

## 2. Assessment of AAAHC's Standards and Methods of Evaluation

As part of the application for renewal of term, AAAHC submitted a crosswalk that compared its standards and methods of evaluations with corresponding MA audit requirements in six areas: Quality Improvement, Access to Services, Antidiscrimination, Information on Advance Directives, Provider Participation Rules, and Confidentiality and Accuracy of Enrollee Records.

## 3. Past Performance and Results of Deeming Validation Review (Look-behind Audit)

We also considered AAAHC's past performance in the deeming program and results of recent deeming validation reviews, or look-behind audits conducted as part of continuing Federal oversight of the deeming program under § 422.157(d).

### B. Results of the Review Process

Using the information listed in section III.A. of this notice, we determined that AAAHC's current accreditation program for managed care plans continues to be at least as stringent as the MA requirements contained in the six categories set forth in section 1852(e)(4)(C) of the Act and our methods of evaluation for those areas.

## IV. Term of Approval

Based on the review and observations described in section III of this proposed notice, we have determined that AAAHC's requirements for HMOs and local PPOs continue to meet or exceed our requirements. Therefore, we are proposing to recognize AAAHC as a national accreditation organization for HMOs and PPOs that request participation in the Medicare program. As a result, we are proposing to approve AAAHC's deeming program effective July 12, 2006 through July 11, 2012.

## V. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 (Pub. L. 96-354)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for

major rules with economically significant effects (\$100 million or more in any 1 year). This notice would not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this notice would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

This notice merely recognizes AAAHC as a national accreditation organization that has approval for deeming authority for HMOs or PPOs that are participating in the MA program.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This notice would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice would not impose any costs on State or local governments, the

requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

**Authority:** Secs. 1851 and 1855 of the Social Security Act (42 U.S.C. 1395w-21 and 42 U.S.C. 1395w-25).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 20, 2006.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. E6-18044 Filed 10-26-06; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3174-N]

### Medicare Program; Meeting of the Medicare Coverage Advisory Committee—December 13, 2006

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

**ACTION:** Notice.

**SUMMARY:** This notice announces a public meeting of the Medicare Coverage Advisory Committee ("MCAC" or "the Committee"). MCAC provides guidance and advice to CMS on specific clinical topics under review for Medicare coverage. This meeting concerns reconsideration of the Medicare clinical trial policy.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

**DATES:** *Meeting Date:* The public meeting will be held on Wednesday, December 13, 2006 from 8 a.m. until 4:30 p.m., e.s.t.

*Registration Deadline:* For security reasons, registration must be made no later than 5 p.m. on November 29, 2006. Requests for special accommodations must be received by 5 p.m. on November 29, 2006.

*Presentation and Written Comments Deadline:* Written comments and presentations must be received by November 13, 2006, e.s.t. Presentations once submitted are final. No further changes to the presentation can be accepted after submission.

**ADDRESSES:** *Meeting Location:* The meeting will be held in the main

auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21244.

**Registration:** Individuals who intend to register may register by contacting Maria Ellis at (410) 786-0309; e-mail to [Maria.Ellis@cms.hhs.gov](mailto:Maria.Ellis@cms.hhs.gov); or by regular mail to Maria Ellis, Centers for Medicare & Medicaid Services, OCSQ-Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244.

#### **Presentation and Comment**

**Submission:** Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Presentation and written comments can be submitted by e-mail or by regular mail to Kimberly Long or Janet Brock, Executive Secretary for MCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244.

**Web Site Address for Additional Information:** You may access up-to-date information on this meeting at [http://www.cms.hhs.gov/FACA/02\\_MCAC.asp#TopOfPage](http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage).

**FOR FURTHER INFORMATION CONTACT:** Kimberly Long or Janet Brock, Executive Secretaries for MCAC; Kimberly Long at 410-786-5702 or e-mail at [Kimberly.Long@cms.hhs.gov](mailto:Kimberly.Long@cms.hhs.gov) or Janet Brock at 410-786-2700 or e-mail at [Janet.Brock@cms.hhs.gov](mailto:Janet.Brock@cms.hhs.gov); or contact by regular mail to Kimberly Long or Janet Brock, Executive Secretary for MCAC, Centers for Medicare & Medicaid Services, OCSQ-Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Meeting Topic**

In the December 14, 1998 **Federal Register** (63 FR 68780), we published a notice to describe the Medicare and Coverage Advisory Committee ("MCAC" or "the Committee"), which provides guidance and advice to CMS on specific clinical topics under review for Medicare coverage.

This notice announces the December 13, 2006 public meeting of the Committee. During this meeting, the Committee will discuss evidence and hear presentations and public comments concerning the clinical trial policy National Coverage Determination (NCD) reconsideration. On July 10, 2006, CMS posted on its Web site for a 30-day public comment period, information to initiate the NCD reconsideration and we received numerous comments.

The MCAC will discuss three important proposed changes to the Medicare clinical trial policy: (1) Review the set of standards for qualified studies; (2) recommend processes through which a trial is determined to meet those standards; and (3) advise on the items and services provided to Medicare beneficiaries in qualified studies. In addition to evaluating the available data, the Committee will provide recommendations on the content and implementation of the clinical trial policy National Coverage Determination (NCD) reconsideration.

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

##### **II. Meeting Procedures**

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 one of the Executive Secretaries for MCAC and submit the following to the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice: (1) A brief statement of the general nature of the evidence or arguments you wish to present; (2) the names and addresses of proposed participants; and (3) a written copy of your presentation. Your presentation should consider the questions we have posed to the Committee and focus on the issues specific to the topic. The questions will be available on the following Web site: [http://www.cms.hhs.gov/FACA/02\\_MCAC.asp#TopOfPage](http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage). We require that you declare at the meeting information pertinent to your relationship with the topic, such as, for example, financial involvement or institutional support. The Committee will also allow a 15 minute unscheduled open public session for any attendee to address issues specific to the topic.

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. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

##### **III. Registration Instructions and Requests for Special Accommodations**

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. All persons interested in attending must register by contacting Maria Ellis at the address specified in the **ADDRESSES** section of this notice by November 29, 2006.

Please provide your name, address, organization, telephone number(s), fax number(s), 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.

Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, must submit their request with their registration information to one of the Executive Secretaries listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

##### **IV. Security, Building, and Parking Guidelines**

This meeting will be held in a Federal Government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend that you arrive reasonably early to allow additional time to clear security.

In order to gain access to the building and grounds, individuals must present photographic identification to the Federal Protective Service or Guard Service personnel before being allowed entrance.

Security measures also include a full inspection of vehicles, inside and exterior areas, at the entrance to the grounds. In addition, all individuals entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of or support of a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Parking permits and instructions will be issued upon arrival.

**Note:** *Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.* The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting. Visitors must be escorted in all areas except for the lower and first floor levels of the Central Building.

**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: October 17, 2006.

**Barry M. Straube,**

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

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1381-N]

#### Medicare Program; Meeting of the Practicing Physicians Advisory Council, December 4, 2006

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

**ACTION:** Notice.

**SUMMARY:** This notice announces a quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Council will meet to discuss certain proposed changes in regulations and manual instructions related to physicians' services, as identified by the Secretary of Health and Human Services (the Secretary). This meeting is open to the public.

**DATES:** *Meeting Date:* Monday, December 4, 2006, from 8:30 a.m. to 5 p.m. e.s.t.

*Deadline for Registration without Oral Presentation:* Friday, December 1, 2006, 12 noon, e.s.t.

*Deadline for Registration of Oral Presentations:* Friday, November 17, 2006, 12 noon, e.s.t.

*Deadline for Submission of Oral Remarks and Written Comments:* Wednesday, November 22, 2006, 12 noon, e.s.t.

*Deadline for Requesting Special Accommodations:* Monday, November 27, 2006, 12 noon, e.s.t.

**ADDRESSES:** *Meeting Location:* The meeting will be held in the Multi-purpose Room, 1st floor, at the CMS Central Office, 7500 Security Boulevard, Baltimore, Maryland, 21244.

*Submission of Presentations:* Presentations should be mailed to Kelly Buchanan, DFO, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mail stop C4-13-07, Baltimore, MD 21244-1850, or contact the DFO via e-mail at [PPAC@cms.hhs.gov](mailto:PPAC@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Kelly Buchanan, the Designated Federal Official (DFO), (410) 786-6132, or e-mail [PPAC@cms.hhs.gov](mailto:PPAC@cms.hhs.gov). News media representatives must contact the CMS Press Office, (202) 690-6145. Please refer to the CMS Advisory Committees' Information Line (1-877-449-5659 toll free), (410) 786-9379 local) or the Internet at <http://www.cms.hhs.gov/home/regsguidance.asp> for additional information and updates on committee activities.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Secretary is mandated by section 1868(a)(1) of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory Council based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the Council's consultation must occur before **Federal Register** publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) not later than December 31 of each year.

The Council consists of 15 physicians, including the Chair. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before its termination.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Section 1868(a)(3) of the Act provides for payment of expenses and per diem for Council members in the same manner as members of other advisory committees

appointed by the Secretary. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. The current members are: Anthony Senagore, M.D., Chairperson; Jose Azocar, M.D.; M. Leroy Sprang, M.D.; Karen S. Williams, M.D.; Peter Grimm, D.O.; Carlos R. Hamilton, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Vincent J. Bufalino, M.D.; Tye J. Ouzounian, M.D.; Geraldine O'Shea, D.O.; Laura B. Powers, M.D.; Gregory J. Przybylski, M.D.; Jeffrey A. Ross, DPM, M.D.; and Robert L. Urata, M.D.

##### II. Meeting Format and Agenda

The meeting will commence with the Council's Executive Director providing a status report, and the CMS responses to the recommendations made by the Council at the August 28, 2006 meeting, as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- Durable Medical Equipment (DME) Update;
- Physician Fee Schedule: Final Rule with Comment;
- Outpatient Prospective Payment System (OPPS)/ Ambulatory Surgical Center (ASC): Final Rule;
- Medicare Contractor Provider Satisfaction Survey (MCPSS) Update-2006 Results;
- Pay for Voluntary Reporting Update; and
- Transparency Initiative.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to Council members for review before the meeting by the date listed in the **DATES** section of this notice.