

## II. Summary of Errors

In section II.B. of the November 25, 2009 notice, we list the criteria that an accreditation organization must furnish to CMS to be considered for approval as a designated accreditation organization for Medicare under 42 CFR 414.68 (as issued in the "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" final rule with comment period, FR Doc. E9-26502, posted for public inspection by OFR on October 30, 2009). Due to a technical error, the list of criteria does not accurately reflect the requirements set out at new § 414.68.

## III. Correction of Errors

In FR Doc. E9-26502 published on November 25, 2009 (74 FR 62189), correct section II.B. to read as follows:

*"B. Application Requirements*

To be considered for approval as a designated accreditation organization for Medicare requirements, an accreditation organization must furnish CMS the information and meet the criteria set out at 42 CFR 414.68, as issued in the "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" final rule with comment period, FR Doc. E9-26502, posted for public inspection by OFR on October 30, 2009."

## III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

We note that section 1834(e) of the Act requires us to designate organizations to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging services by January 1, 2010. Given the

statutory deadline to designate organizations and the timing of the publication of this final rule with comment period, we believe it is impracticable to provide a notice and comment period or to delay the effective date of these criteria for designating organizations to accredit suppliers furnishing the TC of advanced diagnostic imaging services. In addition, it is unnecessary to provide a period for notice and comment or delay the effective date of this correction, because this correction notice does not change our policies regarding the application process, but merely clarifies that the application process is subject to a regulation that has already been the subject of notice and comment rulemaking. Therefore, we believe that we have good cause for waiving a notice and comment period, and making the imaging accreditation application process correction effective upon publication.

**Authority:** Section 1834(e) of the Act.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: November 23, 2009.

**Dawn L. Smalls,**

*Executive Secretary to the Department.*

[FR Doc. E9-28541 Filed 11-25-09; 11:15 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3218-N]

### Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee

January 27, 2010.

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) ("Committee") will be held on Wednesday, January 27, 2010. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the sufficiency of currently available evidence to determine whether the results of pharmacogenomic testing

affect health outcomes of patients with cancer when used as a guide for certain drug treatments. This meeting is open to the public in accordance with 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, January 27, 2010 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (E.S.T.).

*Deadline for Submission of Written Comments:* Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m., E.S.T. on December 28, 2009. Once submitted all comments are final.

*Deadlines for Speaker Registration and Presentation Materials:* The deadline to register to be a speaker and to submit powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., E.S.T. on Monday, December 28, 2009. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

*Deadline for All Other Attendees Registration:* Individuals may register via e-mail at [MEDCAC\\_Registration@cms.hhs.gov](mailto:MEDCAC_Registration@cms.hhs.gov) or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m., E.S.T. on Wednesday, January 20, 2010.

*Deadline for Submitting a Request for 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 contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., E.S.T., Friday, January 8, 2010.

**ADDRESSES:** *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

*Submission of Presentations and Comments:* Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov) or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Maria Ellis, Executive Secretary for

MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via e-mail at [Maria.Ellis@cms.hhs.gov](mailto:Maria.Ellis@cms.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 *Federal Register* (63 FR 68780)). This notice announces the January 27, 2010, public meeting of the Committee. During this meeting, the Committee will discuss the sufficiency of currently available evidence to determine whether the results of pharmacogenomic testing affect health outcomes of patients with cancer when used as a guide for certain drug treatments. Background information about this topic, including panel materials, is available at <http://www.cms.hhs.gov/coverage>. We encourage the participation of appropriate organizations with expertise in pharmacogenomics and oncology.

##### II. Meeting Format

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. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: [http://www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=mcac](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac). We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. 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 topics under consideration. At the conclusion of the day, the members will vote and

the Committee will make its recommendation(s) to CMS.

##### III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your State-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

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

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, 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 presentation or to support a presentation.

**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 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

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

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

Dated: November 19, 2009.

**Barry M. Straube,**

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

[FR Doc. E9-28457 Filed 11-27-09; 8:45 am]

**BILLING CODE 4120-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

##### Pediatric Advisory Committee; Amendment of Notice; Correction

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

**ACTION:** Notice; correction.

The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of November 2, 2009 (74 FR 56652). The document announced an amendment to the notice of meeting of the Pediatric Advisory Committee. This meeting was announced in the *Federal Register* of October 6, 2009 (74 FR 51289). The document was published with an inadvertent error. This document corrects that error.

##### FOR FURTHER INFORMATION CONTACT:

Joyce A. Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20957, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E9-26262, appearing on page 56652, in the *Federal Register* of Monday, November 2, 2009, the following correction is made:

1. On page 56652, in the first column, the heading “[Docket No. 2009-N-0664]” is corrected to read “[Docket No. FDA-2009-N-0664]”.

Dated: November 20, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-28448 Filed 11-27-09; 8:45 am]

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