



1904 Naomi Place • Prescott, AZ 86303 • Prescott, AZ 86303 • Phone: 928-717-1156 • Fax: 928-441-3857

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## NEWS UPDATE

### **CMS-1418-P - "Medicare Programs; End-Stage Renal Disease Prospective Payment System" Proposed Rule Overview is Now on Display at:**

<http://www.cms.hhs.gov/ESRDPayment/> or read below.

Click on this link [http://www.federalregister.gov/OFRUpload/OFRData/2009-22486\\_PL.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-22486_PL.pdf) to view the full version (547 pages) of the proposed rule.

#### **Overview**

Medicare payment to ESRD facilities for outpatient maintenance dialysis services furnished to Medicare beneficiaries with End-Stage Renal Disease (ESRD) is based on a prospective payment system known as the basic case-mix adjusted composite payment system. The base composite rate covers the costs of the dialysis treatment and certain routine drugs, laboratory tests, and supplies furnished at home or in a facility. Other items and services, particularly injectable drugs (for example, erythropoietin (EPO), iron sucrose, vitamin D), and non-routine laboratory tests are not included in the composite rate and are billed separately to Medicare. Separately billable services represent about 40 percent of total Medicare payments per dialysis treatment. The base composite rate is adjusted by a drug add-on payment to account for changes in the drug pricing methodology that occurred in 2005 and by case-mix factors, that is, age, body size, and a special adjustment for pediatric patients.

Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) replaces the current basic case-mix adjusted composite payment system with a bundled ESRD prospective payment system, or the ESRD PPS, for Medicare outpatient ESRD facilities beginning January 1, 2011. There will be a 4-year transition period, with full implementation beginning January 1, 2014. ESRD facilities may make a one-time election to be excluded from the transition and accept payment entirely based on the payment amount under the ESRD PPS. During the transition, ESRD facilities will be paid a blend of the ESRD PPS and the current payment system (which is described in detail below).

#### **Basic Case-Mix Adjusted Composite Payment System**

The basic case-mix adjusted composite payment system is a comprehensive prospective payment system that covers a bundle of dialysis related items and services routinely required for dialysis treatments to be furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home. For example, those items and services include supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, and support services. Payment for all modalities of in-facility dialysis and Method I home dialysis are paid under the basic case-mix adjusted composite payment rate system. Payment for Method II home dialysis is not paid under the basic case-mix adjusted composite payment system and is described in detail below.

The following components are not paid under the basic case-mix adjusted composite payment system:

Method II home patients;

Physician's professional services;  
Separately billable laboratory services;  
Separately billable drugs;  
Blood and blood products; and  
Bad debt.

Beneficiaries may either receive maintenance dialysis at a Medicare-certified dialysis facility or at home. Each Medicare home dialysis beneficiary must choose the method by which Medicare pays for his or her dialysis services.

Under Method I, the dialysis facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies, and home support services. For these services, the facility receives the same payment rate as it would receive for an in-facility patient under the basic case-mix adjusted composite payment system. Under this arrangement, the ESRD facility bills the Fiscal Intermediary/Medicare Administrative Contractor (FI/MAC), and the beneficiary is responsible for paying unmet Part B deductible and the 20 percent coinsurance requirement to the ESRD facility.

Under Method II, the beneficiary deals directly with a single Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies supplier to secure the necessary supplies and equipment to dialyze at home. The selected supplier (not a dialysis facility) must take assignment and bill the Durable Medical Equipment Medicare Administrative Contractor. The beneficiary is responsible to his or her supplier for unmet Part B deductible and for the 20 percent Medicare Part B coinsurance requirement.

### **Basic Case-Mix Adjusted Composite Rate Payment Methodology Including Adjustment Factors**

The base composite payment rate is paid on a per-treatment basis, with payments capped at an amount equal to three dialysis sessions per week. The base composite payment rate is adjusted by:

A case-mix budget neutrality adjustment;

The following case-mix adjustment factors:

- Age (<18, 18-44, 45-59, 60-69, 70-79, ≥ 80 years);
- Body surface area;
- Body mass index; and
- A special adjustment for pediatric patients;

A wage index based on acute hospital and employment data;

A wage index budget neutrality adjustment; and

A drug add-on adjustment, which accounts for the difference between payments for separately billable drugs and payments based on a revised drug pricing methodology that occurred in 2005. The drug add-on adjustment is updated annually to reflect the growth in per patient expenditures for separately billable drugs.

The base composite payment rate for CY 2009 is \$133.81 for both hospital-based facilities and independent facilities and the drug add-on adjustment to the composite rate is 15.2 percent.

Effective January 1, 2009, the wage index adjustment is based on 100 percent of the Core-Based Statistical Area geographic definitions for purposes of determining urban and rural locales and the wage index floor is set at .70.

### **SEPARATELY BILLABLE ITEMS AND SERVICES**

In addition to the composite rate, dialysis facilities may receive additional payment for separately billable

laboratory tests and drugs.

### **Separately Billable Laboratory Tests**

Separately billable laboratory tests are paid according to the Clinical Diagnostic Laboratory Fee Schedule. Laboratory tests that are usually performed for dialysis patients and are routinely covered at the frequency specified in the absence of indications to the contrary, that is, 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 Medicare beneficiaries do not pay a copay-ment for separately billable laboratory tests.

### **Separately Billable Drugs**

Some drugs administered in the facility by facility staff are not covered under the composite rate but may be medically necessary for some beneficiaries who receive dialysis. These drugs must be billed separately and accompanied by medical justification either through information on the claim form or as requested by the FI/MAC. Staff time used to administer the drugs is covered under the composite rate. Supplies used to administer the drugs may be billed in addition to the composite rate. Hospital-based facilities and independent ESRD facilities are paid the Average Sales Price of drugs plus six percent for separately billable drugs. Medicare beneficiaries pay a 20 percent copay-ment for separately billable drugs.

### **Report to Congress**

On February 20, 2008, the **Report to Congress: A Design for a Bundled End Stage Renal Disease Prospective Payment System** was released as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The report can be accessed in the Downloads section below.

Additional information about ESRD can be found at the links below.

### **Legislative Citations**

**Section 153(a) Public Law 110-275, the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)**(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

### **Pertinent Portion of Section 623(d) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Mandating Implementation of a Basic Case-Mix Adjustment**

(d) Basic Case-Mix Adjusted Composite rate for Renal Dialysis Facility Services (1) Section 1881(b)(42) U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraphs: (12)(A) In lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics.

### **Section 623(e)(1) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)**

(e) Demonstration of Bundled Case-Mix Adjusted Payment System for ESRD Services(1) In General.—The Secretary shall establish a demonstration project of the use of a fully case-mix adjusted payment system for

end stage renal disease services under section 1881 of the Social Security Act (42 U.S.C. 1395rr) for patient characteristics identified in the report under subsection (f) that bundles into such payment rates amounts for—(A) drugs and biologicals (including erythropoietin furnished to end stage renal disease patients under the Medicare program which are separately billed by end stage renal disease facilities (as of the date of the enactment of this Act); and(B) clinical laboratory tests related to such drugs and biologicals.

**Section 623(f) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)**

(f) Report on a Bundled Payment System for End Stage Renal Disease Services (1) Report— (A) In General.—Not later than October 1, 2005, the Secretary shall submit to Congress a report detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including components of the new system described in paragraph (2).

(B) The Secretary shall include in such report, recommendations on elements, features, and methodology for a bundled prospective payment system or other issues related to such system as the Secretary determines to be appropriate.

(2) Elements and Features of a Bundled Prospective Payment System—The report required under paragraph (1) shall include the following elements and features of a bundled prospective payment system:

(A) Bundle of Items and Services.—A description of the bundle of items and services to be included under the prospective payment system.

(B) Case-mix.—A description of the case-mix adjustment to account for the relative resource use of different types of patients.

(C) Wage Index.—A description of an adjustment to account for geographic differences in wages.

(D) Rural Areas.—The appropriateness of establishing a specific payment adjustment to account for additional costs incurred by rural facilities.

(E) Other Adjustments.—Such other adjustments as may be necessary to reflect the variation in costs incurred by facilities in caring for patients with end stage renal disease.

(F) Update Framework.—A methodology for appropriate updates under the prospective payment system.

(G) Additional Recommendations.—Such other matters as the Secretary determines to be appropriate.

**Section 422(c)(1) Pub. L. 106-554, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)**

(c) Inclusion of Additional Services in Composite Rate (1) Development—The Secretary of Health and Human Services shall develop a system which includes, to the maximum extent feasible, in the composite rate used for payment under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)), payment for clinical diagnostic laboratory tests and drugs (including drugs paid under section 1881(b)(11) of such Act (42 U.S.C. 1395rr(b)(11)(B)) that are routinely used in furnishing dialysis services to Medicare beneficiaries but which are currently separately billable by renal dialysis facilities.