CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 136	**Date: JANUARY 28, 2011**
	Change Request 7312

SUBJECT: Clarification of Existing Policy Regarding Items and Services Included Under the End Stage Renal Disease (ESRD) Composite Payment Rate

I. SUMMARY OF CHANGES: This change request provides clarification to the existing policy regarding items and services included under the End Stage Renal Disease composite rate located in Pub. 100-02, Medicare Benefit Policy Manual, chapter 11, section 30.

EFFECTIVE DATE: January 1, 2011
IMPLEMENTATION DATE: February 25, 2011

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	11/30/Composite Rate for Outpatient Maintenance Dialysis

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

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction
Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-02	Transmittal: 136	Date: January 28, 2011	Change Request: 7312

SUBJECT: Clarification of Existing Policy Regarding Items and Services Included Under the End Stage Renal Disease (ESRD) Composite Payment Rate

Effective Date: January 1, 2011

Implementation Date: February 25, 2011

I. GENERAL INFORMATION

A. Background: CMS has received numerous inquiries about whether or not certain types of protective catheter coverings are considered to be an ESRD-related service and, as such, included under the ESRD composite rate. In response to these questions, this change request provides clarification to the existing policy regarding items and services included under the ESRD composite rate for dialysis patients, located in Pub 100-02, Medicare Benefit Policy Manual, chapter 11, section 30. As dressings or protective catheter coverings may be used to protect the dialysis access site, these supplies are considered ESRD-related and are included in the ESRD composite rate for all dialysis patients regardless of the method of dialysis, or where they receive dialysis treatment, and, therefore are not separately billable. All dressings and protective catheter coverings are also included in the ESRD Prospective Payment System (PPS) bundled payment amount, effective January 1, 2011.

B. Policy: ESRD facilities and Monthly Capitated Payment (MCP) physicians and practitioners may determine that it is medically required for a dialysis patient to use dressings or protective access coverings, including catheter coverings, on their access site. All medically required dressings or protective access coverings used during or after dialysis to protect a dialysis patient's access site, including for example, coverings used for day-to-day activities such as bathing, are considered to be ESRD-related items. To the extent that dressings and protective access coverings, including catheter coverings, are determined to be medically required, an ESRD facility can provide them. Medicare payment for ESRD-related items and services are included in the ESRD composite payment rate, and are therefore included in the ESRD PPS, for all dialysis patients regardless of the method of dialysis or where they receive dialysis treatments.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7312.1	Medicare contractors shall ensure that their policies acknowledge that all dressings and/or protective access coverings are included in the ESRD composite rate and ESRD PPS bundled base rate and therefore are not separately payable.	X	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7312.2	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web site and include information about it in a listserv message within 1 week of the release of this instruction. In addition, the entire instruction must be included in your next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X							

IV. SUPPORTING INFORMATION

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

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): DME suppliers: Susan.Webster@cms.hhs.gov or (410) 786-3384. ESRD facility claim inquires: Wendy.Tucker@cms.hhs.gov or (410) 786-3004. ESRD payment policy: Michelle.Cruse@cms.hhs.gov or (410) 786-7540.

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

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

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

Section B: *For Medicare Administrative Contractors (MACs),* include the following statement:

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

30 - Composite Rate for Outpatient Maintenance Dialysis

(Rev. 136, Issued: 01-28-11, Effective: 01-01-11, Implementation: 02-25-11)

The composite payment rate system is a prospective system for the payment of outpatient maintenance dialysis services furnished to Medicare beneficiaries. All maintenance dialysis treatments furnished to Medicare beneficiaries in an approved ESRD facility are covered by this system. Further, the composite rate system is one of two methods by which Medicare pays for maintenance dialysis performed in a beneficiary's home. (For a description of the other method, see §50)

The facility's composite payment rate is a comprehensive payment for all modes of infacility and Method I home dialysis. Most items and services related to the treatment of the patient's end-stage renal disease are covered under the composite rate payment. 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. The composite rate is payment for the complete dialysis treatment except for physicians' professional services, separately billable laboratory services, and separately billable drugs. This payment is subject to the normal Part B deductible and coinsurance requirements.

Under the composite rate, a dialysis facility must furnish all of the necessary dialysis services, equipment, and supplies. If it fails to furnish (either directly under arrangement or under an agreement with another approved ESRD facility) 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.

A certified hospital-based outpatient dialysis facility that is not the patient's usual facility can provide and must bill Medicare directly for routine maintenance services. The certified hospital-based dialysis facility cannot bill the patient's usual facility for payment and have the patient's usual facility bill Medicare.

Other ESRD Items and Services

Items and services included under the composite rate must be furnished by the facility, either directly or under arrangements to all of its dialysis patients. Examples of such items and services are:

- Bicarbonate dialysate;
- Cardiac monitoring;
- Catheter changes (Ideal Loop);
- Suture removal;

- Dressing changes *(all dressings or protective access coverings, including catheter coverings, used to conceal a dialysis patient's access site, for any purpose, including allowing dialysis patients to bathe or shower as well as perform other day-to-day activities, are included in the composite rate)*;

- Crash cart usage for cardiac arrest;

- Declotting of shunt performed by facility staff in the dialysis unit;

- All oxygen and its administration furnished in the dialysis unit;

- Staff time to administer blood;

- Staff time used to administer separately billable parenteral items; and

- 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 (ER)). These services may be paid in addition to the composite payment 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 found only in the other department. In the case of emergency services furnished in the hospital 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;

- Serious impairment to bodily functions; or

- Serious dysfunction of any bodily organ or part.

Since the above noted situations rarely occur, they require clinical documentation to validate they were met; otherwise, they would be denied services.