

Dated: August 28, 2012.

**Martique Jones,**

Director, Regulations Development Group,  
Division B, Office of Strategic Operations and  
Regulatory Affairs.

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Centers for Medicare & Medicaid  
Services**

[CMS-3274-N]

**Medicare Program; Meeting of the  
Medicare Evidence Development and  
Coverage Advisory Committee—  
November 14, 2012**

**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, November 14, 2012. 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 use of ventricular assist devices (VADs), a clinical strategy for the management of heart failure. 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, November 14, 2012 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (EST).

*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., Eastern Daylight Time (EDT), Monday, October 15, 2012. 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 5:00 p.m., EDT on Monday, October 15, 2012. Speakers may register by phone or via email 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 online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone

by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. EST, Wednesday, November 7, 2012. We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.

*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 5:00 p.m., EDT Friday, November 2, 2012.

**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 email 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, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via email 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 Wednesday, November 14, 2012, public meeting of the Committee. During this meeting, the Committee will discuss the use of VADs, a clinical strategy for the management of heart failure. Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=>

[BAAAAAAAAAAAA&](http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&). CMS will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of appropriate organizations with expertise in the use of VADs.

**II. Meeting Format**

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. 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, CMS 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 22, 2012. 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.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. 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 online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone 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 email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that 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 brought 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: August 23, 2012.

#### Patrick Conway,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Eukaryotic Parasite Vector Biology.

*Date:* September 20–21, 2012.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692, (301) 435–1149, [elzaataf@csr.nih.gov](mailto:elzaataf@csr.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group, Behavioral Medicine, Interventions and Outcomes Study Section.

*Date:* October 4–5, 2012.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin Riverwalk, 420 W Market Street, San Antonio, TX 78205.

*Contact Person:* Lee S Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0677, [mannl@csr.nih.gov](mailto:mannl@csr.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group, Social Psychology, Personality and Interpersonal Processes Study Section.

*Date:* October 4–5, 2012.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Marriott, 1221 22nd Street NW., Washington, DC 20037.

*Contact Person:* Monica Basco, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3220, MSC 7808, Bethesda, MD 20892, 301–496–7010, [bascoma@mail.nih.gov](mailto:bascoma@mail.nih.gov).

*Name of Committee:* Vascular and Hematology Integrated Review Group, Vascular Cell and Molecular Biology Study Section.

*Date:* October 4–5, 2012.

*Time:* 8:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn—Bethesda Downtown, 7355 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, [pinkusl@csr.nih.gov](mailto:pinkusl@csr.nih.gov).

*Name of Committee:* Cell Biology Integrated Review Group, Cellular Mechanisms in Aging and Development Study Section.

*Date:* October 4–5, 2012.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

*Contact Person:* John Burch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301–408–9519, [burchjb@csr.nih.gov](mailto:burchjb@csr.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group, Psychosocial Development, Risk and Prevention Study Section.

*Date:* October 4–5, 2012.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Marriott, 1221 22nd Street NW., Washington, DC 20037.

*Contact Person:* Anna L Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, [rileyann@csr.nih.gov](mailto:rileyann@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group, Host Interactions with Bacterial Pathogens Study Section.

*Date:* October 4, 2012.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza Hotel—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

*Contact Person:* Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, [elzaataf@csr.nih.gov](mailto:elzaataf@csr.nih.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Biophysics of Neural Systems Study Section.

*Date:* October 4, 2012.

*Time:* 8:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Harborplace Hotel, 202 East Pratt Street, Baltimore, MD 21202.