

the number of registered participants; however, written submissions will be accepted. Individuals who wish to provide written feedback should e-mail their feedback to Colette Shatto at [MFG@cms.hhs.gov](mailto:MFG@cms.hhs.gov). Written feedback will be accepted through November 6, 2009. Consideration will be given to feedback received on the topics discussed at the meeting, but written responses will not be provided.

Registered participants from the meeting will be included as volunteer participants in the MPPFG and may be contacted throughout the year for follow-up meetings to solicit additional opinions or clarify any issues that may arise from the October 29, 2009 meeting.

### III. Registration Instructions

The Division of Provider Relations and Evaluations, Provider Communications Group, Center for Medicare Management is coordinating the meeting registration. While there is no registration fee, individuals must register to participate both on-site and by teleconference. Individuals must complete the on-line registration located at <http://registration.intercall.com/go/cms2>.

The on-line registration system will capture contact information and practice characteristics (for example, names, e-mail addresses, and provider and supplier types). Registration will be open beginning September 28, 2009 and will close on October 23, 2009. Registration after 5 p.m. EDT on October 23, 2009 will not be accepted.

The on-line registration system will generate a confirmation page to indicate the completion of your registration. Participants should print this page as his or her registration receipt. Teleconference instructions will be issued as part of the confirmation page once participants have registered through the on-line registration instrument. Seating capacity is limited to the first 250 registrants.

If seating capacity has been reached for on-site participants, notification will be sent that the meeting has reached capacity; however, those wishing to participate may still do so by teleconference.

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

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by 5 p.m. EDT on October 23, 2009. Individuals who have not registered by the registration deadline will not be allowed to enter the building to attend the

meeting or attend the meeting by teleconference.

The on-site check-in for visitors will be held from 12:30 p.m. to 1:30 p.m. EDT. Participants should allow sufficient time to go through the security checkpoints. It is suggested that participants arrive at 7500 Security Boulevard no later than 1:30 p.m. EDT in order to arrive promptly at the meeting by 2 p.m.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to the building, whether personal or for the purpose of the meeting, are subject to inspection. In order to gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license or passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the CMS building and will not be permitted to attend the meeting.

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 the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the Designated Federal Officer specified in the "**FOR FURTHER INFORMATION CONTACT**" section of this notice by October 23, 2009.

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

Dated: September 3, 2009.

**Charlene Frizzera,**

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

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Anti-Infective Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Anti-Infective Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 27, 2009, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

*Contact Person:* Minh Doan, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail:

[minh.doan@fda.hhs.gov](mailto:minh.doan@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss biologics license application (BLA) 125349, for raxibacumab injection, manufactured by Human Genome Sciences, Inc., proposed for the treatment of inhalational anthrax disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 16, 2009. Oral presentations from the public will

be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 9, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-23143 Filed 9-24-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3216-N]

#### Medicare Program; Request for Nominations for Members of the Medicare Evidence Development & Coverage Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the request for nominations for consideration for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Among other things, the MEDCAC advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services, as requested by the Secretary, whether medical items and services are "reasonable and necessary" and therefore eligible for coverage under Title XVIII of the Social Security Act.

We are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the MEDCAC. Therefore, we encourage nominations of qualified candidates from these groups.

The MEDCAC reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare.

**DATES:** Nominations will be considered if postmarked by Monday, October 26, 2009 and mailed to the address specified in the **ADDRESSES** section of this notice.

**ADDRESSES:** You may mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Attention: Maria Ellis, 7500 Security Boulevard, Mail Stop: Central Building 1-09-06, Baltimore, MD 21244.

**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

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the Medicare Coverage

Advisory Committee on November 24, 1998. On January 26, 2007 the Secretary published a notice in the **Federal Register** (72 FR 3853), changing the Committee's name to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). The charter for the committee was renewed by the Secretary and will terminate on November 24, 2010, unless renewed again by the Secretary.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

The MEDCAC consists of a pool of 100 appointed members including: 6 patient advocates, who are standard voting members, and 6 representatives of industry interests, who are nonvoting members. Members are selected from among authorities in clinical medicine of all specialties, administrative medicine, public health, biologic and physical sciences, health care data and information management and analysis, patient advocacy, the economics of health care, medical ethics, and other related professions such as epidemiology and biostatistics, and methodology of trial design.

The MEDCAC functions on a committee basis. The committee reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare. The Committee works from an agenda provided by the Designated Federal Official that lists specific issues, and develops technical advice to assist us in determining reasonable and necessary applications of medical services and technology when we make national coverage decisions for Medicare. The Committee also advises CMS as part of Medicare's coverage evidence development activities.

##### II. Provisions of the Notice

As of December 2009, there will be 45 terms of membership expiring, 3 of which are nonvoting industry representatives.

Accordingly, we are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that women,