

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.*

[FR Doc. 05-1743 Filed 1-27-05; 8:45 am]

**BILLING CODE 4120-01-P**

## **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

Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

***Presentations and Comments:***

Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Kimberly Long, by e-mail at [klong@cms.hhs.gov](mailto:klong@cms.hhs.gov) or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1-09-06, Baltimore, MD 21244.

***Web site:*** You may access up-to-date information on this meeting at [www.cms.hhs.gov/mcac/default.asp#meetings](http://www.cms.hhs.gov/mcac/default.asp#meetings).

***Hotline:*** You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1-877-449-5659 (toll free) or in the Baltimore area (410) 786-9379.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Long, Executive Secretary, by telephone at 410-786-5702 or by e-mail at [klong@cms.hhs.gov](mailto:klong@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces a public meeting of the Committee.

***Meeting Topic:*** The Committee will discuss evidence, hear presentations and public comment and make recommendations regarding the standard treatment of chronic wounds. Discussion will address such usual care treatment as cleansing, debridement, dressings, compression, off-loading and antibiotics. Members will also review factors necessary for quality clinical trials that address other wound healing technologies. The Committee will not discuss other treatments that may be used when wounds do not heal.

Background information about this topic, including panel materials, is available on the Internet at <http://www.cms.hhs.gov/coverage/>.

***Procedure:*** This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section and submit the following by the **Deadline for Presentations and Comments** date listed in the **DATES**

section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Committee member before offering your public comments. Your presentation must address the questions asked by CMS to the Committee. The questions will be available on our Web site at <http://www.cms.hhs.gov/mcac/default.asp> meetings. If the specific questions are not addressed, your presentation will not be accepted. We request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

**Registration Instructions**

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410-786-0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1-09-06; Baltimore, MD 21244, or by e-mail at [Mellis@cms.hhs.gov](mailto:Mellis@cms.hhs.gov). Please provide your name, address, organization, telephone and fax number, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

Because the meeting is located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on January 17, 2005. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel, government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

**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 21, 2005.

**Sean R. Tunis,**

*Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.*

[FR Doc. 05-1503 Filed 1-27-05; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0010]

**High Chemical Co. et al.; Proposal to Withdraw Approval of 13 New Drug Applications; Opportunity for a Hearing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

**DATES:** Submit written requests for a hearing by February 28, 2005; submit data and information in support of the hearing request by March 29, 2005.

**ADDRESSES:** Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2005N-0010 and submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Florine P. Purdie, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the approved applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.