

### C. Payment Rates

The payment rates for demonstration services will be the same as under the physician fee schedule.

### D. Budget Neutrality

The statute requires the Secretary to ensure that the aggregate payments made under the Medicare program do not exceed the amount that would have been paid under the Medicare program in the absence of this demonstration.

Ensuring budget neutrality requires that the Secretary develop a strategy for recouping funds should the demonstration result in costs higher than would occur in the absence of the demonstration. We will first determine over the two-year demonstration whether the demonstration was budget neutral. If the demonstration is not budget neutral, we plan to meet the legislative requirements by making adjustments in the national chiropractor fee schedule to recover the costs of the demonstration in excess of the amount estimated to yield budget neutrality. We will assess budget neutrality by determining the change in costs based on a pre-post comparison of costs and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We will not limit our analysis to reviewing only chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs.

A CMS evaluation contractor will conduct the analysis of claims and budget neutrality. Since it will take approximately two years to complete the claims analysis, we anticipate that any necessary reduction will be made in the 2010 and 2011 fee schedules. If we determine that the adjustment for budget neutrality would be greater than two percent of the chiropractor fee schedule, we will implement the adjustment over a two-year period. However, if the adjustment is less than two percent of the chiropractor fee schedule, we will implement the adjustment over a one-year period. We will include the detailed analysis of budget neutrality and the proposed offset in the 2009 **Federal Register** publication of the physician fee schedule.

We invite comments regarding the appropriate methodology for determining budget neutrality. Written materials may be submitted by mail or e-mail to the addresses listed in the **ADDRESSES** section of this notice.

### E. Site Selection

The statute requires that this demonstration be conducted in four

sites—two rural and two urban; one site in each type of area must be a health professional shortage area (HPSA). We have selected:

- 26 northern counties in Illinois which includes Cook, Dekalb, DuPage, Grundy, Kane, Kendall, McHenry, Will, Boone, Bureau, Carroll, Henry, JoDaviess, Kankakee, Lake, LaSalle, Lee, Marshall, Mercer, Ogle, Putnam, Rock Island, Stark, Stephenson, Whiteside, and Winnebago, and Scott county in Iowa (urban);

- 17 central HPSA counties in Richmond, Charlottesville, Lynchburg, and Danville MSAs in Virginia (urban HPSA)—the Virginia counties include Pittsylvania, Campbell, Appomattox, Nelson, Buckingham, Fluvanna, Louisa, Caroline, Hanover, New Kent, Henrico, Richmond City, Goochland, Cumberland, Powhatan, Amelia and Danville City;

- New Mexico (rural HPSA); and
- Maine (rural).

We first grouped States by Medicare carriers, because we determined it was important that control and experimental sites should have the same carriers (since some carriers impose limits on chiropractor claims they approve). We then determined appropriate sites based on the following criteria:

- Exclude States with restrictive practice regulations.
- Exclude States that will not have transitioned to the MCS system in time for the demonstration.
- Exclude States that are ranked in the top or bottom 5 values for two or more of the following six statistics:
  - Medicare per capita claims costs
  - Medicare per capita chiropractic costs
  - Per user (patient) chiropractic costs based on carrier data
  - Chiropractic service users as a percentage of Part B beneficiaries
  - Chiropractors per 10,000 State population
  - Chiropractors per 1,000 Part B beneficiaries
- Exclude States among those remaining that are served by a unique carrier and, thus, would lack a potential comparison site.

- Each carrier group was assessed to determine its ability to support treatment and comparison groups for one or more types of sites.
- Data was then used to estimate the number of beneficiaries residing in Urban/Rural and HPSA/non HPSA areas and determine which of the remaining States could support a demonstration site or sites.

Few States had enough beneficiaries residing in HPSAs to be considered for one of the HPSA demonstration sites.

### III. Collection of Information Requirements

This document does not impose information collection and record-keeping requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

**Authority:** Section 651 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub. L. 108-173). (Catalog of Federal Domestic Assistance Program No. 93.778 and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 17, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Medicare & Medicaid Services

[CMS-5033-N2]

#### Medicare Program; Meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the first public meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. Notice of this meeting is required by the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Advisory Board will provide advice and recommendations with respect to the establishment and operation of the demonstration mandated by section 623(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This notice also announces the appointment of eleven individuals to serve as members of the Advisory Board, including one individual to serve as co-chairperson, and one additional co-chairperson, who is employed by CMS.

**DATES:** The meeting is on February 16, 2005 from 9 a.m. to 5 p.m., eastern standard time.

*Special Accommodations:* Persons attending the meeting, who are hearing

or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify Pamela Kelly by February 8, 2005 by e-mail at [ESRDAdvisoryBoard@cms.hhs.gov](mailto:ESRDAdvisoryBoard@cms.hhs.gov) or by telephone at (410) 786-2461.

**ADDRESSES:** The meeting will be held at the Hyatt Regency, 300 Light Street, Baltimore, MD 21202.

Attendance is limited to the space available, so seating will be on a first come, first served basis.

**Web site:** Up-to-date information on this meeting is located at <http://www.cms.hhs.gov/faca/esrd>.

**Hotline:** Up-to-date information on this meeting is located on the CMS Advisory Committee Hotline at 1 (877) 449-5659 (toll free) or in the Baltimore area at (410) 786-9379.

**FOR FURTHER INFORMATION CONTACT:** Pamela Kelly by e-mail at [ESRDAdvisoryBoard@cms.hhs.gov](mailto:ESRDAdvisoryBoard@cms.hhs.gov) or telephone at (410) 786-2461. The CMS Press Office at (202) 690-6145.

**SUPPLEMENTARY INFORMATION:** On June 2, 2004, we published a **Federal Register** notice requesting nominations for individuals to serve on the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. The June 2, 2004 notice also announced the establishment of the Advisory Board and the signing by the Secretary on May 11, 2004 of the charter establishing the Advisory Board. This notice announces the first public meeting of this Advisory Board and the appointment of eleven individuals to serve as members of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services, including one individual to serve as co-chairperson, and one additional co-chairperson, who is employed by CMS.

### I. Members of the Advisory Board

The Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services members are: Dr. Robert Rubin (Co-Chairperson), Clinical Professor of Medicine at Georgetown University School of Medicine; Dr. John Burkart, Professor of Internal Medicine/ Nephrology at Wake Forest University; Tom Cantor, Owner of Scantibodies Laboratory; Paula Cuellar, RN, Dialysis Care Center Director for the University of Chicago Hospitals; Paul Eggers, Program Director for Kidney and Urology Epidemiology, National Institute for Diabetes and Digestive and Kidney Diseases, National Institute of Health; Bonnie Greenspan, Health Care

Consultant; Dr. Michael J. Lazarus, Chief Medical Officer and Senior Vice President of Clinical Quality, Fresenius Medical Care NA; Dr. William Owen, Adjunct Professor of Medicine, Duke University School of Medicine, and Senior Scholar, Fuqua School of Business; Nancy Ray, Research Director for the Medicare Payment Advisory Commission; Kris Robinson, Executive Director of the American Association of Kidney Patients; and Dr. Jay Wish, President of ESRD Networks 9 and 10. The Advisory Board will also be co-chaired by Brady Augustine, a CMS employee.

### II. Topics of the Advisory Board Meeting

The Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services will study and make recommendations on the following issues:

- The drugs, biologicals, and clinical laboratory tests to be bundled into the demonstration payment rates.
- The method and approach to be used for the patient characteristics to be included in the fully case-mix adjusted demonstration payment system.
- The manner in which payment for bundled services provided by non-demonstration providers should be handled for beneficiaries participating in the demonstration.
- The feasibility of providing financial incentives and penalties to organizations operating under the demonstration that meet or fail to meet applicable quality standards.
- The specific quality standards to be used.
- The feasibility of using disease management techniques to improve quality and patient satisfaction and reduce costs of care for the beneficiaries participating in the demonstration.
- The selection criteria for demonstration organizations.

### III. Procedure and Agenda of the Advisory Board Meeting

This meeting is open to the public. First, the appointees will be sworn in by a Federal Official. Each Advisory Board member will then be given the opportunity to make a self-introduction. The Advisory Board will hear background presentations from CMS. The Advisory Board will then deliberate openly on the general topic and will make recommendations on specific topics for future meetings. The Advisory Board will also allow a 30-minute open public session. Interested parties may speak or ask questions during the public comment period. Comments may be

limited by the time available. Written questions should be submitted by February 8, 2005 to [ESRDAdvisoryBoard@cms.hhs.gov](mailto:ESRDAdvisoryBoard@cms.hhs.gov). Parties may also submit written comments following the meeting to the contact listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

**Authority:** 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)  
Dated: January 26, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3150-N]

### Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 29, 2005

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. This meeting concerns usual care of chronic wounds. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

**DATES:** The public meeting will be held on Tuesday, March 29, 2005 from 7:30 a.m. until 4:30 p.m. e.s.t.

**Deadline for Presentations and Comments:** Written comments and presentations must be received by February 3, 2005, 5 p.m., e.s.t.

**Special Accommodations:** Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by February 3, 2005 (*see FOR FURTHER INFORMATION CONTACT*).

**ADDRESSES:** The meeting will be held in the auditorium at the Centers for