DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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 meeting.

The meeting 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: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: October 28–29, 2009.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Lorraine Gunzerath, PhD, MBA, Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Review Branch, 5635 Fishers Lane, Room 2121, Bethesda, MD 20892–9304, 301–443–2369, *lgunzera@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: August 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–20773 Filed 8–27–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3214–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—October 21, 2009

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, October 21, 2009. 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 catheter ablation for the treatment of atrial fibrillation. 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, October 21, 2009 from 7:30 a.m. until 4:30 p.m., d.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., d.s.t. on Monday, September 21, 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., d.s.t. on Monday, September 21, 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 by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m., d.s.t. on Wednesday, October 14, 2009.

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., d.s.t. Friday, October 2, 2009.

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* 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*.

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 October 21, 2009, public meeting of the Committee. During this meeting, the Committee will discuss the use of catheter ablation for the treatment of atrial fibrillation. Background information about this topic, including panel materials, is available at *http://ww.cms.hhs.gov/coverage*. We encourage the participation of appropriate organizations with expertise in the use of catheter ablation for the treatment of atrial fibrillation.

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.* 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: August 24, 2009.

Barry M. Straube,

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

[FR Doc. E9–20844 Filed 8–27–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Blood Establishment Computer Software: Understanding What to Include in a 510(k) Submission; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Blood Establishment Computer Software: Understanding What to Include in a 510(k) Submission.'' The purpose of the public workshop is to educate industry on the laws and regulations for medical devices that are applicable to Blood Establishment Computer Software (BECS), including requirements for the content of a 510(k) submission. The public workshop will feature presentations and panel discussions led by FDA and other experts in software quality engineering.

Date and Time: The public workshop will be held on November 4, 2009, from 8:30 a.m. to 5 p.m. and November 5, 2009, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at The Universities at Shady Grove Conference Center, Bldg. II, multipurpose room, 9630 Gudelsky Dr., Rockville, MD 20850.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 550N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by October 16, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: BECS is a device used in the prevention of disease in humans, by identifying unsuitable donors and preventing the release of infectious or otherwise harmful blood and blood components for transfusion or for further manufacturing use. Facilities that manufacture and distribute BECS are subject to device provisions of the Federal Food, Drug, and Cosmetic Act (the act), including premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) and applicable regulations at 21 CFR 807, subpart E. The public workshop will consist of a series of presentations, question-and-answer sessions, and a panel discussion on the following topics:

- The history and legal framework of BECS regulation in the United States;
- Content of 510(k) submissions, applicable regulations, and guidance;
- Common challenges in obtaining 510(k) clearance;
- FDA-recognized software standards;
- General software quality engineering;
- Transfusion safety management systems (blood administration software);
- Virtualization; and
- Wireless technology.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857,