 - Facility Billing Requirements to the Intermediary

(Rev. 1, 10-01-03)

A3-3644

See Medicare Benefit Policy Manual, Chapter 11 for coverage and effective dates applicable to intravenous iron therapy services.

For claims with dates of service on or after December 1, 2000, sodium ferric gluconate complex in sucrose injection is covered by Medicare for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy. Payment is made on a reasonable cost basis for

claims with dates of service on or after December 1, 2000 in renal dialysis centers (freestanding facilities). Payment is made pursuant to 42 CFR 405.517 for claims with dates of service on or after January 1, 2001.

For claims with dates of service on or after October 1, 2001, Medicare also covers iron sucrose injection as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy. Payment is made under the outpatient prospective payment system for hospital outpatient departments. Payment is made on a reasonable cost basis in CAHs and in renal dialysis centers (freestanding facilities). See Chapter 17. Deductible and coinsurance apply.

Facilities bill the FI using type of bill 72X and revenue code 0636. For claims with dates of service on or after December 1, 2000, report HCPCS code J3490 (Unclassified drugs) for sodium ferric gluconate complex in sucrose injection. For claims with dates of service on or after January 1, 2001, facilities report HCPCS code J2915 for sodium ferric gluconate complex in sucrose injection. Until a specific code is developed for iron sucrose injection, report HCPCS code J3490 (Unclassified drugs).

60.2.4.2 - Physician Billing Requirements to the Carrier

(Rev. 1, 10-01-03)

B3-4461.1, B3-4461.2, B3-4461.3

A. Sodium Ferric Gluconate Complex in Sucrose Injection

Sodium Ferric Gluconate Complex in sucrose injection may be payable for claims with dates of service on or after December 1, 2000 when furnished intravenously, for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy. Physicians bill and carriers pay for HCPCS codes J1755 or J1756 when submitted with a primary diagnosis for chronic renal failure and a secondary diagnosis for iron deficiency anemia in Item 21. The ICD-9-CM diagnosis codes are:

- 585 - Primary diagnosis for chronic renal failure, and
- 280.0, 280.1, 280.8, or 280.9 - Only one is necessary as a secondary diagnosis for iron deficiency anemia.

This benefit is subject to the Part B deductible and coinsurance and should be paid per current Medicare drug payment reimbursement rules. Carriers may cover other uses of this drug at their discretion.

B. Iron Sucrose Injection

Iron Sucrose injections are payable for claims with dates of service on or after October 1, 2001, when furnished intravenously, for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy. Until a specific code for iron sucrose injection is developed, providers must submit HCPCS code J3490, with the appropriate explanation of drug name and dosage entered in Item 19 of the form CMS-1500 or the corresponding electronic format. The primary diagnosis code ICD-9-CM 585 for chronic renal failure and one of the following

secondary diagnosis codes for iron deficiency anemia ICD-9-CM codes 280.0, 280.1, 280.8, or 280.9 must be entered in Item 21. Iron sucrose injection is subject to the Part B deductible and coinsurance and should be paid per current Medicare drug payment reimbursement rules. Carriers may cover other uses of this drug at their discretion.

C. Messages for Use with Denials

The following denial messages should be used to deny claims for sodium ferric gluconate complex in sucrose injection or iron sucrose injection due to a missing diagnosis code.

Remittance Advice: Claim adjustment reason code 16, Claim/service lacks information which is needed for adjudication, along with remark code M76, Incomplete/invalid patient's diagnosis(es) and condition (s).

Explanation of Medicare Benefits: 9.8, Medicare cannot pay for this service because the claim is missing information/documentation.

Medicare Summary Notice: 9.2, This item or service was denied because information required to make payment was missing.

60.3 - Blood and Blood Services Furnished in Hospital Based and Independent Dialysis Facilities

(Rev. 1, 10-01-03)
A3-3644.G.1 - 3644.G.3, PRM-1-2711.3

Facility staff time used to perform any service in the dialysis unit, including time to administer blood, is included in the composite rate. However, the following may be paid in addition to the composite rate.

- Blood;
- Supplies used to administer blood; and
- Blood processing fees (e.g. blood typing and cross-matching) that are charged by the blood supplier or lb.

Hospital-based facilities - Payment is made on a reasonable cost basis in the same way as for any other Medicare beneficiary receiving blood on an outpatient basis. In determining the reasonable cost for blood, FIs consider the charges for blood from independent blood banks.

Independent dialysis facilities - Payment is made at the lower of the actual charge on the bill or a reasonable charge that the FI determines. In establishing the reasonable charge, FIs consider price lists of independent blood banks (e.g., Red Cross or hospital) that offer services to providers in the area. Also, the carrier allowable charges are considered where available.

Billing Entries related to blood - HCPCS codes and related charges are reported by both hospital-based and independent renal facilities. If HCPCS codes are sufficient to describe the services provided by blood banks in the contractors area, the carrier should

establish reasonable charge amounts for the codes and make payments to facilities based on the lower of the billed charge or the reasonable charge amounts.

In some areas, blood banks group a number of services into one charge. For example, they may have one charge covering washed cells with a crossmatch. There is one HCPCS code for washed red blood cells, and there are others for typing and crossmatching. Facilities should use a combination of the available codes to reflect the one charge by the blood bank. However, if this skews the payment for independent facilities, the contractor should assign a local code for the combination of services.

For supplies, facilities use revenue code 0270. Contractors establish local codes for blood administration sets and filters and set reasonable charge amounts for independent facilities.

Contractors should report local codes, along with the definition and billing frequency, by the 15th of the month following the end of each quarter to:

Centers for Medicare & Medicaid Services
Center for Medicare Management
Chronic Care Policy Group
Room: C5-05-27
Mail Stop C4-10-07
7500 Security Blvd.
Baltimore MD 21244-1850

Also, send a copy to the HCPCS Coordinator in your RO.

NOTE: All unapproved local procedure and modifier codes must be deleted by October 16, 2002. All approved HCPCS Level III local codes and modifiers must be deleted by December 31, 2003. For information on obtaining temporary national codes to replace any essential local codes, see transmittal AB-02-005.

60.4 - Epoetin Alfa (EPO)

(Rev. 1307, Issued: 07-20-07, Effective: 01-01-08, Implementation: 01-07-08)

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 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."

60.4.1 - Epoetin Alfa (EPO) Facility Billing Requirements

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Revenue codes required for reporting EPO:

Revenue Codes	Dates of Service			
	Bill Type 72x	Bill Type 12x	Bill type 13x	Bill type 85x
0634 – administrations under 10,000 units	1/1/04 – present	4/1/06 – present	1/1/04 – present	1/1/04 – present
0635 – administrations of 10,000 units or more	1/1/04 – present	4/1/06 – present	1/1/04 – present	1/1/04 – present
0636 – detailed drug coding	N/A	1/1/04 – 3/31/06	N/A	N/A

For additional hospital billing instructions related to bill types 12x, 13x and 85x see also sections 60.4.3.1 and 60.4.3.2 of this chapter.

The HCPCS code for EPO 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 units (for ESRD on Dialysis)	1/1/2007 to present

The number of units of EPO administered during the billing period is reported with value code 68. Medicare no longer requires value code 68 for claims with dates of service on or after January 1, 2008. Each administration of epoetin alfa (EPO) 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.

Append the GS modifier to report a line item that represents an administration of EPO at the reduced dosage following existing instructions in section 60.4 of this chapter.

The hematocrit reading taken prior to the last administration of EPO during the billing period must also be reported on the UB-*04*/Form CMS-1450 with value code 49. Effective January 1, 2006 the definition of value code 49 used to report the hematocrit reading is changed to indicate the patient's most recent hematocrit reading taken **before** the start of the billing period.

The hemoglobin reading taken during the billing period must be reported on the UB-*04*/Form CMS-1450 with value code 48. Effective January 1, 2006 the definition of value code 48 used for the hemoglobin reading is changed to indicate the patient's most recent hemoglobin reading taken **before** the start of the billing period.

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.

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

60.4.2 - Epoetin Alfa (EPO) Supplier Billing Requirements (Method II) on the Form CMS-1500

(Rev 118, 03-05-04)

A. Claims With Dates of Service Prior to January 1, 2004:

For claims with dates of service prior to January 1, 2004, the correct EPO code to use is the one that indicates the patient's most recent hematocrit (HCT) (rounded to the nearest whole percent) or hemoglobin (Hgb) (rounded to the nearest g/dl) prior to the date of service of the EPO. For example, if the patient's most recent hematocrit was 20.5 percent, bill Q9921; if it was 28.4 percent, bill Q9928.

To convert actual hemoglobin to corresponding hematocrit for Q code reporting, multiply the Hgb value by 3 and round to the nearest whole number. For example, if Hgb = 8.4, report as Q9925 (8.4 X 3 = 25.2, rounded down to 25).

One unit of service of EPO is reported for each 1000 units dispensed. For example if 20,000 units are dispensed, bill 20 units. If the dose dispensed is not an even multiple of 1,000, rounded down for 1 - 499 units (e.g. 20,400 units dispensed = 20 units billed), round up for 500 - 999 units (e.g. 20,500 units dispensed = 21 units billed).

Q9920 Injection of EPO, per 1,000 units, at patient HCT of 20 or less

Q9921 Injection of EPO, per 1,000 units, at patient HCT of 21

Q9922 Injection of EPO, per 1,000 units, at patient HCT of 22

Q9923 Injection of EPO, per 1,000 units, at patient HCT of 23

Q9924 Injection of EPO, per 1,000 units, at patient HCT of 24

Q9925 Injection of EPO, per 1,000 units, at patient HCT of 25

Q9926 Injection of EPO, per 1,000 units, at patient HCT of 26

Q9927 Injection of EPO, per 1,000 units, at patient HCT of 27

Q9928 Injection of EPO, per 1,000 units, at patient HCT of 28

Q9929 Injection of EPO, per 1,000 units, at patient HCT of 29

Q9930 Injection of EPO, per 1,000 units, at patient HCT of 30

Q9931 Injection of EPO, per 1,000 units, at patient HCT of 31

Q9932 Injection of EPO, per 1,000 units, at patient HCT of 32

Q9933 Injection of EPO, per 1,000 units, at patient HCT of 33

Q9934 Injection of EPO, per 1,000 units, at patient HCT of 34

Q9935 Injection of EPO, per 1,000 units, at patient HCT of 35

Q9936 Injection of EPO, per 1,000 units, at patient HCT of 36

Q9937 Injection of EPO, per 1,000 units, at patient HCT of 37

Q9938 Injection of EPO, per 1,000 units, at patient HCT of 38

Q9939 Injection of EPO, per 1,000 units, at patient HCT of 39

Q9940 Injection of EPO, per 1,000 units, at patient HCT of 40 or above.

B. Claims with Dates of Service January 1, 2004 and after

The above codes were replaced effective January 1, 2004 by Q4055. This Q code is for the injection of EPO furnished to ESRD Beneficiaries on Dialysis. The new code does not include the hematocrit. See §60.7.

Q4055 – Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis).

The DMERC shall return to provider (RTP) assigned claims for EPO, Q4055, that do not contain a HCT value. For unassigned claims, the DMERC shall deny claims for EPO, Q4055 that do not contain a HCT value.

DMERCs must use the following messages when payment for the injection (Q4055) does not meet the coverage criteria and is denied:

MSN Message 6.5—English: Medicare cannot pay for this injection because one or more requirements for coverage were not met

MSN Message 6.5—Spanish: Medicare no puede pagar por esta inyeccion porque uno o mas requisitos para la cubierta no fueron cumplidos. (MSN Message 6.5 in Spanish).

Adjustment Reason Code B:5 Payment adjusted because coverage/program guidelines were not met or were exceeded.

The DMERCs shall use the following messages when returning as unprocessable assigned claims without a HCT value:

The ANSI Reason Code 16 – Claim/service lacks information, which is needed for adjudication.

Additional information is supplied using remittance advice remarks codes whenever appropriate.

Remark Code M58 – Missing/incomplete/invalid claim information. Resubmit claim after corrections.

Deductibles and coinsurance apply.

60.4.2.1 - Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO)

(Rev 118, 03-05-04)

The following information is required for EPO. Incomplete assigned claims are returned to providers for completion. Incomplete unassigned claims are rejected. The rejection will be due to a lack of a HCT value. Note that when a claim is submitted on paper Form CMS-1500, these items are submitted on a separate document. It is not necessary to enter them into the claims processing system. This information is used in utilization review.

A. Diagnoses - The diagnoses must be submitted according to ICD-9-CM and correlated to the procedure. This information is in Item 21, of the Form CMS-1500.

B. Hematocrit (HCT)/Hemoglobin (Hgb) - There are special HCPCS codes for reporting the injection of EPO for claims with dates of service prior to January 1, 2004. These allow the simultaneous reporting of the patient's latest HCT or Hgb reading before administration of EPO.

The physician and/or staff are instructed to enter a separate line item for injections of EPO at different HCT/Hgb levels. The Q code for each line items is entered in Item 24D.

1. Code Q9920 - Injection of EPO, per 1,000 units, at patient HCT of 20 or less/Hgb of 6.8 or less.

2. Codes Q9921 through Q9939 - Injection of EPO, per 1,000 units, at patient HCT of 21 to 39/Hgb of 6.9 to 13.1. For HCT levels of 21 or more, up to a HCT of 39/Hgb of 6.9 to 13.1, a Q code that includes the actual HCT levels is used. To convert actual Hgb to corresponding HCT values for Q code reporting, multiply the Hgb value by 3 and round to the nearest whole number. Use the whole number to determine the appropriate Q code.

EXAMPLES: If the patient's HCT is 25/Hgb is 8.2-8.4, Q9925 must be entered on the claim. If the patient's HCT is 39/Hgb is 12.9-13.1, Q9939 is entered.

3. Code Q9940 - Injection of EPO, per 1,000 units at patient HCT of 40 or above.

A single line item may include multiple doses of EPO administered while the patient's HCT level remained the same.

Codes Q9920-Q9940 will no longer be recognized by the system if submitted after March 31, 2004. If claims for dates of service prior to January 1, 2004 are submitted after March 31, 2004, then code Q4055 must be used.

C. Units Administered - The standard unit of EPO is 1,000. The number of 1,000 units administered per line item is included on the claim. The physician's office enters 1 in the units field for each multiple of 1,000 units. For example, if 12,000 units are administered, 12 is entered. This information is shown in Item 24G (Days/Units) on Form CMS-1500.

In some cases, the dosage for a single line item does not total an even multiple of 1,000. If this occurs, the physician's office rounds down supplemental dosages of 0 to 499 units to the prior 1,000 units. Supplemental dosages of 500 to 999 are rounded up to the next 1,000 units.

EXAMPLES:

A patient's HCT reading on August 6 was 22/Hgb was 7.3. The patient received 5,000 units of EPO on August 7, August 9, and August 11, for a total of 15,000 units. The first line of Item 24 of Form CMS-1500 shows:

Dates of Service	Procedure Code	Days or Units
8/7 - 8/11	Q9922	15

On September 13, the patient's HCT reading increased to 27/Hgb increased to 9. The patient received 5,100 units of EPO on September 13, September 15, and September 17, for a total of 15,300 units. Since less than 15,500 units were given, the figure is rounded down to 15,000. This line on the claim form shows:

Dates of Service	Procedure Code	Days or Units
9/13 - 9/17	Q9927	15

On October 16, the HCT level increased to 33/Hgb increased to 11. The patient received doses of 4,850 units on October 16, October 18, and October 20 for a total of 14,550 units. Since more than 14,500 units were administered, the figure is rounded up to 15,000. Form CMS-1500 shows:

Dates of Service	Procedure Code	Days or Units
10/16 - 10/20	Q9933	15

NOTE: Creatinine and weight identified below are required on EPO claims as applicable.

D. Date of the Patient's most recent HCT or Hgb.

E. Most recent HCT or Hgb level - (prior to initiation of EPO therapy).

F. Date of most recent HCT or Hgb level - (prior to initiation of EPO therapy).

G. Patient's most recent serum creatinine - (within the last month, prior to initiation of EPO therapy).

H. Date of most recent serum creatinine - (prior to initiation of EPO therapy).

I. Patient's weight in kilograms

J. Patient's starting **dose per kilogram** - (The usual starting dose is 50-100 units per kilogram.)

60.4.2.2 - Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)

(Rev 118, 03-05-04)

Subsequent claims are completed as initial claims in §60.4.2, except the following fields:

A. Diagnoses.

B. Hematocrit or Hemoglobin – For dates of service prior to January 1, 2004, this is indicated by the appropriate Q code. For dates of service January 1, 2004, and after, suppliers must indicate the beneficiary's hematocrit on the claim. (See 60.4.2.) Claims include an EJ modifier to the Q code. This allows the contractor to identify subsequent claims, which do not require as much information as initial claims and prevent unnecessary development.

Number of Units Administered - Subsequent claims may be submitted electronically.

60.4.3 - Payment Amount for Epoetin Alfa (EPO)

(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)

Dates of service prior to January 1, 2005, the FI pays the facility $10 per 1,000 units of EPO administered, rounded to the nearest 100 units (i.e., $1.00 per 100 units). Effective January 1, 2005, EPO will be paid based on the ASP Pricing File. Also 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. Where EPO is furnished by a supplier that is not a facility, the DMERC pays at the same rate.

Physician payment is calculated through the drug payment methodology described in Chapter 17 of the Claims Processing Manual.

EXAMPLE: The billing period is 2/1/94 - 2/28/94.

The facility provides the following:

Date	**Units**	**Date**	**Units**
2/1	3000	2/15	2500
2/4	3000	2/18	2500
2/6	3000	2/20	2560
2/8	3000	2/22	2500
2/11	2500	2/25	2000
2/13	2500	2/27	2000

Total 31,060 units

For value code 68, the facility enters 31,060. The 31,100 are used to determine the rate payable. This is 31,060 rounded to the nearest 100 units. The amount payable is 31.1 x $10 =$311.00. In their systems, FIs have the option of setting up payment of $1.00 per 100 units. Effective January 1, 2005, EPO will be paid based on the ASP Pricing File.

Effective January 1, 2008, payment is calculated on a renal dialysis facility claim at the line level by multiplying the rate from the ASP pricing file by the number of units reported on the line billing for EPO.

EXAMPLE: 311 x $1.00 = $311.00

If an ESRD beneficiary requires 10,000 units or more of EPO per administration, special documentation must be made in the medical records. It must consist of a narrative report that addresses the following:

- Iron deficiency. Most patients need supplemental iron therapy while being treated, even if they do not start out iron deficient;

- Concomitant conditions such as infection, inflammation, or malignancy. These conditions must be addressed to assure that EPO has maximum effect;

- Unrecognized blood loss. Patients with kidney disease and anemia may easily have chronic blood loss (usually gastrointestinal) as a major cause of anemia. In those circumstances, EPO is limited in effectiveness;

- Concomitant hemolysis, bone morrow dysplasia, or refractory anemia for a reason other than renal disease, e.g., aluminum toxicity;

- Folic acid or vitamin B12 deficiencies;

- Circumstances in which the bone morrow is replaced with other tissue, e.g., malignancy or osteitis fibrosa cystica; and

Patient's weight, the current dose required, a historical record of the amount that has been given, and the hematocrit response to date.

60.4.3.1 - Payment for Epoetin Alfa (EPO) in Other Settings

(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)

In the hospital inpatient setting, payment under Part A is included in the DRG.

In the hospital inpatient setting, payment under Part B is made on bill type 12x. Hospitals report the drug units based on the units defined in the HCPCS description. Hospitals do not report value code 68 for units of EPO. For dates of service prior to April 1, 2006, report EPO under revenue code 0636. For dates of service from April 1, 2006 report EPO under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. Payment will be based on the ASP Pricing File.

In a skilled nursing facility (SNF), payment for EPO covered under the Part B EPO benefit is not included in the prospective payment rate for the resident's Medicare-covered SNF stay.

In a hospice, payment is included in the hospice per diem rate.

For a service furnished by a physician or incident to a physician's service, payment is made to the physician by the carrier in accordance with the rules for 'incident to" services. When EPO is administered in the renal facility, the service is not an "incident to" service and not under the "incident to" provision.

60.4.3.2 - Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

When ESRD patients come to the hospital for a medical emergency their dialysis related anemia may also require treatment. Effective January 1, 2005, EPO will be paid based on the ASP Pricing File.

Hospitals use type of bill 13X (or 85X for Critical Access Hospitals) and report charges under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. Hospitals report the drug units based on the units defined in the HCPCS description. Hospitals do not report value code 68 for units of EPO. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, *and for all claims with dates of service on or after January 1, 2008.*

60.4.4 - Epoetin Alfa (EPO) Furnished to Home Patients
(Rev. 447, Issued: 01-21-05, Effective: 07-01-05, Implementation: 07-05-05)

Medicare covers EPO for dialysis patients who use EPO in the home, when requirements for a patient care plan and patient selection as described in the Medicare Benefit Policy Manual, Chapter 11, are met.

When EPO is prescribed for a home patient, it may be either administered in a facility, e.g., the one shown on the Form CMS-382 (ESRD Beneficiary Method Selection Form) or furnished by a facility or Method II supplier for self-administration to a home patient determined to be competent to administer this drug. For EPO furnished for self-administration to Method I and Method II home patients determined to be competent, the renal facility bills its FI and the Method II supplier bills its DMERC. No additional payment is made for training a prospective self-administering patient or retraining an existing home patient to self-administer EPO.

Method II patients who self-administer may obtain EPO only from either their Method II supplier~~,~~ or a Medicare certified ESRD facility.

In this case, the DMERC makes payment at the same rate that applies to facilities. Program payment may not be made for EPO furnished by a physician to a patient for self-administration.

The DMERCs pay for EPO for Method II ESRD beneficiaries only. DMERCs shall deny claims for EPO where the beneficiary is not a Method II home dialysis patient.

When denying line items for patients that are not Method II, use the following message on the remittance advice:

The ANSI message 7011: Claim not covered by this payer contractor. You must send the claim to the correct payer contractor.

When denying line items for patients that are not Method II, use the following message on the Medicare Summary Notice (MSN):

English: 8.59- Durable Medical Equipment Regional Carriers pay for Epoetin Alfa and Darbepoetin Alfa only for Method II End Stage Renal Disease home dialysis patients.

Spanish: 8.59- Las Empresas Regionales de Equipo Médico Duradero pagan por los medicamentos Epoetina Alfa y Darbepoetina Alfa sólo a pacientes del Método II de diálisis con enfermedad renal en etapa final que están confinados al hogar.

60.4.4.1 - Self Administered EPO Supply
(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)

Initially, facilities may bill for up to a 2-month supply of EPO for Method I beneficiaries who meet the criteria for selection for self-administration. After the initial two months' supply, the facility will bill for one month's supply at a time. Condition code 70 is used to indicate payment requested for a supply of EPO furnished a beneficiary. Usually, revenue code 0635 would apply since the supply would be over 10,000 units. Facilities leave FL 46, Units of Service, blank since they are not administering the drug. For value code 68, they enter the total amount of the supply.

For claims with dates of service on or after January 1, 2008, supplies of EPO for self administration should be billed according to the pre-determined plan of care schedule provided to the beneficiary. Submit a separate line item for each date an administration is expected to be performed with the expected dosage. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule. For patients beginning to self administer EPO at home receiving an extra month supply of the drug, bill the one month reserve supply on one claim line and include modifier EM defined as "Emergency Reserve Supply (for ESRD benefit only)".

Condition code 70 should be reported on claims billing for home dialysis patients that self administer anemia management drugs including epoetin alfa and darbepoetin alfa.

60.5 - Intradialytic Parenteral/Enteral Nutrition (IDPN)

(Rev. 1, 10-01-03)
PRM-1-2711.6

A. General

Parenteral/enteral nutrition (PEN) administered during dialysis may be covered under Medicare, but it is not part of the Medicare ESRD benefit. Therefore, an ESRD facility or PEN supplier may bill Medicare separately from the composite rate for PEN solution if the patient meets all of the requirements for PEN coverage. (See Medicare Benefit Policy Manual for PEN coverage requirements.) If the ESRD facility bills, it does so as a PEN supplier and bills the appropriate DMERC.

B. Staff Time

The ESRD facility staff time used to administer PEN solution is not covered by Medicare, and, therefore, not included in the composite rate. (PEN is considered a self-administered therapy and generally administered in the patient's home.) Since it is not covered under Medicare, it is not part of the composite rate nor may a facility bill Medicare separately for it.

The costs of the staff time used for this purpose are allocated to a nonreimbursable cost center on the facility's Medicare ESRD facility cost report. If the facility cannot determine the cost of this service, any revenue the facility receives commensurate with the value of this service is used as an offset against the facility's cost.

Any payment the facility receives from the PEN supplier (e.g., for administration or record-keeping relating to the provision of parenteral nutritional therapy) is questionable under the Medicare program's anti-kickback provision.

60.6 - Vaccines Furnished to ESRD Patients

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

The Medicare program covers hepatitis B, influenza virus and Pneumococcal pneumonia virus (PPV) vaccines and their administration when furnished to eligible beneficiaries in accordance with coverage rules. Payment may be made for both the vaccine and the administration. The costs associated with the syringe and supplies are included in the administration fee: HCPCS code A4657 should not be billed for these vaccines.

Vaccines and their administration are reported using separate codes. See Chapter 18 of this manual for the codes required for billing vaccines and the administration of the vaccine.

Payment for vaccine administration (PPV, Influenza Virus, and Hepatitis B Virus) to freestanding RDFs is based on the Medicare Physician Fee Schedule (MPFS) according to the rate in the MPFS associated with code 90782 for services provided prior to March 1, 2003 and code 90471 for services provided March 1, 2005 and later and on reasonable cost for provider-based RDFs.

60.7 – Darbepoetin Alfa (Aranesp) for ESRD Patients

(Rev. 1307, Issued: 07-20-07, Effective: 01-01-08, Implementation: 01-07-08)

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 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."

60.7.1 – Darbepoetin Alfa (Aranesp) Facility Billing Requirements

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Revenue code 0636 is used to report Aranesp.

The HCPCS code for aranesp must be included:

HCPCS	HCPCS Description	Dates of Service
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

The hematocrit reading taken prior to the last administration of Aranesp during the billing period must also be reported on the UB-*04*/Form CMS-1450 with value code 49. For claims with dates of service on or after April 1, 2006, a hemoglobin reading may be reported on Aranesp claims using value code 48.

Effective January 1, 2006 the definition of value code 48 and 49 used to report the hemoglobin and hematocrit readings are changed to indicate the patient's most recent reading taken **before** the start of the billing period.

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

The payment allowance for Aranesp is the only allowance for the drug and its administration when used for ESRD patients. 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. The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/ 31days.

60.7.2 - Darbepoetin Alfa (Aranesp) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent

(Rev 118, 03-05-04)

The ESRD patients on dialysis can use Aranesp for the treatment of anemia effective January 1, 2004, the Q code for the injection of Aranesp for ESRD beneficiaries on dialysis, is Q4054.

Q4054 – Injection, Darbepoetin alfa, 1 mcg (for ESRD on Dialysis).

Method II suppliers must use Item 19 on the CMS 1500 to place the most current HCT value (Q4054). Identify HCT as "HCT = the true value HCT". For 837P claims, the Method II supplier must supply the most current HCT value, when billing for darbepoetin alfa Q4054, in the 2400 MEA03 with a qualifier of R2 in 2400 MEA02.

DMERCs must apply coverage rules to Aranesp in the same manner that they apply them to EPO. DMERCs shall accept claims for Aranesp, Q4054, from suppliers that bill for Aranesp furnished to home patients for self-administration who have elected home dialysis and Method II payment.

DMERCs must accept HCPCS code Q4054 for Aranesp on the CMS-1500 or its electronic equivalent 837 P format. The DMERC shall return to provider (RTP) assigned claims for claims for Aranesp, Q4054, that do not contain a HCT value. For unassigned claims, the DMERC shall deny claims for Aranesp, Q4054, that do not contain a HCT value.

Method II suppliers must place number of mcg's of Aranesp Q4054 administered in Item Field 24G Units on the CMS- 1500 form, or 2400 SV104 of the 837P format. Method II suppliers must use Item 19 on the CMS 1500 to place the most current HCT value (Q4054). Identify HCT as "HCT = the true value HCT". For 837P claims, the Method II supplier must supply the most current HCT value, when billing for Aranesp Q4054, in the 2400 MEA03 with a qualifier of R2 in 2400 MEA02.

DMERCs must use the following messages when payment for the Aranesp injection (Q4054) does not meet the coverage criteria and is denied:

MSN Message 6.5—English: Medicare cannot pay for this injection because one or more requirements for coverage were not met

MSN Message 6.5—Spanish: Medicare no puede pagar por esta inyeccion porque uno o mas requisitos para la cubierta no fueron cumplidos. (MSN Message 6.5 in Spanish).

Adjustment Reason Code B:5 Payment adjusted because coverage/program guidelines were not met or were exceeded.

The DMERCs shall use the following messages when returning as unprocessable assigned claims without a HCT value:

ANSI Reason Code 16 – Claim/service lacks information, which is needed for adjudication.

Additional information is supplied using remittance advice remarks codes whenever appropriate.

Remark Code M58 – Missing/incomplete/invalid claim information. Resubmit claim after corrections.

Deductibles and coinsurance apply. DMERCs must pay for Aranesp (Q4054) based on the payment amount in the MMA Drug Payment Limits Pricing File. The contractor can obtain the rates from the CMS website, www.cms.hhs.gov/providers/drugs/default.asp.

60.7.2.1 - Other Information Required on the Form CMS-1500 for Darbepoetin Alfa (Aranesp)

(Rev 118, 03-05-04)

The following information is required for Aranesp. Incomplete assigned claims are returned to providers for completion. Incomplete unassigned claims are rejected. The rejection will be due to a lack of a HCT value. Note that when a claim is submitted on paper Form CMS-1500, these items are submitted on a separate document. It is not necessary to enter them into the claims processing system. This information is used in utilization review.

A. Diagnoses - The diagnoses must be submitted according to ICD-9-CM and correlated to the procedure. This information is in Item 21, of the Form CMS-1500.

B. Date of the Patient's most recent HCT.

C. Most recent HCT (prior to initiation of Aranesp therapy).

D. Date of most recent HCT (prior to initiation of Aranesp therapy).

F. Patient's most recent serum creatinine - (within the last month, prior to initiation of Aranesp therapy).

G. Date of most recent serum creatinine - (prior to initiation of Aranesp therapy).

H. Patient's weight in kilograms

I. Patient's starting dose per kilogram

60.7.2.2 - Completion of Subsequent Form CMS-1500 Claims for Darbepoetin Alfa (Aranesp)

(Rev 118, 03-05-04)

Subsequent claims are completed as initial claims in §60.7.2, except the following fields:

A. Diagnoses.

B. Hematocrit - For dates of service prior to January 1, 2004, this is indicated by the appropriate Q code. For dates of service January 1, 2004 and after, suppliers must indicate the beneficiary's hematocrit on the claim. (See 60.7.2). Claims include an EJ modifier to the Q code. This allows the contractor to identify subsequent claims, which do not require as much information as initial claims and prevent unnecessary development.

C. Number of Units Administered - Subsequent claims may be submitted electronically.

60.7.3 - Payment Amount for Darbepoetin Alfa (Aranesp)

(Rev. 373, Issued: 11-19-04, Effective: 01-01-05, Implementation: 01-03-05)

For Method I patients, the FI pays the facility per one mcg of Aranesp administered, in accordance with the MMA Drug Payment Limits Pricing File rounded up to the next highest whole mcg. Effective January 1, 2005, Aranesp will be paid based on the ASP Pricing File. 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.

Physician payment is calculated through the drug payment methodology described in Chapter 17, of the Claims Processing Manual.

The coinsurance and deductible are based on the Medicare allowance payable, not on the provider's charges. The provider may not charge the beneficiary more than 20 percent of the Medicare Aranesp allowance. This rule applies to independent and hospital based renal facilities.

60.7.3.1 - Payment for Darbepoetin Alfa (Aranesp) in Other Settings

(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)

In the hospital inpatient setting, payment under Part A for Aranesp is included in the DRG.

In the hospital inpatient setting, payment under Part B is made on bill type 12x when billed with revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Reimbursement is based on the payment allowance limit for Medicare Part B drugs as found in the ASP pricing file.

In a skilled nursing facility (SNF), payment for Aranesp covered under the Part B EPO benefit is not included in the prospective payment rate for the resident's Medicare-covered SNF stay.

In a hospice, payment is included in the hospice per diem rate.

For a service furnished by a physician or incident to a physician's service, payment is made to the physician by the carrier in accordance with the rules for 'incident to" services. When Aranesp is administered in the renal facility, the service is not an "incident to" service and not under the "incident to" provision.

60.7.3.2 - Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

When ESRD patients come to the hospital for a medical emergency their dialysis related anemia may also require treatment. For patients with ESRD who are on a regular course of dialysis, Aranesp administered in a hospital outpatient department is paid the MMA Drug Pricing File rate. Effective January 1, 2005, Aranesp will be paid based on the ASP Pricing File.

Hospitals use bill type 13X (or 85X for Critical Access Hospitals) and report charges under revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Value code 49 must be reported with the hematocrit value for the hospital

outpatient visits prior to January 1, 2006, *and for all claims with dates of service on or after January 1, 2008.*

60.7.4 – Darbepoetin Alfa (Aranesp) Furnished to Home Patients

(Rev. 447, Issued: 01-21-05, Effective: 07-01-05, Implementation: 07-05-05)

Medicare covers Aranesp for dialysis patients who use Aranesp in the home, when requirements for a patient care plan and patient selection as described in the Medicare Benefit Policy Manual, Chapter 11, are met.

When Aranesp is prescribed for a home patient, it may be either administered in a facility, e.g., the one shown on the Form CMS-382 (ESRD Beneficiary Method Selection Form) or furnished by a facility or Method II supplier for self-administration to a home patient determined to be competent to administer this drug. For Aranesp furnished for self-administration to Method I and Method II home patients determined to be competent, the renal facility bills its FI and the Method II supplier bills its DMERC. No additional payment is made for training a prospective self-administering patient or retraining an existing home patient to self-administer Aranesp.

Method II home patients who self-administer may obtain Aranesp only from either their Method II supplier or a Medicare-certified ESRD facility.

In this case, the DMERC makes payment at the same rate that applies to facilities. Program payment may not be made for Aranesp furnished by a physician to a patient for self-administration.

The DMERCs pay for Aranesp for Method II ESRD beneficiaries only. DMERCs shall deny claims for Aranesp where the beneficiary is not a Method II home dialysis patient.

When denying line items for patients that are not Method II, use the following message on the remittance advice:

The ANSI message 7011: Claim not covered by this payer contractor. You must send the claim to the correct payer contractor.

When denying line items for patients that are not Method II, use the following message on the Medicare Summary Notice (MSN):

English: 8.59- Durable Medical Equipment Regional Carriers pay for Epoetin Alfa and Darbepoetin Alfa only for Method II End Stage Renal Disease home dialysis patients.

Spanish: 8.59- Las Empresas Regionales de Equipo Médico Duradero pagan por los medicamentos Epoetina Alfa y Darbepoetina Alfa sólo a pacientes del Método II de diálisis con enfermedad renal en etapa final que están confinados al hogar.

60.8 - Shared Systems Changes for Medicare Part B Drugs for ESRD Independent Dialysis Facilities

(Rev. 771, Issued: 12-02-05, Effective: 01-03-06, Implementation: 01-03-06)

Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides that the payment limits for ESRD-related drugs billed by differing types of facilities vary depending on the site of service. For calendar year 2005, the

payment limits for Medicare Part B drugs will be updated on a quarterly basis. Therefore, Medicare Shared Systems (FISS) must be able to accommodate at least two payment limits for HCPCS drug codes per quarter effective for dates of service on or after January 1, 2005.

Fiscal intermediaries (FIs) shall use the 95 percent of the Average Wholesale Price (AWP) payment amount provided solely to pay independent dialysis facilities with type of bill (TOB) 72X for separately billable drugs furnished to ESRD beneficiaries. Specifically, the ESRD drug payment limit shall be used to determine payment for TOB 72X, but only for independent dialysis facilities.

70 - Payment for Home Dialysis

(Rev. 1, 10-01-03)

A3-3644, PRM-1-2706.1.E, PRM-1-2706.2, A3-3169, RO-2 3440.2, B3-4270.1

Home dialysis is dialysis performed by an appropriately trained dialysis patient at home. Hemodialysis, CCPD, IPD and CAPD may be performed at home. For all dialysis services furnished by an ESRD facility, the facility must accept assignment, and only the facility may be paid by the Medicare program. Method II suppliers can receive payment for patients selecting Method II. The Method II supplier must accept assignment. Method II suppliers receive payment for supplies and equipment only.

For purposes of home dialysis, a skilled nursing facility (SNF) may qualify as a beneficiary's home. The services are excluded from SNF consolidated billing for its inpatients. The home dialysis services are billed either by the ESRD facility or the supplier depending on the Method selection made by the beneficiary.

70.1 - Method Selection for Home Dialysis Payment

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

Medicare beneficiaries dialyzing at home can choose between two methods for Medicare program payment for care (exclusive of physician services), Method I or Method II as described below in §70.2.

When an ESRD beneficiary begins a course of home dialysis, he or she fills out the Form CMS-382, "ESRD Beneficiary Selection," to choose whether he or she wants to use Method I or Method II to obtain home dialysis equipment and supplies. Refer to http://www.cms.hhs.gov/cmsforms/downloads/cms382.pdf for a copy of the ESRD Method Selection Form CMS-382, and the related instructions.

The beneficiary and or provider must:

- Furnish the information requested in items 1-6;
- Check only one block in items 7-9; and
- Enter the effective date at the bottom of item 7

The beneficiary must sign and date in items 11 and 12.

The facility sends the completed form to the FI. When the FI receives the correctly completed Form CMS-382, it must enter the beneficiary's choice into the common

working file (CWF) within 30 days of receipt. The format is in Chapter 27. For method II selections, the FI must follow-up every 30 days until the method selection has been correctly entered.

If a claim is received by the Intermediary on behalf of a beneficiary for whom an initial election is not recorded on CWF, CWF informs the FI to return the claim to the provider. The provider must submit a copy of the completed Form CMS-382 prior to resubmitting the claim.

If a claim is received by the Intermediary on behalf of a beneficiary for whom Method I has been selected, CWF informs the FI to deny the claim.

DMERCs deny Method II claims where there is no method selection on file at CWF.

70.1.1 - Change in Method

(Rev. 1, 10-01-03)

PRM-1-2740.2.D

Changes in method selection are effective January 1 of the year following the year in which the beneficiary requested the change. However, the FI may grant an exception in certain situations. The following is a sample list (i.e., not all-inclusive) of possible situations:

- Failure of a kidney transplant occurred within the past 6 months;
- Patient becomes confined to a nursing home or hospice;
- Home patient becomes an in-facility patient for any reason and then elects to go on home dialysis again after at least 6 full months in the center;
- Patient changes the place of residence to a location where the new facility does not recognize present method of payment and another facility is not available; or
- Patient is in a life threatening situation.

70.2 - Prevention of Double Billing Under Method I and II

(Rev. 1, 10-01-03)

PRM-1-2740.3

Under Method I payment is made to the ESRD facility by the FI. Under Method II, payment is made to the facility for support services by the FI, but payment for home dialysis equipment and supplies is made to the supplier by the DMERC. The beneficiary's method and effective date are recorded on CWF.

The FI or contractor must pay claims in accordance with the documentation on the CWF record.

70.3 - Overpayments

(Rev. 1, 10-01-03)

PRM-1-2740.4

Any overpayments that occur are subject to recovery following the usual Medicare program rules and procedures.

80 - Home Dialysis Method I Billing to the Intermediary

(Rev. 1, 10-01-03)

A3-3644.A, PRM-1-2710, PRM-1-2710.4, A3-3169, RDF-318, RO2-3440, B3-4270, B3-4271

If the Medicare home dialysis patient chooses Method I, the dialysis facility with which the Medicare home patient is associated assumes responsibility for providing all home dialysis equipment and supplies, and home support services. For these services, the facility receives the same Medicare dialysis payment rate as it would receive for an in-facility patient under the composite rate system. The beneficiary is responsible for paying any unmet Part B deductible and the 20-percent coinsurance. After the beneficiary's Part B deductible is met, the FI pays 80 percent of the specific facility's composite rate for each in-facility outpatient maintenance dialysis treatment.

Under Method I items and services included in the composite rate must be furnished by the facility, either directly or under arrangement. The cost of an item or service is included under the composite rate unless specifically excluded. Therefore, the determination as to whether an item or service is covered under the composite rate payment does not depend on the frequency that dialysis patients require the item or service, or the number of patients who require it. If the facility fails to provide (either directly or under arrangement) any part of the items and services covered under the rate, the facility cannot be paid any amount for the items and services that it does furnish.

New items or services developed after the rate applicable for that particular year was computed are included in the composite rate payments. As such, ESRD facilities assume the responsibility for providing a dialysis service and must decide whether a particular item or service is medically appropriate and cost effective. Since the composite rate is adjusted, as necessary, based on the most recent cost data available to CMS, the costs of new items and services are taken into account in setting future rates. Similarly, any savings attributable to advancements in the treatment of ESRD accrue to the facility because no adjustment to any individual facility's rate is made.

80.1 - Items and Services Included in the Composite Rate for Home Dialysis

(Rev. 1, 10-01-03)

A3-3169.1, PRM-1-2712

The following items are paid for and must be furnished under the composite rate. The facility may furnish them directly under arrangements, to all of its home dialysis patients. If the facility fails to furnish (either directly or under arrangements) any part of the items and services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that the facility does furnish.

- Medically necessary dialysis equipment and dialysis support equipment;

- Home dialysis support services including the delivery, installation, maintenance, repair, and testing of home dialysis equipment, and home support equipment;
- Purchase and delivery of all necessary dialysis supplies;
- Routine ESRD related laboratory tests; and
- All dialysis services furnished by the facility's staff.

The following items and services are included in the composite rate and may not be billed separately when furnished by a dialysis facility:

- Staff time used to administer blood;
- Declotting of shunts and any supplies used to declot shunts by facility staff in the dialysis unit;
- Oxygen and the administration of oxygen furnished in the dialysis unit;
- Staff time used to administer separately billable parenteral items;
- Bicarbonate dialysate;
- Cardiac monitoring;
- Catheter changes (Ideal Loop);
- Suture removal;
- Dressing changes;
- Crash cart usage for cardiac arrest; or
- Staff time used to collect specimens for all laboratory tests.

Sometimes outpatient dialysis related services (e.g., declotting of shunts, suture removal, injecting separately billable ESRD related drugs) are furnished in a department of the hospital other than the dialysis unit (e.g., the emergency room). These services may be paid in addition to the composite rate only if the services could not be furnished in a dialysis facility or the dialysis unit of the hospital, due to the absence of specialized equipment or staff, which can be found only in the other department. In the case of emergency services furnished in the hospital emergency room (ER), the services are paid separately subject to the additional requirement that there is a sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention in the ER could reasonably be expected to result in either:

- Placing the patient's health in serious jeopardy;
- Causing serious impairment to bodily functions; or
- Causing serious dysfunction of any bodily organ or part.

These situations are rare and, in the absence of documentation to the contrary, these conditions are deemed to be not met.

80.2 - General Intermediary Bill Processing Procedures for Method I Home Dialysis Services

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

A3-3644, CWF documentation

General instructions for completing the UB-*04* or ANSI X12N formats are in Chapter 25. Instructions in §§50 and 50.3, above, apply to provider reporting of ESRD home dialysis services under Method I.

All home dialysis patients must have chosen either Method I or Method II.

The FI uses the method of election information provided in the "Method" field of CWF trailer 14 "ESRD Method Trailer" attached to the query response when an ESRD claim is submitted for approval.

If the beneficiary has elected Method I, the FI pays the facility the composite rate plus any additional billable services.

If the beneficiary has elected Method II, the facility is not paid the composite rate or for home dialysis supplies and equipment. Payment is made only for support, backup, and emergency dialysis services.

80.2.1 - Required Billing Information for Method I Claims

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Method I claims require the same information as listed in §50.3 above with the following changes.

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.

74 - Home - Providers enter this code to indicate the billing is for a patient who received dialysis services at home.

80 – Home Dialysis-Nursing Facility – Home dialysis furnished in a SNF or Nursing Facility.

80.3 - Calculating Payment for Intermittent Peritoneal Dialysis (IPD) for Method I Claims Submitted to the Intermediary

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

The value of a typical week of dialysis services generally serves as the maximum weekly payment; e.g., where, for nonmedical reasons, more frequent dialysis sessions of shorter duration are furnished.

While maintenance IPD is usually accomplished in sessions of 10-12 hours duration, three times per week, it is sometimes accomplished in fewer sessions of longer duration. Regardless of the particular regimen used, under the composite rate IPD is paid based on a weekly equivalence of three composite rates per week.

80.3.1 - IPD at Home for Method I Claims Submitted to the Intermediary

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

IPD in the home is accomplished according to any one of several schedules. The total weekly dialysis time varies from 50 to 80 hours. For example, home IPD may be furnished everyday for 10 hours per day, every other day for 15 hours per dialysis day, every night for 8 hours per night, etc. Regardless of the particular regimen used, under the composite rate home IPD is paid based on a weekly equivalence of three composite rates per week.

Effective for claims with dates of service on or after April 1, 2007, line item billing is required for all dialysis sessions. For intermittent home dialysis under method one, the provider submits a separate line item for each dialysis session using the dates in the pre-determined plan of care and the units reported on each line should be one. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule.

80.4 - Calculating Payment for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD) Under the Composite Rate

(Rev. 1084, Issued: 10-27-06; Effective: 04-01-07; Implementation: 04-02-07)

CAPD and CCPD are furnished on a continuous basis, not in discrete sessions and, therefore, are paid on a weekly or daily basis, not on a per treatment basis. Billing instructions require providers to report the number of days in the units field. A facility's daily payment rate is 1/7 of three times the composite rate for a single hemodialysis treatment.

The equivalent weekly or daily IPD or CAPD/CCPD payment does not depend upon the number of exchanges of dialysate fluid per day (typically 3-5) or the actual number of days per week that the patient undergoes dialysis. The weekly (or daily) rate is based on the equivalency of one week of IPD or CAPD/CCPD to one week of hemodialysis, regardless of the actual number of dialysis days or exchanges in that week.

All home dialysis support services, equipment and supplies necessary for home IPD or CAPD/CCPD are included in the composite rate payment. No support services, equipment or supplies may be paid in addition to the composite rate.

Effective for claims with dates of service on or after April 1, 2007, line item billing is required for all dialysis sessions. For claims billing for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD), the provider may submit a separate dialysis line for each day of the month. If the provider is aware of an inpatient stay for the beneficiary within the month, the RDF may include the

date of admission and date of discharge as a billable day for the dialysis but should omit the dates within the inpatient stay. In the event that the RDF is unaware of an inpatient stay during the month, the Medicare system shall detect the overlapping dates and reject only the line item dates within the inpatient stay but pay the remainder of the claim for any dates that are not within the inpatient stay.

90 - Method II Billing

(Rev. 1, 10-01-03)

A3-3644.A, RO-2-3440.C, B3-4270, B3-4271, B3-4270.1, B3-4270.2, B3-34271, PRM-1-2740, A3-3644.3

Physicians and independent laboratories, must submit claims (Form CMS-1500 or electronic equivalent) to their local carrier for services furnished to end stage renal disease (ESRD) beneficiaries. Suppliers of Method II dialysis equipment and supplies will submit their claims (Form CMS-1500 or electronic equivalent) to the appropriate Durable Medical Equipment Regional Carriers (DMERCs). All ESRD facilities must submit their claims to their appropriate FI.

The amount of Medicare payment under Method II for home dialysis equipment and supplies may NOT exceed $1974.45 for continuous cycling peritoneal dialysis (CCPD) and $1490.85 for all other methods of dialysis.

All laboratory tests furnished to home dialysis patients who have selected payment Method II (see §70.1 above), are billed to and paid by the carrier at the fee schedule, if the tests are performed by an independent laboratory for an independent dialysis facility patient.

If the beneficiary elects to deal directly with a supplier and make arrangements for securing the necessary supplies and equipment to dialyze at home, and chooses Method II, he/she deals directly with a supplier of home dialysis equipment and supplies (this supplier is not a dialysis facility). A supplier other than a facility bills the DMERC. There can be only one supplier per beneficiary, and the supplier must accept assignment. The beneficiary is responsible for any unmet Part B deductible and the 20 percent coinsurance.

Only a supplier that is not a dialysis facility may submit a claim to a DMERC for home dialysis supplies and equipment. Suppliers will submit these claims on Form CMS-1500, or electronic equivalent. Under Method II, beneficiaries may not submit any claims and cannot receive payment for any benefits for home dialysis equipment and supplies.

The supplier must have a written agreement with a Medicare approved dialysis facility that will provide all necessary support, backup, and emergency dialysis services. The dialysis facility will not receive a regular per treatment payment for a patient who chooses Method II.

However, if the facility provides any support services, backup, and emergency dialysis services to a beneficiary who selects this option, the facility is reimbursed for the items or services it furnishes. Hospital-based facilities are paid the reasonable cost of support services, subject to the lesser of cost or charges provisions of §1833(a)(2)(A) of the Act.

Independent facilities are paid on a reasonable charge basis for any home dialysis support services they furnish.

A. Description of Support Services

Support services specifically applicable to home patients include but are not limited to:

- Surveillance of the patient's home adaptation, including provisions for visits to the home in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition;
- Furnishing dialysis-related emergency services;
- Consultation for the patient with a qualified social worker and a qualified dietician;
- Maintaining a record-keeping system which assures continuity of care;
- Maintaining and submitting all required documentation to the ESRD network;
- Assuring that the water supply is of the appropriate quality;
- Assuring that the appropriate supplies are ordered on an ongoing basis;
- Arranging for the provision of all ESRD laboratory tests;
- Testing and appropriate treatment of water used in dialysis;
- Monitoring the functioning of dialysis equipment;
- All other necessary dialysis services as required under the ESRD conditions for coverage;
- Watching the patient perform CAPD and assuring that it is done correctly, and reviewing with the patient any aspects of the technique he/she may have forgotten, or informing the patient of modification in apparatus or technique;
- Documenting whether the patient has or has not had peritonitis that requires physician intervention or hospitalization, (unless there is evidence of peritonitis, a culture for peritonitis is not necessary);
- Inspection of the catheter site; and
- Since home dialysis support services include maintaining a medical record for each home dialysis patient, the Method II supplier must report to the support service dialysis facility within 30 days all items and services that it furnished to the patient so that the facility can record this information in the patient's medical record.

The services must be furnished in accordance with the written plan required for home dialysis patients. See the Medicare Benefit Policy Manual, Chapter 15, for coverage of telehealth services, and this manual, Chapter 12 for billing telehealth.

Each of the support services may be paid routinely at a frequency of once per month. Any support services furnished in excess of this frequency must be documented for being

reasonable and necessary. For example, the patient may contract peritonitis and require an unscheduled connecting tube change.

B. Reasonableness Determinations

Support services (which include the laboratory services included under the composite rate for in-facility patients) are paid on a reasonable charge basis to independent facilities and a reasonable cost basis to hospital-based facilities, subject to the Method II payment cap (refer to §140). A reasonable cost/charge determination must be made for each individual support service furnished to home patients. With respect to the connecting tube change, facilities may bill Medicare for the personnel services required to change the connecting tube, but must look to the Method II supplier for payment for the connecting tube itself.

The payment cap is not a payment rate that is paid automatically each month. Accordingly, in no case may the FI routinely pay any monthly amount for support services without a claim that shows the services actually furnished.

90.1 - DMERC Denials for Beneficiary Submitted Claims Under Method II

(Rev. 1, 10-01-03)

A3-3170.6, A3-3644.3, A3-3644.3.A - E, HO-238.2.C, HO-238.3, HO-238.3.A, B3-2231.3.A and B, B3-2231, B3-4270.1, PRM-1-2709.2.A

Under Method II, beneficiaries may not submit any claims and cannot receive payment for any benefits for home dialysis equipment and supplies. DMERCs must deny unassigned and beneficiary submitted claims with the following MSN messages.

MSN # 16.6: "This item or service cannot be paid unless the provider accepts assignment."

Spanish: "Este articulo o servicio no se pagará a menos de que el proveedor acepte asignación."

MSN # 16.7: "Your provider must complete and submit your claim."

Spanish: "Su proveedor debe completar y someter su reclamación."

MSN # 16.36: "If you have already paid it, you are entitled to a refund from this provider."

Spanish: "Si usted ya lo ha pagado, tiene derecho a un reebolso de su proveedor."

90.2 - Requirements for Payment by the DMERC

(Rev. 1, 10-01-03)

B3-4270.1, B3-3045.7

The DMERCS may make payment to home dialysis suppliers only if all of the following conditions are met:

- The beneficiary has elected Method II and to receive home dialysis equipment and supplies from an independent supplier. (Method II);
- The supplier is not a Medicare approved dialysis facility;

- The supplier accepts assignment for all Method II equipment and supplies;
- The supplier agrees to be the beneficiary's sole supplier for all home dialysis equipment and supplies;
- The supplier agrees to bill on a monthly basis for the quantity of supplies appropriate for that period. (However, there is one exception to this rule. Beneficiaries are permitted to have one month's supplies in reserve in case of emergency.);
- The supplier maintains a written certification in its files that it has a written agreement with a Medicare approved dialysis facility under which the facility will furnish all necessary support, backup, and emergency dialysis services, for each beneficiary the supplier services. (For Medicare beneficiaries who are also entitled to military or veterans benefits, a military or Veteran's Administration (VA) hospital satisfies this requirement.) As of July 1, 2002, suppliers are required to use a modifier (Specific required documentation on file) on any claim for services requiring such a backup agreement. See §90.4 for more information. The supplier may not provide supplies or services to the beneficiary, or submit a claim to the DMERC, until they have a valid written support service facility agreement for that beneficiary. The dialysis facility must be a reasonable distance from the beneficiary's home in order to furnish these services. Determine a reasonable distance by considering such variables as terrain, whether the patient's home is located in a rural or urban area, and the usual distances traveled and time in transit by patients in the area in obtaining health care services;
- In cases where a supplier cannot establish an agreement with a support service facility that is within a reasonable distance from the patient's home, the supplier must establish a written agreement with a support service facility outside of the geographic area of the patient's home. However, in this situation, the support service facility must establish a written agreement with a dialysis facility within the beneficiary's geographic region to provide any required in-facility dialysis treatments. In this situation, the support service facility will be responsible for providing all other necessary services for the patient, and must provide for the coordination of the patient's care and monitor the patient through frequent visits to the patient's home. The signed agreement with the Method II supplier must stipulate how the support services facility will provide each of the required support services. The written agreement must include documentation to support the arrangement with the local facility for any needed in-facility services;
- The supplier reports to the backup facility within 30 days all items and services that it furnishes to the patient so that the facility can record this information in the patient's medical record; and
- The supplies and equipment are reasonable and necessary for that patient.

90.2.1 - Supplier Documentation Required

(Rev. 797, Issued: 12-30-05; Effective: 10-01-05; Implementation: 01-30-06)

An order for the supplies or equipment which is reviewed, signed, and dated by the ordering physician must be kept on file by the supplier. The medical records must contain information which supports the medical necessity of the items ordered.

If a miscellaneous supply or equipment code (A4910, A4913, E1699) is used and if the monthly charges for the other codes billed is lower than the payment cap, then the claim must include a narrative which adequately describes each item billed using the miscellaneous codes.

The supplier also must have on file the original written agreement with a Medicare approved dialysis facility (or military or VA hospital) which specifies that it will provide at least the following support services:

- Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;
- Consultation for the patient with a qualified social worker and a qualified dietician;
- Maintain a record-keeping system which assures continuity of care and includes a record of supplies and equipment provided by the Method II supplier;
- Maintaining and submitting all required documentation to the ESRD network;
- Assuring that the water supply is of the appropriate quality if hemodialysis is the dialysis method;
- Assuring that the appropriate supplies are ordered on an ongoing basis;
- Arranging for the provision of all ESRD related laboratory tests, and billing for the laboratory tests that are included in the composite rate;
- Furnishing institutional dialysis services and supplies;
- Furnishing dialysis-related emergency services; and
- Furnishing all other necessary dialysis services and supplies, dialysate, tubing and gauze pads.

NOTE: As of July 1, 2002, claims to DMERCS must include modifier KX (Specific required documentation on file) on any claim for services requiring such a backup agreement. See §90.4 for more information.

90.2.2 - DMERC Letter Explaining Requirements to Method II Supplier

(Rev. 1, 10-01-03)

B3-4270.1 updated with transmittal B3-1729 (11-01)

The DMERCs must explain the Medicare requirements to every Method II supplier they service. Below is a sample letter to use.

Dear Method II Supplier:

Our records show that you supply home dialysis equipment and/or supplies to Medicare home dialysis beneficiaries who have chosen payment Method II. Effective February 1, 1990, there is a limit on the amount that a dialysis supplier may be paid under Method II.

The payment limit for Method II benefits for all forms of dialysis except continuous cycling peritoneal dialysis (CCPD) cannot exceed the median composite rate for hospital-based dialysis facilities. This rate is $1,974.45 for continuous cycling peritoneal dialysis (CCPD) and $1,490.85 for all other methods of dialysis. These limits are subject to the usual Medicare Part B deductible and coinsurance amounts.

There are additional requirements for Method II benefits. Each Method II beneficiary that did not choose Method II before February 1, 1990 must certify in writing that he/she deals with a single supplier for all home dialysis equipment and supplies. Beneficiaries who chose Method II before February 1, 1990, are presumed to meet this requirement and need not submit this certification. If a beneficiary chooses Method II on or after February 1, 1990, the beneficiary (or the dialysis facility or the supplier on the beneficiary's behalf) must write the following in Block 8 of the Form CMS-382:

"I certify that I have only one Method II supplier."

As a Method II home dialysis supplier, in order to be paid Medicare benefits, the supplier must:

- Be the beneficiary's sole supplier for all home dialysis equipment and supplies needed by the beneficiary;
- Accept assignment of Medicare benefits for home dialysis equipment and supplies. If the supplier does not accept assignment, inform your Medicare beneficiaries that the supplier does not accept assignment and that, therefore, Medicare CANNOT pay for his/her home dialysis equipment or supplies;
- Maintain written certifications that there is a written agreement with a Medicare approved dialysis facility under which the facility will furnish all necessary support, backup, and emergency dialysis services for each beneficiary you serve. Support services include, but are not limited to, maintaining the patient's medical record and providing information required by the ESRD network. For each Medicare beneficiaries, there must be an agreement with a dialysis facility that is a reasonable distance from the beneficiary's home. The CMS determines a reasonable distance by considering such variables as terrain, whether the beneficiary's home is in an urban or rural area, and the usual distances traveled and time in transit by patients in the area when obtaining health services. In cases where an agreement with a support service facility cannot be established that is within a reasonable distance from the patient's home, a written agreement with a support service facility outside of the geographic area of the patient's home must be established. In this situation, the support service facility must establish a written arrangement with a dialysis facility within the beneficiary's geographic region to provide any required in-facility dialysis treatments. In this situation, the support service facility will be responsible for providing all other necessary services for the beneficiary and must provide for the coordination of the patient's

care and monitor the patient through frequent visits to the patient's home. The signed agreement with the Method II supplier must stipulate how the support services facility will provide each of the required support services. The written agreement must include documentation to support the arrangement with the local facility for any needed in-facility services. Suppliers may not provide services or submit a claim to Medicare before this agreement is obtained. They need not identify individual beneficiaries.

- Report to the support service dialysis facility within 30 days all items and services that are furnished to the patient so that this information can be recorded by the facility in the medical record; and
- Agree to generally bill once a month and for only one month's quantity of supplies at a time. In the event that a beneficiary becomes a hospital inpatient for at least three days (not counting the day of admission or discharge), suppliers must prorate the following month's supply bills to account for supplies the beneficiary did not use while an inpatient.

90.3 - Amount of Payment by the DMERC

(Rev. 1, 10-01-03)

PM B-01-56, B3-3045.7

The statute requires that Medicare payment for home dialysis supplies and equipment be determined using the reasonable charge payment methodology. The reasonable charge for an item is generally set at the lowest of the supplier's actual charge for the item, the supplier's customary charge for the service, the prevailing charge in the locality for the item (the prevailing charge may not exceed the 75th percentile of the customary charges of suppliers in the locality), or the inflation indexed charge (IIC). The IIC is the lowest of the customary charge, prevailing charge, or IIC from the previous year, updated by an inflation adjustment factor. However, whenever supplier charges are not available for use in determining reasonable charges, as is usually the case for new HCPCS codes, the initial reasonable charges must be "gap-filled" using other pricing methods.

The DMERCs must pay only on an assignment basis for home dialysis supplies and equipment furnished a beneficiary who has selected Method II. The amount of Medicare payment under Method II for home dialysis equipment and supplies may NOT exceed $1,974.45 for continuous cycling peritoneal dialysis (CCPD) and $1,490.85 for all other methods of dialysis. The actual amount paid is based on reasonable charges limited by the monthly cap less the Part B coinsurance and any unmet Part B deductible amounts. (Note, however, that beneficiaries are permitted to have on hand one month's emergency reserve supplies.) This payment may be made to only one supplier per beneficiary.

90.3.1 - Billing Instructions for Method II to DMERCs

(Rev. 1, 10-01-03)

B3-3045.7

Suppliers of Method II home dialysis supplies and equipment must complete their claims as follows:

- Submit claims to the appropriate DMERC on a monthly basis for one month's worth of supplies and equipment;
- Enter appropriate Healthcare Common Procedure Coding System (HCPCS) codes for each supply for piece of equipment provided, with a "KX" modifier on each line item to signify that the supplier has a valid agreement with an appropriate support service facility; and
- Use modifier "EM" to designate each HCPCS code for emergency reserve supplies. This allows the DMERC to identify situations in which the payment limit for a given month may be exceeded if an emergency reserve is billed for in addition to regular monthly supplies. It also allows DMERCs to ensure that emergency supplies are not purchased more frequently than once in a beneficiary's lifetime per mode of dialysis. Suppliers must bill for all emergency dialysis supplies in the same calendar month.

90.3.2 - Home Dialysis Supplies and Equipment HCPCS Codes Used to Bill the DMERC

(Rev. 1, 10-01-03)

PM B-01-56, B3-4270 updated 11-16-01(CR 1799)

A. HCPCS Codes

Prior to January 1, 2002, suppliers billed for dialysis supplies using codes describing "kits" of supplies. The use of kit codes such as A4820, A4900, A4901, A4905, and A4914 allows suppliers to bill for supply items without separately identifying the supplies that are being furnished to the patient. Effective January 1, 2002, these kit codes were deleted and suppliers are now required to bill for dialysis supplies using existing and newly developed HCPCS codes for individual dialysis items. Refer to the LMRP for the HCPCS codes for dialysis supplies and equipment that are effective for claims received on or after January 1, 2002.

A4651	A4652	A4656	A4657	A4660	A4663	A4680	A4690	A4706
A4707	A4708	A4709	A4712	A4714	A4719	A4720	A4721	A4722
A4723	A4724	A4725	A4726	A4730	A4736	A4737	A4740	A4750
A4755	A4760	A4765	A4766	A4770	A4771	A4772	A4773	A4774
A4801	A4802	A4860	A4870	A4911	A4913	A4918	A4927	A4928
A4929	E1500	E1510	E1520	E1530	E1540	E1550	E1560	E1570
E1575	E1580	E1590	E1592	E1594	E1600	E1610	E1615	E1620
E1625	E1630	E1632	E1635	E1636	E1637	E1638	E1639	E1699

The DMERCs gap-fill reasonable charge amounts for 2002 for all of the applicable codes other than codes A4913 and E1699, the codes used for miscellaneous supplies and equipment that do not fall under any of the other HCPCS codes. The gap-filled amounts should be established using price lists in effect as of December 31, 2000 if available. These gap-filled payment amounts will apply to all claims with dates of service from January 1, 2002, through December 31, 2002.

Codes A4650 - A4927 and E1510 - E1702 may be used only for supplies and equipment relating to home dialysis. In particular, items not related to dialysis should not be included in the supply kit codes (A4820, A4900, A4901, A4905) or listed in the miscellaneous codes (A4910, A4913, E1699). Conversely, supplies and equipment relating to home dialysis should not be billed using other HCPCS codes.

Dialysis supply kits (A4820, A4900, A4901, A4905) billed by an individual supplier must contain the same type and quantity of supplies each time that it is billed. One unit of service would represent the typical amount of supplies needed for one month of dialysis. The content of the kit may not vary from patient to patient or in a single patient from month to month unless the 52 modifier is used (see below). If more than this typical amount of supplies is needed in one month, the excess supplies should be billed using other dialysis supply codes. If significantly less than the usual amount is needed for 1 month, the 52 modifier should be added to the code and the submitted charge reduced accordingly. A listing of the components of each kit billed by a supplier must be available for review by the DMERC.

For items before January 1, 2002, dialysis solutions (A4700, A4705) should not be included in the supply kit but should be separately billed. One unit of service for these codes is for one liter of dialysis solution.

For items before January 1, 2002, items not included in kits must be billed separately, using either a specific code (A4650 - A4927) or miscellaneous code (A4910, A4913, E1699).

Code A4901 and/or E1594 should be billed for each month that the patient receives CCPD.

An EM modifier should be added to a dialysis supply code when it represents emergency reserve supplies over and above the typical monthly amount.

B. Modifiers

Method II suppliers must maintain documentation to support the existence of a written agreement with a Medicare certified support service facility within a reasonable distance from the beneficiary's home.

Effective July 1, 2002, suppliers must use "KX" modifier on the line item level for all Method II home dialysis claims to indicate that they have this documentation on file, and must provide it to the DMERC upon request. As of July 1, 2002, DMERCs must front end reject any Method II claims that do not have the "KX" modifier at the line level. The supplier may correct and resubmit the claim with the appropriate modifier. DMERCs and the shared systems must make all systems changes necessary to reject Method II claims that do not have the "KX" modifier.

The following listed modifiers are frequently used to identify the service/charges billed for Dialysis Supplies.

CC-Procedure code change - Used by the carrier when the procedure code submitted was changed either for administrative reasons or because an incorrect procedure code was filed. Do not use this modifier when filing claims to Palmetto GBA.

EJ-Subsequent Claim (for Erythropoietin Alpha-EPO injection only)

EM-Emergency reserve supply [for End Stage Renal Disease (ESRD) benefit only]

KY-Specific requirements found in the Documentation section of the Medical Policy have been met and evidence of this is available in the supplier's record. Effective July 1, 2002, suppliers must use the " KY" modifier on the line item level for all Method II home dialysis claims.

NU-New Equipment - Used when purchasing new equipment.

RR-Initial Rental - Rental (use the -RR modifier when DME is to be rented).

UE-Used durable medical equipment

ZU-Advance notice of possible medical necessity denial on file (this modifier will be discontinued with the implementation of HIPAA)

ZY-Potentially noncovered item or service billed for denial or at the beneficiary's request (not to be used for medical necessity denials) (this modifier will be discontinued with the implementation of HIPAA)

90.3.3 - DMERC Claims Processing Instructions

(Rev. 116, 03-05-04)

B3-3045.7.C

The monthly limit applies to all home dialysis supplies and equipment furnished to the beneficiary. More than one supply or piece of equipment may be furnished for a given month. Regardless of the order in which suppliers bill supplies and equipment to the DMERC, the payment limits under Method II for home dialysis equipment and supplies may not exceed the limits prescribed under Chapter 8, Section 90 of the Medicare Claims Processing Manual. Once the limits are met, additional miscellaneous ESRD codes that do not fall under any of the HCPCS codes listed in Section 90.3.2, need not be manually priced inasmuch as the capitation amount has been met on the lines that the system prices automatically for dialysis items, regardless of the order in which they are received on the claim.

If a claim identifies the beneficiary as a CCPD patient, apply the higher monthly limit.

If two different suppliers submit bills for the same month for the same beneficiary, DMERCs pay only the first supplier that submits a bill.

The DMERCs must deny payment for home dialysis supplies and equipment if any of the following conditions are met:

- The supplier has not accepted assignment;

- The supplies were furnished by a second supplier;
- The monthly limit has been paid;
- The beneficiary filed the claim;
- The beneficiary has elected Method I for the date of service on the claim;
- The DMERC finds that the supplier does not have a valid written agreement with a support service facility, or
- The supplier did not use the "KX" modifier on each line item to indicate that it has a valid written backup agreement with a support service facility.

90.4 - Equipment and Equipment Related Services Provided to Direct Dealing Beneficiary

(Rev. 1, 10-01-03)

Under the direct dealing method the beneficiary may deal directly with suppliers and make his or her own arrangements for securing the necessary supplies and equipment or deal with the facility.

The direct dealing patient has the choice of buying or renting (leasing) the equipment with the exception of purchased items costing $120 or less, which may be reimbursed in a single payment. DMERCs pay for both rented and purchased equipment in monthly installments. Installment payments are made regardless of whether the patient pays for purchased equipment in a lump sum or in installments. The payment rate approximates the monthly rental fee for similar equipment until either its share of the allowed purchase price is paid, or until the equipment is no longer medically necessary, whichever comes first.

Medicare will pay 80 percent of the allowed amount as long as the equipment is medically necessary. When payments stop because the beneficiary's condition has changed and the equipment is no longer necessary, the beneficiary is responsible for the remaining charges. Similarly, when payments stop because the beneficiary dies, his estate is responsible for the remaining charges. A beneficiary may sell or otherwise dispose of purchased equipment for which he/she has no further use. If, after disposal of such equipment, there is again medical need for similar equipment, Medicare can pay for the rental or purchase of that equipment.

Payment can also be made for the installation, delivery, repair, maintenance, or replacement of home dialysis equipment. This payment also includes the costs of necessary supply items needed to effectively perform the dialysis. See the Medicare Benefit Policy Manual Chapter 11, for related coverage rules.

When covered, these items are reimbursed in a lump sum.

90.5 - Method II Support Services Billed to the Intermediary by the Facility

(Rev. 1364, Issued: 11-02-07: Effective: 04-01-08; Implantation: 04-07-08)

A3-3644.3.C, A3-3644.3.D, PRM-1-2740.1, PRM-1-2743.1

In addition to the supplier billing the DMERC for equipment and supplies, the dialysis facility may bill the FI for home dialysis support services. Those services include, but are not limited to:

- Surveillance of the patient's home adaptation, including provisions for visits to the home in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition;

- Furnishing dialysis-related emergency services;

- Consultation for the patient with a qualified social worker and a qualified dietician;

- Maintaining a record-keeping system which assures continuity of care;

- Maintaining and submitting all required documentation to the ESRD network;

- Assuring that the water supply is of the appropriate quality;

- Assuring that the appropriate supplies are ordered on an ongoing basis;

- Arranging for the provision of all ESRD related laboratory tests;

- Testing and appropriate treatment of water used in dialysis;

- Monitoring the functioning of dialysis equipment;

- All other necessary dialysis services as required under the ESRD conditions for coverage; and

- Since home dialysis support services include maintaining a medical record for each home dialysis patient, the Method II supplier must report to the support service dialysis facility within 30 days all items and services that it furnished to the patient so that the facility can record this information in the patient's medical record.

Support services specifically applicable to home CAPD patients must be furnished and billed by the sponsoring CAPD certified facility. These include, but are not limited to:

- Changing the connecting tube (also referred to as an "administration set");

- Watching the patient perform CAPD and assuring that it is done correctly. This includes reviewing for the patient any aspects of the technique he/she may have forgotten or informing the patient of modifications in apparatus or technique;

- Documenting whether the patient has or has had peritonitis that requires physician intervention or hospitalization (unless there is evidence of peritonitis, a culture for peritonitis is not necessary); and

- Inspecting the catheter site.

Each of the CAPD support services may be covered and reimbursed routinely at a frequency of once per month. Any support services furnished in excess of this frequency must be documented for medical necessity. For example, the patient may contract peritonitis and require an unscheduled visit.

Support services are paid on a reasonable charge basis to independent facilities and a reasonable cost basis to hospital-based facilities. A reasonable cost determination must be made for each individual support service furnished to home CAPD patients. *The allowance per month under Method II for home dialysis support services may NOT exceed $121.15 per month for all forms of dialysis. Medicare contractors may not routinely pay any monthly amount for support services without some assurance as to the nature of the services actually furnished.*

90.5.1 - *Billable Revenue Codes Under Method II*

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Revenue codes that may be billed for Method II beneficiaries by an ESRD facility are:
Support Services

0825 - Hemodialysis - Support Services - HEMO/HOME/SUPSERV

0835 - Peritoneal Dialysis - Support Services - PERTNL/HOME/SUPSERV

0845 - Continuous Ambulatory Peritoneal Dialysis (CAPD) - Support Services - CAPD/HOME/SUPSERV

0855 - Continuous Cycling Peritoneal Dialysis (CCPD) - Support Services - CCPD/HOME/SUPSERV

25X - Pharmacy

The description for pharmacy is - charges for medication produced, manufactured, packaged, controlled, assayed, dispensed and distributed under the direction of a licensed pharmacist.

Drugs and biologicals such as blood may be covered in the home dialysis setting only if the “incident to a physician’s services” criteria are met. Normally, a physician is not in the patient’s home when the drugs or biologicals are administered, and therefore,

generally drugs and biologicals are not covered in the home setting. This includes blood plasma, other components of blood, and IV solutions.

This category should be used only for non-routine drugs and biologicals since routine drugs and biologicals are included in the composite rate under Method I and are part of home dialysis supplies under Method II. They must be documented for medical necessity. The administration of drugs and biologicals (both staff time and supplies are covered and billed as revenue code 0259).

0 - General Classification - PHARMACY
1 - Generic Drugs - DRUGS/GENERIC
2 - Nongeneric Drugs - DRUGS/NONGENERIC
4 - Drugs Incident to Other Diagnostic Services - DRUGS/INCIDENT ODX
5 - Drugs Incident to Radiology - DRUGS/INCIDENT RAD 8 - IV Solutions - IV SOLUTIONS
9 - Other Pharmacy- DRUGS/OTHER

027X - Medical/Surgical Supplies

Charges for supply items required for patient care.

Rationale: Additional breakdowns are provided for items that hospitals may wish to identify because of internal or third party payer requirements.

030X - Laboratory

Charges for the performance of diagnostic and routine clinical laboratory tests.

Rationale: A breakdown of the major areas in the laboratory is provided in order to meet hospital needs or third party billing requirements.

3 - Renal Patient (Home) - LAB/RENAL HOME
4 - Non-routine Dialysis - LAB/NR DIALYSIS

031X - Laboratory Pathological

Charges for diagnostic laboratory tests on tissues and culture.

Rationale: A breakdown of the major areas that providers may wish to identify is provided.

0 - General Classification - PATHOLOGY LAB or (PATH LAB)
1 - Cytology - PATHOL/CYTOLOGY
2 - Histology - PATHOL/HYSTOL
4 - Biopsy - PATHOL/BIOPSY
9 - Other - PATHOL/OTHER

032X - Radiology - Diagnostic

Charges for diagnostic radiology services provided for the examination and care of patients. Includes: taking, processing, examining and interpreting radiographs and fluorographs.

Rationale: A breakdown is provided of the major areas and procedures that individual providers or third party payers may wish to identify.

0 - General Classification - DX X-RAY
4 - Chest X-Ray - DX X-RAY/CHEST
9 - Other - DX X-RAY/OTHER

038X - Blood

Rationale: Charges for blood must be separately identified for private payer purposes.

0 - General Classification (Washed red blood cells) - BLOOD
1 - Packed Red Cells - BLOOD/PKD RED
2 - Whole Blood - BLOOD/WHOLE
3 - Blood Plasma - BLOOD/PLASMA
4 - Blood Platelets - BLOOD/PLATELETS
5 - Blood Leucocytes - BLOOD/LEUCOCYTES
6 - Blood - Other Components - BLOOD/OTHER COMP
7 - Blood - Other Derivatives - BLOOD/ OTHER DER (Cryoprecipitates)
9 - Other Blood (Describe) - BLOOD /OTHER

039X - Blood Storage and Processing

Charges for the storage and processing of whole blood.

0 - General Classification - BLOOD/STOR-PROC
1 - Blood Administration - BLOOD/ADMIN.
9 - Other Blood Storage & Processing - BLOOD/OTHER STOR

063X - Erythropoietin (EPO)

4 - Erythropoietin (EPO) administration under 10,000 units per administration.
5 - Erythropoietin (EPO) administration of 10,000 units or more per administration.

073X - EKG/ECG (Electrocardiogram)

Charges for operation of specialized equipment to record electromotive variations in action of the heart muscle on an electrocardiograph for diagnosis of heart ailments.

0 - General Classifications - EKG/ECG

l - Holter Monitor - Holter Mont
9 - Other EKG/ECG - Other EKG-ECG

90.5.1.1 - *Unbillable Revenue Codes Under Method II*

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

The facility bills the FI using UB-*04* (Form CMS-1450) for support services and back up dialysis and emergency services only. Bills for supplies and equipment are billed to the DMERC on the 1500. Therefore, the following revenue codes may not be used on Method II bills:

0822 Hemodialysis - Home Supplies
0823 Hemodialysis - Home Equipment
0832 Peritoneal Dialysis - Home Supplies
0833 Peritoneal Dialysis - Home Equipment
0842 CAPD - Home Supplies
0852 CCPD - Home Supplies
0853 CCPD - Home Equipment

100 - Dialysis Sessions Furnished to Patients Who are Traveling

(Rev. 1, 10-01-03)

PRM-1-2713, RO-2 3440.3, A3-3169.3, RDF-245.2.E

100.1 - Traveling Patients Who Are Normally In-Facility Dialysis Patients

(Rev. 1, 10-01-03)

PR 12713.1

A. Dialysis at Another Facility

All in-facility dialysis treatments furnished by and in a facility are billed by and paid to that facility at its composite rate. This is true even if the patient is only temporary.

B. Temporary Home Dialysis

Patients who normally dialyze in a facility may wish to dialyze temporarily as home dialysis patients while they travel or vacation. In this situation, benefits may be paid only under Method I. If the patient is not normally a home dialysis patient and has no intention of becoming one except for a temporary period, e.g., a vacation, then the patient does not complete Form CMS-382, Beneficiary Selection Form. Instead, the patient informs his/her facility:

- He/she will be in travel status, and
- The dates in travel status.

The facility is responsible for obtaining this information from the patient and entering it in the “remarks” section of any claims the facility submits for the patient. The facility indicates “traveling patient, temporary Method I” as well as the dates of travel.

1. Temporary Method I

The patient’s regular facility bills its composite rate and no other party submits bills to the program. All suppliers must seek payment from the facility. The facility bills these services as though the patient were a home dialysis patient (e.g., the appropriate revenue code in item 51, on the Form CMS-1450). The FI processes these bills outside the usual system because the patient does not file a Form CMS-382 selection form.

2. Self-Care Dialysis Training

Training services furnished to temporary home dialysis patients are covered and paid at the training rate subject to the usual rules for reimbursement of training services. Since the patient does not expect to remain on home dialysis, he/she should understand that he/she is expected to perform in-facility dialysis when he/she returns to the facility.

Under this temporary Method I arrangement, the Regional Office (RO) must coordinate with the appropriate FI to override the normal check in the system that prevents payment of any home dialysis items or services on behalf of a patient who has not filed a Form CMS-382 selection form.

100.2 - Traveling Patients Who are Normally Home Dialysis

(Rev. 1, 10-01-03)

PRM-1-2713.2, B3-4271.1, B3-4272

A. Dialysis at Another Facility

All in-facility dialysis treatments furnished by and in a facility are billed by and paid to that facility. This is true even if the patient is only temporary.

B. Home Dialysis

The manner of payment depends upon which method of reimbursement the home patient has chosen.

1. Method I (Composite Rate)

If the patient travels from place to place and never spends a continuous 30 days at a single facility, then all facilities or suppliers which furnish any home dialysis items or services to the patient, must seek payment from the patient’s home town facility. The home town facility bills the program its composite rate for all home dialysis treatments the patient performs.

If the patient spends 30 days or more at a single facility away from his/her home town facility:

- The two facilities may reach an agreement between them as to which facility will bill the program the composite rate. The facility that does not bill the composite rate is paid by the other facility during this period of time. The temporary facility

may bill the program directly only for items and services that it furnishes to a patient after a patient has been under its care for 30 days.

If the facility that bills the composite rate is the temporary facility, then it indicates on its claim "temporary patient," and the name and address of the patient's home town facility. The FI receiving this claim must send a copy of the MSN to the FI servicing the home town facility in order to assure that the home town facility is not also paid during this time.

If the two facilities cannot reach an agreement as to which one will bill the program, then after the 30-day waiting period the temporary facility bills its FI; the home town facility does not bill. The procedure outlined for completing and processing the claim must be followed.

2. Method II (Direct Dealing)

Under Method II, dialysis facilities may bill or be paid by the program only for home dialysis support services; not equipment or supplies.

The patient may choose to purchase the equipment under Method II, but the program will make installment payments only for the temporary period. No lump sum purchase payment may be authorized.

Patients who usually receive dialysis in an ESRD facility may become home dialysis patients temporarily because they are traveling. In this situation, the patient may choose only payment Method I. DMERCs must not pay any of these claims. Facilities must submit all of their claims to their FIs. If the patient is not normally a home dialysis patient, and has no intention of becoming one except for a temporary period; e.g., a vacation, then the patient does not complete Form CMS-382, Beneficiary Selection Form.

Under either Method I or II, the RO must coordinate with the appropriate contractor (FI or carrier as the case may be) to override the normal check in the system that prevents payment of any home dialysis items or services on behalf of a patient who has not filed a Form CMS-382 selection form.

These special procedures may be followed only for items and services furnished during the precise period the patient is traveling away from home.

100.3 - Physician's Services Furnished to a Dialysis Patient Away From Home or Usual Facility

(Rev. 1, 10-01-03)

B3-4272.4

When a dialysis patient whose attending physician receives a monthly payment receives maintenance dialysis services of any kind outside the usual setting from any physician who is neither the attending physician nor that physician's substitute, the following procedures apply:

- The physician who furnished the service submits a claim to the local carrier of jurisdiction;
- The carrier will process the claim and send an MSN to the patient;

- The carrier that has jurisdiction over the usual dialysis setting adjusts the MCP to the usual attending physician to account for the time the patient was absent from the usual dialysis setting.
- The carrier that has jurisdiction over the usual dialysis setting adjusts the MCP to the usual attending physician per §140.3.E below to account for the time the patient was absent from the usual dialysis setting.

Carriers must notify physicians that claims for services furnished to temporary patients must be identified as a claim for a temporary patient. The physician must indicate "temporary patient" under element 24C of the Form CMS-1500.

110 - Reduction in Medicare Program Payment to Fund ESRD Networks

(Rev. 1, 10-01-03)

A3-3644.C.1, A3-3644.C.3, PRM-1-2706.2

A. General

Section 9335(j) of OBRA 1986 requires the Secretary to reduce the amount of each composite rate payment for each treatment by 50 cents and to allocate these amounts to ESRD network activities. This applies to all dialysis treatments furnished on or after January 1, 1987 for all treatment modalities, including training treatments. All Medicare hospital-based and independent ESRD facilities paid the composite rate are affected.

B. Calculating the Reduction

Intermediaries apply a reduction of 50 cents per treatment on each claim from the amount paid to ESRD facilities for all treatments furnished on or after January 1, 1987. For example, if a facility's composite rate payment is $120, Medicare pays the renal facility $95.50 per treatment ($120 x 80% -$.50). The 50-cent reduction is also applicable to modes of dialysis other than hemodialysis (including training treatments). The facility's weekly composite rate payment is reduced by $1.50 for CAPD or continuous CCPD. Where there is less than a week of CCPD or CAPD treatment, the $1.50 is prorated. For peritoneal dialysis furnished in sessions of greater than 20 or 30 hours per treatment, the 50-cent reduction is multiplied times 1.5 or 3 depending upon the length of the treatment.

The reduction amount is reported in the Provider Statistics and Reimbursement Report (PS&R) and CWF using value code 71 to identify monies withheld to fund ESRD networks.

The Medicare payment reduction allocated toward funding the ESRD networks for the individual claims will be indicated on the remittance record to the facility.

Facilities may not claim the 50-cent reduction as an expense on their Medicare cost reports.

C. Application of ESRD Network Funding to MSP Claims

The ESRD offset for network funding on MSP claims will be applied as follows:

- Where another payer, primary to Medicare, pays the claim in full, no ESRD offset is applicable;

- Where another payer, primary to Medicare, makes a partial payment, the ESRD offset is deducted for each treatment as described in subsection C2 from the Medicare secondary payment; and
- Where the ESRD offset amount is greater that the secondary payment amount, the entire Medicare secondary payment amount is applied towards the ESRD network funding. No Medicare secondary payment is made to the facility in this situation and no further ESRD offset is applicable. No additional ESRD offset for treatments on this claim will be made against other payments to the facility on the same remittance or on future payments for the same beneficiary.

120 - Renal Transplantation and Related Services

(Rev. 1341, Issued: 09-21-07, Effective: 06-28-07, Implementation: 10-22-07)

Renal transplantation is a principal form of treatment available to patients with end-stage renal disease. See Medicare Provider Reimbursement Manual, Part I, §§2771, for a description of related payment policies. For a list of approved facilities, refer to the following Web site:
http://www.cms.hhs.gov/CertificationandComplianc/20_Transplant.asp#TopOfPage

120.1 - Payment for Immunosuppressive Drugs Furnished to Transplant Patients

(Rev. 1, 10-01-03)

PRM-1-2711.5, B3-4471, AB-01-10

A. General

Effective January 1, 1987, Medicare pays for FDA approved self-administered immunosuppressive drugs. Generally, under this benefit, payment is made for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, as well as those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. This benefit is subject to the Part B deductible and coinsurance provision. There is no time limitation on the coverage of these drugs; however, if a beneficiary loses Medicare coverage as a result of the transplant, the drugs are no longer covered. When the beneficiary reaches the age of 65 and becomes entitled, that person can have the drugs covered again. The hospital pharmacy must ask the physician to furnish the patient with a non-refillable 30-day prescription for the immunosuppressive drugs. This is because the dosage of these drugs frequently diminishes over a period of time, and it is not uncommon for the physician to change the prescription from one drug to another because of the patient's needs. Also, these drugs are expensive, and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, the FI and carrier do not consider a supply of drugs in excess of 30 days to be reasonable and necessary and limits payment accordingly.

B. Payment

Payment is made on a reasonable cost basis if the beneficiary is the outpatient of a participating hospital. In all other cases, payment is made on an allowable charge basis.

C. FDA Approved Drugs

Some of the most commonly prescribed immunosuppressive drugs are:

- Sandimmune (cyclosporine), Sandoz Pharmaceutical (oral or parenteral),
- Imuran (azathioprine), Burroughs Wellcome Vial (oral),
- Atgam (antithymocyte/globulin), Upjohn (parenteral); and
- Orthoclone OKT3 (muromonab - CD3) Ortho Pharmaceutical (parenteral).

Also covered are prescription drugs used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs.

The payment for the drug is limited to the cost of the most frequently administered dosage of the drug (adjusted for medical factors as determined by the physician).

Consult such sources as the Drug Topics Red Book, American Druggists Blue Book, and Medispan, realizing that substantial discounts are available.

130 - Physicians and Supplier (Nonfacility) Billing for ESRD Services - General

(Rev. 1, 10-01-03)

B3-4270 updated with Transmittal 1729

Payment for renal-related physicians' services to ESRD patients is made in either of the following ways:

- Under the Monthly Capitation Payment (MCP) (see §140 below for an explanation of the MCP); or
- Using the daily codes for ESRD services (CPT codes 90922-90925) with units that represent the number of days services were furnished.
- Under the Initial method (IM)

The carrier receives bills (Form CMS--1500 or electronic equivalent) from physicians for services furnished ESRD beneficiaries. DMERCs receive bills for equipment and supplies for Method II beneficiaries. Intermediaries receive bills from ESRD facilities. Lab bills from CLIA certified independent dialysis facilities were billed to the carrier before September 1, 1997, and to the FI beginning on that date. Other certified labs continue to bill the carrier.

130.1 - Initial Method for Physician's Services to Maintenance Dialysis Patients

(Rev. 1, 10-01-03)

B3-4275, B3-4275.1, B3-4275.2, PRM-1-2715, PRM-1-2715.1, PRM-1-2715.2

Under the Initial Method (IM), do not pay for physician's routine professional dialysis services. Instead, the dialysis facility's FI pays the dialysis facility for them as part of the facility's composite rate. Physician's professional services that are not routine professional dialysis services are billed to the contractor and paid in the same way as any other Medicare covered physician professional service.

1. For the physician to be paid under the IM, the following requirements must be met:

All physicians of the facility must choose the IM with respect to all of the patients treated at the facility and all of the facility's Method I home dialysis patients. (See §70.1 for a description of Method I). All of the facility's physicians must file a written statement with their carrier and the facility's FI to this effect. For example:

> The physicians practicing at _____ dialysis facility are listed below. The signature of each physician indicates the physician's election to be paid for their routine professional dialysis services under the Initial Method. This election is effective for services furnished beginning with the second month after the month in which this statement is filed with the carrier(s) and the facility's intermediary.

This written statement must be signed and dated by each physician.

2. The physician may bill the carrier only those physician's professional services that are not routine professional dialysis services. (See paragraph 3 below).

The election of the IM is effective for services furnished beginning with the second calendar month after the month in which all the physicians of a facility elect it. A physician may terminate the election by written notice to the carrier and to the facility's FI that the physician thereby terminates the IM. If the carrier and the FI receive the termination notice on or before November 1, it is effective the following January 1. If the carrier or the FI receives it after November 1, it is effective January 1 of the second year after the calendar year in which the notice of termination is received. Note that if the IM is terminated by one physician, it is thereby terminated for all physicians at the same facility with respect to the patients treated through that facility.

3. Definitions

A. Administrative Services

Physician services that are differentiated from routine professional services and other physician services. They include supervision, as described in the definition of "supervision of staff," are not related directly to the care of an individual patient and are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

B. Dialysis Session

The period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the

machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's private office.

C. Medical Direction

Routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

D. Routine Professional Services

Physicians' services furnished during a dialysis session and all services listed under "Types of routine professional services" that:

- Are personally furnished by a physician to an individual patient.
- Contribute directly to the diagnosis or treatment of an individual patient.
- Ordinarily must be performed by a physician.

E. Supervision of Staff

Administrative services that do not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

F. Types of Routine Professional Services

Routine professional services include at least the following services when medically appropriate:

- Visits to the patient during dialysis, and in conjunction with review of laboratory test results,
- Nurses' notes and any other medical documentation, as a basis for:
    - Adjustment of the patient's medication, diet or the dialysis procedure;
    - Prescription of medical supplies; and
    - Evaluation of the patient's psychosocial status and the appropriateness of the modality,
    - Medical direction of staff in delivering services to a patient during a dialysis session, and
    - Pre-dialysis and post-dialysis examinations or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

140 - Monthly Capitation Payment Method for Physicians' Services Furnished to Patients on Maintenance Dialysis

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Physicians and practitioners managing patients on dialysis (center based) are paid a monthly capitation payment (MCP) for most outpatient dialysis-related physician services furnished to a Medicare end stage renal disease (ESRD) beneficiary. The

payment amount varies based on the number of visits provided within each month and the age of the ESRD beneficiary. Physicians and practitioners managing ESRD patients who dialyze at home are paid a single monthly rate based on the age of the ESRD beneficiary, regardless of the number of face-to-face physician or practitioner visits. The MCP is reported once per month for services performed in an outpatient setting that are related to the patients' ESRD.

Physicians and practitioners may receive payment for managing patients on dialysis for less than a full month of care in specific circumstances as discussed in section 140.2. Payment for ESRD related services, less than a full month, is made on a per diem bases.

Payment for ESRD-related services is made at 80 percent of the Medicare approved amount (lesser of the actual charge or applicable Medicare fee schedule amount) after the beneficiary's Part B deductible is met. The beneficiary is responsible for the Part B deductible and the 20 percent coinsurance for physician and practitioner ESRD-related services.

A. Services Included in Monthly Capitation Payment

The following physician services are included in the MCP:

- Assessment of the need for a specified diet and the need for nutritional supplementation for the control of chronic renal failure. Specification of the quantity of total protein, high biologic protein, sodium, potassium, and amount of fluids to be allowed during a given time period. For diabetic patients with chronic renal failure, the prescription usually specifies the number of calories in the diet.

- Assessment of which mode(s) of chronic dialysis (types of hemodialysis or peritoneal dialysis) are suitable for a given patient and recommendation of the type(s) of therapy for a given patient.

- Assessment and determination of which type of dialysis access is best suited for a given patient and arrangement for creation of dialysis access.

- Assessment of whether the patient meets preliminary criteria as a renal transplant candidate and presentation of this assessment to the patient and family.

- Prescription of the parameters of intradialytic management. For chronic hemodialysis therapies, this includes the type of dialysis access, the type and amount of anticoagulant to be employed, blood flow rates, dialysate flow rate, ultrafiltration rate, dialysate temperature, type of dialysate (acetate versus bicarbonate) and composition of the electrolytes in the dialysate, size of hemodialyzer (surface area) and composition of the dialyzer membrane (conventional versus high flux), duration and frequency of treatments, the type and frequency of measuring indices of clearance, and intradialytic medications to be administered. For chronic peritoneal dialysis therapies, this includes the type of

peritoneal dialysis, the volume of dialysate, concentration of dextrose in the dialysate, electrolyte composition of the dialysate, duration of each exchange, and addition of medication to the dialysate, such as heparin, and the type and frequency of measuring indices of clearance. For diabetics, the quantity of insulin to be added to each exchange is prescribed.

- Assessment of whether the patient has significant renal failure-related anemia, determination of the etiology(ies) for the anemia based on diagnostic tests, and prescription of therapy for correction of the anemia, such as vitamins, oral or parenteral iron, and hormonal therapy such as erythropoietin.

- Assessment of whether the patient has hyperparathyroidism and/or renal osteodystrophy secondary to chronic renal failure and prescription of appropriate therapy, such as calcium and phosphate binders for control of hyperphosphatemia. Based upon assessment of parahormone levels, serum calcium levels, and evaluation for the presence of metabolic bone disease, the physician determines whether oral or parenteral therapy with vitamin D or its analogs is indicated and prescribes the appropriate therapy. Based upon assessment and diagnosis of bone disease, the physician may prescribe specific chelation therapy with deferoxamine and the use of hemoperfusion for removal of aluminum and the chelation.

- Assessment of whether the patient has dialysis-related arthropathy or neuropathy and adjustment of the patient's prescription accordingly. Referral of the patient for any additional needed specialist evaluation and management of these end-organ problems.

- Assessment of whether the patient has fluid overload resulting from renal failure and establishment of an estimated "ideal (dry) weight." The physician determines the need for fluid removal independent of the dialysis prescription and implements these measures when indicated.

- Determination of the need for and prescription of antihypertensive medications and their timing relative to dialysis when the patient is hypertensive in spite of correction of fluid overload.

- Periodic review of the dialysis records to ascertain whether the patient is receiving the prescribed amount of dialysis and ordering of indices of clearance, such as urea kinetics, in order to ascertain whether the dialysis prescription is producing adequate dialysis. If the indices of clearance suggest that the prescription requires alteration, the physician orders changes in the hemodialysis prescription, such as blood flow rate, dialyzer surface area, dialysis frequency, and/or dialysis duration (length of treatment). For peritoneal dialysis patients, the physician may order changes in the volume of dialysate, dextrose concentration of the dialysate, and duration of the exchanges.

- Periodic visits (at least one per month) to the patient during dialysis to ascertain whether the dialysis is working well and whether the patient is tolerating the procedure well (physiologically and psychologically). During these visits, the physician determines whether alteration in any aspect of a given patient's prescription is indicated, such as changes in the estimate of the patient's dry weight. Review of the treatment with the nurse or technician performing the therapy is also included. The frequency of these visits will vary depending upon the patient's medical status, complicating conditions, and other determinants.

- Performance of periodic physical assessments, based upon the patient's clinical stability, in order to determine the necessity for alterations in various aspects of the patient's prescription. Similarly, the physician reviews the results of periodic laboratory testing in order to determine the need for alterations in the patient's prescription, such as changes in the amount and timing of phosphate binders or dose of erythropoietin.

- Periodic assessment of the adequacy and function of the patient's dialysis access appropriate tests and antibiotic therapy.

- Interpretations of the following tests:

    - Bone mineral density studies (CPT codes 76070, 76075, 78350, and 78351);

    - Noninvasive vascular diagnostic studies of hemodialysis access (CPT codes 93925, 93926, 93930, 93931, and 93990);

    - Nerve conduction studies (CPT codes 95900, 95903, 95904, 95925, 95926, 95927, 95934, 95935, and 95936);

    - Electromyography studies (CPT codes 95860, 95861, 95863, 95864, 95867, 95867, 95869, and 95872).

- Periodic review and update of the patient's short-term and long-term care plans with staff.

- Coordination and direction of the care of patients by other professional staff, such as dieticians and social workers.

- Certification of the need for items and services such as durable medical equipment and home health care services. Care plan oversight services described by CPT code 99375 are included in the MCP and may not be separately reported.

B. Services Excluded from Monthly Capitation Payment

The following physician services furnished to the physician's ESRD patients are excluded from the MCP and should be paid in accordance with the physician fee schedule:

1. Administration of hepatitis B vaccine.
2. Surgical services such as:
    - Temporary or permanent hemodialysis catheter placement;
    - Temporary or permanent peritoneal dialysis catheter placement;
    - Repair of existing dialysis accesses;
    - Placement of catheter(s) for thrombolytic therapy;
    - Thrombolytic therapy (systemic, regional, or access catheter only; hemodialysis or peritoneal dialysis);
    - Thrombectomy of clotted cannula;
    - Arthrocentesis;
    - Bone marrow aspiration; and
    - Bone marrow biopsy.
3. Interpretation of tests that have a professional component such as:
    - Electrocardiograms (12 lead, Holter monitor, stress tests, etc.);
    - Echocardiograms;
    - 24-hour blood pressure monitor;
    - Biopsies; and
    - Spirometry and complete pulmonary function tests.

4. Complete evaluation for renal transplantation. While the physician assessment of whether the patient meets preliminary criteria as a renal transplant candidate is included under the MCP, the complete evaluation for renal transplantation is excluded from the MCP

5. Evaluation of potential living transplant donors.

6. The training of patients to perform home hemodialysis, self hemodialysis, and the various forms of self peritoneal dialysis.

7. Non-renal related physician's services. These services may be furnished by the physician providing renal care or by another physician. They may not be incidental to services furnished during a dialysis session or office visit necessitated by the renal condition. The physician must provide documentation that the illness is not related to the renal condition and that the added visits are required. The contractor's medical staff determines whether additional reimbursement is warranted for treatment of the unrelated illness. For example, the medical management of diabetes mellitus that is not related to the dialysis or furnished during a dialysis session is excluded.

8. Covered physician services furnished to hospital inpatients.

9. All physician services that antedate the initiation of outpatient dialysis.

10. Covered physician services furnished by another physician when the patient is not available to receive the outpatient services as usual; for example, when the patient is traveling out of town.

140.1 - Payment for ESRD-Related Services Under the Monthly Capitation Payment (Center Based Patients)

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Physicians and practitioners managing center based patients on dialysis are paid a monthly rate for most outpatient dialysis-related physician services furnished to a Medicare ESRD beneficiary. The payment amount varies based on the number of visits provided within each month and the age of the ESRD beneficiary. Under this methodology, separate codes are billed for providing one visit per month, two to three visits per month and four or more visits per month. The lowest payment amount applies when a physician provides one visit per month; a higher payment is provided for two to three visits per month. To receive the highest payment amount, a physician or practitioner would have to provide at least four ESRD-related visits per month. The MCP is reported once per month for services performed in an outpatient setting that are related to the patients' ESRD.

The physician or practitioner who provides the complete assessment, establishes the patient's plan of care, and provides the ongoing management is the physician or practitioner who submits the bill for the monthly service.

a Month defined.

For purposes of billing for physician and practitioner ESRD related services, the term 'month' means a calendar month. The first month the beneficiary begins dialysis treatments is the date the dialysis treatments begin through the end of the calendar month. Thereafter, the term 'month' refers to a calendar month.

b. Determination of the age of beneficiary.

The beneficiary's age at the end of the month is the age of the patient for determining the appropriate age related ESRD-related services code.

c. Qualifying Visits Under the MCP

- General policy.

Visits must be furnished face-to-face by a physician, clinical nurse specialist, nurse practitioner, or physician's assistant.

- Visits furnished by another physician or practitioner (who is not the MCP physician or practitioner).

The MCP physician or practitioner may use other Medicare certified physicians or practitioners to provide some of the visits during the month. The MCP physician or practitioner does not have to be present when these other physicians or practitioners provide visits. In this instance, the rules are consistent with the requirements for split/shared evaluation and management visits. The non-MCP physician or practitioner must be a partner, an employee of the same group practice, or an employee of the MCP physician or practitioner. For example, the physician or practitioner furnishing visits under the MCP may be either a W-2 employee or 1099 independent contractor.

When another physician is used to furnish some of the visits during the month, the physician who provides the complete assessment, establishes the patient's plan of care and provides the ongoing management should bill for the MCP service.

If the nonphysician practitioner is the practitioner who performs the complete assessment and establishes the plan of care, then the MCP service should be billed under the PIN of the clinical nurse specialist, nurse practitioner, or physician assistant.

- Residents, interns and fellows.

Patient visits by residents, interns and fellows enrolled in an approved Medicare graduate medical education (GME) program may be counted towards the MCP visits if the teaching MCP physician is present during the visit.

- Patients designated/admitted as hospital observation status.

ESRD-related visits furnished to patients in hospital observation status that occur on or after January 1, 2005, should be counted for purposes of billing the MCP codes. Visits furnished to patients in hospital observation status are included when submitting MCP claims for ESRD-related services.

- ESRD-related visits furnished to beneficiaries residing in a SNF.

ESRD-related visits furnished to beneficiaries residing in a SNF should be counted for purposes of billing the MCP codes.

- SNF residents admitted as an inpatient.

Inpatient visits are not counted for purposes of the MCP service. If the beneficiary residing in a SNF is admitted to the hospital as an inpatient, the appropriate inpatient visit code should be billed.

- ESRD Related Visits as a Telehealth Service

ESRD-related services with 2 or 3 visits per month and ESRD-related services with 4 or more visits per month may be furnished as a telehealth service. However, at least one visit per month is required in person to examine the vascular access site. A clinical examination of the vascular access site must be furnished face-to-face (not as a telehealth service) by a physician, nurse practitioner or physician's assistant. For more information on how ESRD-related visits may be furnished as a Medicare telehealth service and for general Medicare telehealth policy see Pub. 100-02, Medicare Benefit Policy manual, chapter 15, section 270. For claims processing instructions see Pub. 100-04, Medicare Claims Processing manual chapter 12, section 190.

140.1.1 - Payment for Managing Patients on Home Dialysis

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Physicians and practitioners managing ESRD patients who dialyze at home are paid a single monthly rate based on the age of the beneficiary, regardless of the number of face-to-face physician or practitioner visits. A frequency of required visits does not apply to patients on home dialysis. The management of home dialysis patients who remain a home dialysis patient the entire month should be coded using the ESRD-related services for home dialysis patients HCPCS codes.

140.1.2 - Patients Who Switch Modalities (Center to Home and Vice Versa)

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

If a home dialysis patient receives dialysis in a dialysis center or other outpatient facility during the month, the MCP physician or practitioner is paid the management fee for the home dialysis patient and cannot bill the ESRD-related services codes for managing center based patients.

This situation should be coded using the ESRD–related services G codes for a home dialysis patient per full month. Physicians and practitioners should use the ESRD–related services G codes for a home dialysis patient per full month when billing for outpatient ESRD-related services when a home dialysis patient receives dialysis in a dialysis center or other outpatient facility during the month.

Physicians and practitioners should use the ESRD–related services G codes for a home dialysis patient per full month for patients that switch modalities regardless of whether the ESRD beneficiary went from home dialysis to center-based dialysis, or vice versa, and regardless of the proportion of the month that the beneficiary was receiving each modality.

140.2 - Payment for ESRD-related services (Per Diem)

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Physicians and practitioners may receive payment for managing patients on dialysis for less than a full month of care in specific circumstances as discussed in this section. Payment for ESRD related services, less than a full month, is paid on a per diem basis.

Per diem ESRD-related services should be coded using the ESRD related services (less than full month), per day HCPCS codes for ESRD-related services furnished in the situations described below.

- Home dialysis patients (less than full month);
- Transient patients – Patients traveling away from home (less than full month);
- Partial month where there was one or more face-to-face visits without a complete assessment of the patient and the patient was either hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had a transplant.
- Patients who have a permanent change in their MCP physician during the month.

The ESRD-related services (less than full month), per day HCPCS codes should only be used for the circumstances described above. The per diem codes may not be used for a full month when a complete monthly assessment is not furnished.

140.2.1 - Guidelines for Physician or Practitioner Billing -- (Per Diem)

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

A. Home dialysis, transient patient and partial month

When submitting claims for ESRD-related services (less than full month) per day, the physician or practitioner should specify the number of days he or she was responsible for the beneficiary's outpatient ESRD-related services during the month.

Only one code should be used to report the daily management of home dialysis patients, transient patients, and for partial month scenarios. For example, if a home dialysis patient receives dialysis at home for two weeks and is hospitalized for the remainder of the month, then 14 units of the age appropriate ESRD-related per day code is billed. The MCP service is not billed.

For transient patients, the physician or practitioner responsible for the transient patient's ESRD-related care should bill the appropriate ESRD-related services, per day code. Only the physician or practitioner responsible for the traveling ESRD patient's care is permitted to bill for ESRD-related services using the per diem ESRD-related services HCPCS codes.

For partial month scenarios resulting from hospitalization, kidney transplant, or the patient expired, if the MCP physician or practitioner furnished a complete monthly assessment of the patient, he or she should bill using the age appropriate MCP service that reflects the number of visits furnished during the month.

Example #1: An ESRD beneficiary was hospitalized on the tenth through the twentieth day of the month. On the third day of the month, the MCP physician or practitioner furnished a face-to-face visit including a complete assessment and a subsequent outpatient visit on the twenty-fifth day of the month. While the patient was hospitalized, an inpatient ESRD-related visit was furnished.

In this scenario, the MCP physician or practitioner may bill for the appropriate outpatient MCP service based on the age of the beneficiary and number of visits furnished during the month. The physician or practitioner who furnished the inpatient visit may bill for the appropriate inpatient ESRD-related service code.

Example #2: An ESRD beneficiary vacationing in Florida is away from his or her home dialysis site from August fifteenth through September seventh. On August tenth, the MCP physician furnishes a face-to-face visit. For the month of September, the MCP physician furnishes a visit on the ninth and a subsequent visit on the twenty-fifth of the month. A physician in Florida is responsible for the beneficiary's ESRD-related care from August fifteenth through September seventh.

In this scenario, the physician or practitioner responsible for the transient patient's ESRD-related care bills sixteen units of the age appropriate ESRD-related services for dialysis less than full month, per day code for the month of August and seven units of the per day code for the month of September. The MCP physician bills the MCP service with one visit for the month of August and the MCP service with two to three visits for the month of September.

If the transient beneficiary is under the care of a physician or practitioner other than his or her regular MCP physician for an entire calendar month, the physician or practitioner responsible for the transient patient's ESRD-related care must furnish a complete assessment and bill for ESRD-related services under the MCP.

B. Patient has a permanent change in their MCP physician during the month

ESRD-related services (less than full month) per day HCPCS codes should be billed in situations where an ESRD beneficiary permanently changes their MCP physician during the month. For example, the new MCP physician has the ongoing responsibility for the evaluation and management of the patient's ESRD-related care and is not part of the same group practice or an employee of the first MCP physician. The new MCP physician should use the appropriate per diem HCPCS code when submitting claims for ESRD-related services for the remainder of the month, when the first MCP physician furnishes a complete assessment of the beneficiary during the month.

If the first MCP physician does not furnish a complete assessment of the patient during the month the patient permanently changes their MCP physician, the new MCP physician may bill for the appropriate MCP service based on the age of the patient and number of visits furnished and the first MCP physician may bill the appropriate per day HCPCS code as discussed above.

Example: An ESRD patient residing in Virginia Beach, Virginia for the first 20 days of the month, moves to Atlanta, Georgia. As a result, a different physician or practitioner is now responsible for the ongoing management of the beneficiary's ESRD-related care. Both the first and second MCP physician furnishes a visit with a complete assessment of the patient and establishes a monthly plan of care. In this situation, the first MCP physician should bill the MCP service that reflects the number of visits he or she furnished during the month and the second MCP physician should bill the age appropriate per day ESRD-related services code. Thereafter, the new MCP physician would bill for the MCP service.

In this example, if the first MCP physician does not provide a complete assessment of the patient, he or she should bill 20 units of the per day ESRD-related services code, but may not bill for the MCP during the month the beneficiary permanently changes his or her MCP physician. The second MCP physician may bill for the MCP service after furnishing a complete monthly assessment of the ESRD beneficiary that includes establishing the patient's plan of care and at least one face-to-face visit.

140.3 - Data Elements Required on Claim for Monthly Capitation Payment

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

A. Elements 1 through 13 of the Form CMS-1500 are completed in accordance with the regular instructions

B. Elements 14 through 20 of the Form CMS-1500 are omitted.

C. Element 21 must contain the name and address of the facility involved with the patient's maintenance care or training.

D. Element 23A must show the diagnosis, and whether the patient is in training for self-dialysis. Element 23B is left blank.

E. Element 24A must show the dates of service during the month that are included in the MCP. The period includes the full calendar month the MCP physician or practitioner was responsible for the beneficiary's ESRD related care.

For the first month the beneficiary begins dialysis treatments, the first date the dialysis treatments begin through the end of the calendar month should be used as the dates of service.

For outpatient ESRD-related services furnished for less than a full month, per day as discussed in 140.2 (e.g. transient patients, partial month due to hospitalization, transplant, or death), the first and last date the physician or practitioner was responsible for the beneficiary's ESRD-related care during the month should be used as the dates of service. Noncontinuous dates should be billed on separate claim lines, (e.g. 1/1/08 – 1/7/08 and 1/20/08 – 1/31/08). A separate monthly claim should be submitted when the duration of ESRD-related services, per day, overlaps two different months as discussed in 140.21 (e.g. August 15 – September 7).

F. Element 24C must show the initials "MCP" as the indicator needed to identify the claim as a request for the MCP.

G. The remainder of the Form CMS-1500 is completed in accordance with the general instructions.

140.4 - Controlling Claims Paid Under the Monthly Capitation Payment Method

(Rev. 1456, Issued: 02-22-08, Effective: 03-24-08, Implementation: 03-24-08)

Contractors must be able to identify dialysis patient history records and physicians who furnish services related to dialysis.

In processing claims reimbursed under this method, contractors must assure that:

- Only one monthly payment is made for any renal disease patient per month;
- The MCP payment is made after the month has passed; i.e., do not pay the MCP in advance of the services actually furnished;
- The payment amount is based on the age of the beneficiary and the number of visits furnished during a calendar month (center based patients);
- Duplicate charges billed as a duplicate MCP or as separate charges for services covered by the monthly payment are denied;
- Where several physicians or practitioners form a team to provide the monthly continuity of services to a group of patients, make only one monthly payment for each patient.
- Concurrent services by another physician or practitioner who is part of the MCP practice team are covered and reimbursed separately only for services not included in the MCP (e.g. a visit not related to managing the patients ESRD); and
- If payment for inpatient hospital services is claimed in addition to the MCP, and assignment is taken only with respect to the MCP, follow the instructions in Pub. 100-04, chapter 1, §30.3.12.3.

Contractors must conduct periodic review of a randomly selected sample of patients' histories with reimbursement under the MCP method, to evaluate whether the number of and types of services billed separately from the MCP are appropriate considering the individual patient's medical condition.

Make separate payments for medically necessary services that are included or bundled into the MCP (e.g., test interpretations) when furnished by physicians other than the monthly capitation payment physician. According to the Renal Physicians Association, these test interpretations are billed separately only in rare circumstances.

150 - Physician's Self-Dialysis Training Services

B3-15060.5

Pay physicians for physician training services furnished to dialysis patients undergoing training by a flat fee of $500 (subject to the deductible and coinsurance requirements) for each patient under the physician's supervision during the training course. Pay this upon completion of the training course in addition to the monthly capitation payment for physician's maintenance dialysis services. If the training period is not completed, such as in instances where the patient can no longer be trained, prorate the training rate in proportion to the number of training treatments completed, but not to exceed $500. For purposes of this pro-ration, consider 25 training treatments as a complete course of training. Therefore, for an incomplete training course, pay the physician for the training services based on an amount of $20 per treatment times the number of treatments completed. This rule applies to all modes of treatment, including CAPD.

Occasionally, it is necessary to furnish additional training to an ESRD self-dialysis beneficiary after the initial training course is completed; e.g., because of a change from hemodialysis to peritoneal dialysis, a change in equipment. The amount of additional training required depends upon the transferability of the skills the patient has already learned; subsequent training would normally be very limited. Physicians' training services furnished during subsequent training of an ESRD beneficiary are covered and reimbursed in addition to the initial training fee.

Subsequent training sessions that are reimbursable under this rule must be distinguished from the ongoing services for which the original training fee is considered payment in full; e.g., answering the patient's questions arising after home dialysis has begun about the machine the patient has already been trained to use. No additional payment is made after the initial training course unless the subsequent training is required because of a change from the patient's treatment machine to a machine that he had not been trained to use in the initial training course, a change in the type of dialysis, or a change in setting or dialysis partner

160 - Payment for Physician's Services Furnished to Dialysis Inpatients

(Rev. 1, 10-01-03)

B3-15062.1, B3-4275

The following instructions cover physicians services to inpatients for all types of dialysis patients; e.g., hemodialysis, intermittent peritoneal dialysis (IPD), continuous ambulatory peritoneal dialysis (CAPD), and continuous cycling peritoneal dialysis (CCPD). Note that the hospitalization need not be related to dialysis.

Payment is made on the claim only if the place of service on the claims is inpatient hospital. See §170 for proper HCPCS coding.

160.1 - Determining Whether Physician Services Furnished on Day of Dialysis

(Rev. 1, 10-01-03)

B3-15062.1

If the patient is admitted to a hospital to receive dialysis for a reason not related to the patient's ESRD condition (e.g., there was no space available in the dialysis unit), the dialysis is covered as an outpatient service. In this case, carriers do not pay separately for any physicians' ESRD services because these services are covered under the physician's MCP or under the add-on to the hospital's composite rate for physicians under the initial method. (See §130.1 for a description of the initial method.)

160.2 - Physicians' Services Furnished on Day of Dialysis

(Rev. 1, 10-01-03)

B3-15062.1

Supervision or direction of a dialysis treatment by a physician does not ordinarily meet the requirements for physicians' services and, therefore, is not paid for as such under the fee schedule. However, physicians are responsible for the medical care and treatment of the dialysis patients. Physicians' services furnished to those patients that meet the requirements and are medically necessary are covered. The hospital medical record must document the services furnished and the medical reasons for them.

Generally, claims from the physician receiving a procedure code payment for additional services furnished to the same patient on the day of dialysis must be reviewed by medical staff prior to payment. Follow §170.B for dialysis and evaluation and management services performed on the same day.

Payment in addition to the procedure code payment is made only if the service is not related to the treatment of the patient's ESRD, and the service was not, and could not have been, furnished during the dialysis treatment. However, an exception to this rule is physicians' surgical services; e.g., catheter insertion. Physicians' surgical services are generally billed under the appropriate procedure code for payment. If more than one physician furnishes care to the same dialysis patient, follow the usual coverage rules on concurrent care.

160.3 - Physicians' Services Furnished on Non-Dialysis Days

(Rev. 1, 10-01-03)

B3-15062.1

Physicians' services furnished on non-dialysis days are coded and paid under the same rules as any other physicians' services when non-renal related services are furnished. Renal-related services may also be paid if the physician chooses to prorate the MCP payment. Generally, these services are the physicians' hospital visits and are coded and paid as such.

160.4 - Requirements for Payment

(Rev. 1, 10-01-03)

B3-15062.1

A. General

When paying for physicians' services furnished to dialysis inpatients, whether they are ESRD patients or acute dialysis patients, there are several factors to consider.

- The payment must be for covered physicians' services;
- The services must be medically necessary; and
- The payment for the services must be reasonably related to the nature of the services actually furnished.

B. Physicians' Services - Criteria for Procedure Codes

The procedure code covers the full range of physicians' renal-related services furnished during an inpatient dialysis treatment.

In order to be paid on the basis of a procedure code, the physician must have been physically present with the patient at some time during the course of the dialysis, and the medical record (e.g., the physician's progress note or the nurse's notes in the patient's hospital medical record) must document this.

If the physician visits the dialysis inpatient on a dialysis day, but not during the dialysis treatment, do not pay the physician on the basis of a procedure code. The nature of these services is the same as physicians' services furnished to any inpatient during a hospital visit. Therefore, use the same hospital visit codes that apply to any other physicians treating hospital inpatients.

Physicians' services furnished to patients who are dialyzed as inpatients because there is no room in the outpatient dialysis units are covered under the MCP, and physicians are not paid amounts in addition to or in place of the MCP.

Effective January 1, 1995, all evaluation and management services provided on the same day as inpatient dialysis codes should be denied without review with the exception of CPT codes 99221-99223, 99251-99255, and 99238. These codes may be billed with modifier "-25" and reviewed for possible allowance if the evaluation and management service is unrelated to the treatment of ESRD and was not and could not have been furnished during the dialysis treatment.

C. Peritoneal Dialysis

Peritoneal dialysis is typically furnished in extended periods. For example, CAPD is continuous, and the patient may actually be dialyzed seven days per week. IPD may be

furnished in extended periods of 30 hours or more. The fact that a patient is dialyzed continuously for an extended period does not justify payment in excess of the average weekly allowance made for hemodialysis services. Payment in excess of this amount is made only if it is determined that the same kind and intensity of physicians' hemodialysis treatment beyond the number ordinarily furnished in a 7-day period, and the patient's condition was similar to that of a hemodialysis patient who would have required these additional services.

170 - Billing Physician Dialysis Services (codes 90935 - 90999) and Related Payment

(Rev. 1, 10-01-03)

B3-15350.B.3

Except when the MCP applies claims for physicians' inpatient dialysis services furnished to ESRD or acute dialysis patients are processed using physicians' inpatient dialysis services procedure codes 90935, 90937, 90945, and 90947. All carriers must use these codes for these services.

Carriers make payment on the basis of ESRD procedure codes, i.e., codes 90935, 90937, 90945, or 90947, only if the place of service on the claim is inpatient hospital. This is because all physicians' outpatient renal-related services are included in payment made under the monthly capitation payment.

A. ESRD Monthly Capitation Payments

Effective January 1, 1995, monthly capitation payments are made under the physician fee schedule. For their adult patients, physicians may bill either the monthly code (CPT code 90921) or the daily code (CPT code 90922) with units that represent the number of days in a single month, but may not bill both.

To bill for a month of services for pediatric patients, providers should bill the appropriate monthly code (CPT codes 90919, 90920, or 90921). To bill for less than a month of service, providers bill the appropriate daily code (CPT codes 90923-90925) and units that represent the number of days. Providers may bill either the monthly code or the daily code, but not both. Since billing is done at the conclusion of the month, the patient's age at the end of month is the age of the patient for billing purposes.

B - Inpatient and Outpatient Dialysis Services On Same Date As An Evaluation and Management Service

CPT codes 90935 and 90937 are used to report inpatient ESRD hemodialysis and outpatient hemodialysis performed on non-ESRD patients (e.g., patients in acute renal failure requiring a brief period of dialysis prior to recovery). CPT codes 90945 and 90947 are used to report all non-hemodialysis procedures. All four of these codes include payment for any evaluation and management services related to the patients renal disease that are provided on the same date as the dialysis service. Therefore, payment for all evaluation and management services is bundled into the payment for 90935, 90937, 90945, and 90947, except for the following evaluation and management services which may be reported on the same date as a dialysis service with the use of the –25 modifier

and they are significant and separately identifiable and met any medical necessity requirements:

99201-99205	Office or Other Outpatient Visit for a New Patient
99211-99215	Office or Other Outpatient Visit for an Established Patient
99221-99223	Initial Hospital Care for a New or Established Patient
99238-99239	Hospital Discharge Day Management Services
99241-99245	Office or Other Outpatient Consultations, New or Established Patient
99251-99255	Initial Inpatient Consultations, New or Established Patient
99291-99292	Critical Care Services

In the absence of one of these codes being reported with the –25 modifier and meeting the other requirements listed above, pay only the dialysis service and deny the evaluation and management service. Furthermore, payment is not allowed for more than one dialysis service per day.

180 - Noninvasive Studies for ESRD Patients - Facility and Physician Services

(Rev. 1, 10-01-03)

AB-01-189, AB-03-001

For Medicare coverage of noninvasive vascular studies, see the Medicare Benefit Policy Manual, Chapter 11.

For dialysis to take place there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for monitoring access, and when occlusions occur, either declot the access or refer the patient for appropriate treatment. Procedures associated with monitoring access involve taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are covered under the composite rate.

ESRD facilities may not monitor access through noninvasive vascular studies such as duplex and Doppler flow scans and bill separately for these procedures. Noninvasive vascular studies are not covered as a separately billable service if used to monitor a patient's vascular access site.

Medicare pays for the technical component of the procedure in the composite payment rate.

Where there are signs and symptoms of vascular access problems, Doppler flow studies may be used as a means to obtain diagnostic information to permit medical intervention to address the problem. Doppler flow studies may be considered medically necessary in

the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining the clinical course of the treatment for the patient.

The only Current Procedural Terminology (CPT) billing code for noninvasive vascular testing of a hemodialysis access site is 93990. Carriers must deny separate billing of the technical component of this code if it is performed on any patient for whom the ESRD composite rate for dialysis is being paid, unless there is appropriate medical indication of the need for a Doppler flow study.

When a dialysis patient exhibits signs and symptoms of compromise to the vascular access site, Doppler flow studies may provide diagnostic information that will determine the appropriate medical intervention. Medicare considers a Doppler flow study medically necessary when the beneficiary's dialysis access site manifests signs or symptoms associated with vascular compromise, and when the results of this test are necessary to determine the clinical course of treatment.

Examples supporting the medical necessity for Doppler flow studies include:

a. Elevated dynamic venous pressure >200mm HG when measured during dialysis with the blood pump set on a 200cc/min.,

b. Access recirculation of 12 percent or greater,

c. An otherwise unexplained urea reduction ration <60 oercebtm abd

d. An access with a palpable "water hammer" pulse on examination, (which implies venous outflow obstruction).

Unless the documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both.

An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates reduced flow (blood flow rate less than 800cc/min or a decreased flow of 25 percent or greater from previous study) and the physician requires an arteriogram to further define the extent of the problem. The patient's medical record(s) must provide documentation supporting the need for more than one imaging study.

This policy is applicable to claims from ESRD facilities and all other sources, such as independent diagnostic testing facilities, and hospital outpatient departments.

Carriers shall develop LMRP for Doppler flow studies if this service meets the criteria listed in the Medicare Program Integrity Manual, Chapter 1. This provides guidance to contractors on the scope, purpose, and meaning of LMRP.

The professional component of the procedure is included in the monthly capitation payment (MCP) (See §140 above.) The professional component should be denied for code 93990 if billed by the MCP physician. Medically necessary services that are included or bundled into the MCP (e.g., test interpretations) are separately payable when furnished by physicians other than the MCP physician.

If the claim is denied, carriers report this on a remittance advice with group code "CO," and claim adjustment reason code 24, "Payment for charges denied. Charges are covered under a capitation agreement."

The Medicare Summary Notice denial message number is 16.32; "Medicare does not pay separately for this service."

Billing for monitoring of hemodialysis access using CPT codes for noninvasive vascular studies other than 93990 is considered a misrepresentation of the service actually provided and contractors will consider this action for fraud investigation. They will conduct data analysis on a periodic basis for noninvasive diagnostic studies of the extremities (including CPT codes 93922, 93923, 93924, 93925, 93926, 93930, 93931, 93965, 93970, 93971). Contractors should handle aberrant findings under normal program safeguard processes by taking whatever corrective action is deemed necessary.

190 - Appeal Rights for Denied Claims

For appeal rights if the claim is denied see Chapter 29.

200 – Utilization of REMIS for Carrier Claims Adjudication

(Rev. 82, 02-06-04)

Renal Management Information System (REMIS) determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access information in the ESRD Program Management and Medical Information System Database. REMIS is used by CMS and the renal community to monitor the Medicare status, transplant activities, dialysis activities, and Medicare utilization of ESRD patients and their Medicare provider.

The following fields are contained in the (Dialysis) auxiliary file:

- **ESRD Coverage Start Date** (The date on which the beneficiary is entitled to Medicare, in some part, because of a diagnosis of End Stage Renal Disease.)
- **ESRD Coverage Source Code** (The source of the information that establishes Medicare-based End-Stage Renal Disease Coverage; A= Part A and Dialysis Training, B= Part A and Dialyzing (No 3 month wait), C= Part A and 3 months after Dialysis, D= Part A and Functioning Transplant, E= Part A and Month of Pre-Transplant Stay, F= Part A and ESRD (Verified Source), Blank= No ESRD Involvement.)
- **ESRD Coverage Termination Date** (The date on which the beneficiary is no longer entitled to Medicare under ESRD Provisions.)
- **ESRD Coverage Termination Reason** (A code that indicates the reason Medicare-based End-Stage Renal Disease Coverage was terminated; codes: A= Month of transplant plus 36 months, B=Last month of chronic dialysis, C= Part A termination, D=Death, E=ESRD ended: other verified source.)
- **ESRD Dialysis Start Date** (A date that indicates when ESRD dialysis started.)
- **ESRD Dialysis Stop Date** (A date that indicates when ESRD dialysis ended.)

- **ESRD Transplant Start Date** (A date that indicates when a kidney transplant operation occurred.)
- **ESRD Transplant Stop Date** (A date that indicates when a kidney transplant failed.)

The above data elements are in CWF and stored in the dialysis auxiliary file, which can be used to identify a beneficiary's ESRD eligibility. This data source will assist carriers in reviewing overpayment determination and accurately processing claims.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR #
R1472CP	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
R1456CP	02/22/2008	Manualization of Payment for Outpatient ESRD-Related Services	03/24/2008	5931
R1421CP	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
R1412CP	01/11/2008	Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD Indications, and Reporting of Hematocrit/Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs	04/07/2008	5699
R1389CP	12/07/2007	Implementation of Change in End Stage Renal Disease (ESRD) Payment for Calendar Year 2008	01/07/2008	5827
R1364CP	11/02/2007	Common Working File (CWF) Informational Unsolicited Responses for RDF Claims Overlapping Patient Hospital Stays	04/07/2008	5768
R1341CP	09/21/2007	New Web Site for Approved Transplant Centers	10/22/2007	5724
R1307CP	07/20/2007	Modification to the National Monitoring Policy for Erythropoietic Stimulating Agents (ESAs) for End-Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities	01/07/2008	5700
R1285CP	07/13/2007	Renal Dialysis Facility Line Item Billing Requirements for Epoetin Alfa (EPO) Submitted on End Stage	01/07/2008	5545

Rev #	Issue Date	Subject	Impl Date	CR #
		Renal Disease (ESRD) Claims		
R1212CP	03/30/2007	Requirements for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)	06/29/2007	5480
R1043CP	08/25/2006	Revisions to the EPO/ Aranesp Monitoring Policy	10/02/2006	5251
R1041CP	08/25/2006	(HCPCS) for Renal Dialysis Facilities and Hospitals Billing for End Stage Renal Disease (ESRD) Related Epoetin Alfa (EPO)	01/01/2007	5216
R1007CP	07/28/2006	(HCPCS) for Renal Dialysis Facilities and Hospitals Billing for End Stage Renal Disease (ESRD) Related Epoetin Alfa (EPO)	01/02/2007	5216
R849CP	02/10/2006	Update to the ESRD Composite Payment Rates	02/13/2006	4291
R797CP	12/30/2005	Full Replacement of CR 4095, Diagnosis Code Requirements for Method II Home Dialysis Claims	01/30/2006	4227
R781CP	12/16/2005	Revised Manual Instructions for Processing End Stage Renal Disease Exceptions Under the Composite Rate Reimbursement System	01/17/2006	4188
R774CP	12/02/2005	Implementation of Change in End Stage Renal Disease Payment for Calendar Year 2006	01/03/2006	4196
R771CP	12/02/2005	Revisions to Pub. 100-04, Medicare Claims Processing Manual in Preparation for the National Provider Identifier	01/03/2006	4181
R751CP	11/10/2005	National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease Patients Treated in Renal Dialysis Facilities	04/03/2006	4135

Rev #	Issue Date	Subject	Impl Date	CR #
R737CP	10/31/2005	New ICD-9-CM Code for Beneficiaries with Chronic Kidney Disease and new HCPCS for Reporting Epoetin Alfa and Darbepoetin Alfa	04/03/2006	4108
R736CP	10/31/2005	Clarification and Update to Hospital Billing Instructions and Payment for Epoetin Alfa and Darbepoetin Alfa for Beneficiaries with End Stage Renal Disease	04/03/2006	4103
R725CP	10/21/2005	New ICD-9-CM Code for Beneficiaries with Chronic Kidney Disease	04/03/2006	4108
R721CP	10/21/2005	Use of Value Codes 48 and 49 on End Stage Renal Disease Bills	01/03/2006	4087
R719CP	10/21/2005	Clarification and Update to Hospital Billing Instructions and Payment for Epoetin Alfa and Darbepoetin Alfa (Aranesp) for Beneficiaries with End Stage Renal Disease	04/03/2006	4103
R701CP	10/07/2005	New Diagnosis Code Requirements for Method II Home Dialysis Claims	11/07/2005	4095
R634CP	08/03/2005	Guidelines for Payment of Vaccines (Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus) and their Administration at Renal Dialysis Facilities	01/03/2006	3936
R610CP	07/22/2005	Guidelines for Payment of Vaccines (Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus) and their Administration at Renal Dialysis Facilities	01/03/2006	3936
R598CP	06/27/2005	Implementation of Carrier Guidelines for End Stage Renal Disease Reimbursement For Automated Multi-Channel Chemistry Test Supplemental To Change Request	01/01/2006	3890

Rev #	Issue Date	Subject	Impl Date	CR #
		2813		
R595CP	06/24/2005	Implementation of Carrier Guidelines for End Stage Renal Disease Reimbursement For Automated Multi-Channel Chemistry Tests Supplemental To Change Request 2813	07/25/3005	3890
R477CP	02/18/2005	New Case-Mix Adjusted End Stage Renal Disease Composite Payment Rates and New Composite Rate Exceptions Window for Pediatric ESRD Facilities	04/04/2005	3720
R447CP	01/21/2005	CWF Editing for Method Selection on DMERC Claims for EPO and Aranesp	07/05/2005	3547
R373CP	11/19/2004	New ESRD Composite Payment Rates Effective January 1, 2005	01/03/2005	3554
R370CP	11/19/2004	New Case-Mix Adjusted End Stage Renal Disease Composite Payment Rates and New Composite Rate Exceptions Window for Pediatric ESRD Facilities	04/04/2005	3572
R257CP	07/30/2004	Informs the FISS to carry at least two Payments Limits for ESRD	01/03/2005	3332
R197CP	06/04/2004	Epoetin Alfa	10/04/2004	3184
R146CP	04/23/2004	Dialysis Provider Number Series	10/04/2004	3176
R118CP	03/05/2004	Epoetin Alfa	04/05/2004	2984
R116CP	03/05/2004	DMERC Claims Processing Instructions	04/05/2004	3019
R110CP	02/27/2004	Drugs Furnished in Dialysis	03/29/2004	3078
R101CP	02/20/2004	Processing Requests for Composite Rate Exception	04/01/2004	3119
R082CP	02/06/2004	Utilization of REMIS for Carrier	07/06/2004	3066

Rev #	Issue Date	Subject	Impl Date	CR #
		Claims Adjudication		
R031CP	11/21/2003	Dialysis Provider Number Series	N/A	2877
R001CP	10/01/2003	Initial Publication of Manual	NA	NA