

*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, May 9, 2008.

**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.

*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 May 21, 2008, public meeting of the Committee. During this meeting, the Committee will discuss the desirable characteristics of research trials in neurorehabilitation. Due to the broad nature of this topic, the Committee will focus on the key questions of clinical trial design, methodology and analysis in the context of stroke rehabilitation. Background information about this topic, including panel materials, will become available at <http://www.cms.hhs.gov/coverage>.

##### **II. Meeting Format**

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 30 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 the 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 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 30 to 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: March 14, 2008.

**Barry M. Straube,**

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

[FR Doc. E8-5882 Filed 3-31-08; 8:45 am]

**BILLING CODE 4120-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **The Essentials of Food and Drug Administration Medical Device Regulations: A Primer for Manufacturers and Suppliers; Public Seminar**

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

**ACTION:** Notice of public seminar.

**SUMMARY:** The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health and Office of Regulatory Affairs, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a series of three seminars on FDA medical device regulations. These 2-day seminars, which are designed to address the training needs of startup and small device manufacturers and their suppliers, will include both industry and FDA perspectives and a question and answer period.

*Dates:* The seminars are planned for the following dates:

1. April 8 and 9, 2008, in Rosemont, IL 60018. Details about dates are posted on AdvaMed's Web site at:

[www.Advamedmtli.org/Chicago](http://www.Advamedmtli.org/Chicago).<sup>1</sup>

2. May 13 and 14, 2008, Bethesda, MD 20852. Details about dates are posted on AdvaMed's Web site at

[www.Advamedmtli.org/Bethesda](http://www.Advamedmtli.org/Bethesda).

3. June 17 and 18, 2008, Queens, NY. Details about dates are posted on AdvaMed's Web site at:

[www.Advamedmtli.org/New York](http://www.Advamedmtli.org/New York).

*Locations:* The seminars are planned for the following locations:

1. April 8 and 9, 2008, Westin O'Hare, 6100 North River Rd., Rosemont, IL 60018. Details about location sites are posted on AdvaMed's Web site at:

[www.Advamedmtli.org/Chicago](http://www.Advamedmtli.org/Chicago).

2. May 13 and 14, 2008, Marriott Bethesda North Conference Center, White Flint Auditorium, 5101 Marinelli Rd., North Bethesda, MD 20852. Details about location sites are posted on AdvaMed's Web site at:

[www.advamedmtli.org/Bethesda](http://www.advamedmtli.org/Bethesda).

3. June 17 and 18, 2008, Crowne Plaza New York-LaGuardia, 104-04-Ditmars Blvd., East Elmhurst, NY 11369. Details about location sites are posted on AdvaMed's Web site at:

[www.advamedmtli.org/NewYork](http://www.advamedmtli.org/NewYork).

*Contact:* For FDA: William Sutton, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, 800-638-2041, ext. 125, FAX: 240-276-3151, e-mail: [William.sutton@fda.hhs.gov](mailto:William.sutton@fda.hhs.gov).

For AdvaMed: Veronica Allen, 202-434-7231, FAX: 202-783-8750, e-mail: [VAllen@AdvaMed.org](mailto:VAllen@AdvaMed.org).

*Registration:* The registration fee for a limited number of FDA employees is waived. Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$525 per person to AdvaMed, contact Veronica Allen, 202-434-7231, FAX: 202-783-8750. Payment forms accepted are major credit card (MasterCard, Visa, or American Express) or company check. If you wish to pay by check, contact Veronica Allen at [VAllen@Advamed.org](mailto:VAllen@Advamed.org).

To register via the Internet, go to [www.AdvaMed.org](http://www.AdvaMed.org). The latest information on dates/venue sites will be posted on this Web site at: [www.advamedmtli.org/Chicago](http://www.advamedmtli.org/Chicago),

[www.admedmtli.org/Bethesda](http://www.admedmtli.org/Bethesda), and [www.advamedmtli.org/NewYork](http://www.advamedmtli.org/NewYork) (FDA has verified the Web site addresses, but is not responsible for changes to the Web sites after this document publishes in the **Federal Register**).

For more information on the meeting, or for questions on registration, contact Veronica Allen (see *Contact*).

Attendees are responsible for their own accommodations. For further hotel information and driving directions, go to the registration Web site.

The registration fee will be used to offset the expenses of hosting the conference, including meals (breakfast and a lunch), refreshments, meeting rooms, and training materials. It also includes a networking reception on the evening of the first day of each seminar.

Space is limited; therefore, interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Veronica Allen (see *Contact*) at AdvaMed as soon as possible.

**SUPPLEMENTARY INFORMATION:** The "Essentials of FDA Medical Device Regulations: A Primer for Manufacturers and Suppliers" seminar helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating new entrepreneurs on the essentials of FDA device regulations. FDA has made education of the medical device community a high priority to assure the quality of products reaching the marketplace and to increase the rate of voluntary industry compliance with regulations.

The seminar helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The seminar also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed at small businesses.

The following topics, as well as others, will be discussed at the seminar:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- Overview of the quality system regulation;
- Design controls;
- Documents, records, and change control;
- Purchasing controls and acceptance activities;
- Production and process control;

- Corrective and preventive actions;
- Complaints, medical device reports, corrections, and recalls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—Where do you go for assistance?
- General question and answer session;
- Manufacturers and suppliers—the chain regulatory responsibility;
- Reimbursement of medical technology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

Dated: March 27, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 08-1085 Filed 3-28-08; 11:48 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Tribal Management Grant Program

*Announcement Type:* New and Competing Continuation Discretionary Funding Cycle for Fiscal Year 2009.

*Funding Announcement Number:* HHS-2009-IHS-TMD-0001.

*Catalog of Federal Domestic Assistance Numbers(s):* 93.228.

*Key Dates:* Training: Application Requirements Session: April 30–May 1, May 14–15, and June 11–12, 2008.

Grant Writing Session: June 23–27, 2008.

Application Deadline Date: August 1, 2008.

Receipt Date for Final Tribal Resolution: October 3, 2008.

Review Date: October 6–10, 2008.

Application Notification Date: November 12, 2008.

Earliest Anticipated Start Date: January 1, 2009.

#### I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Tribal Management Grant (TMG) Program. This program is authorized under Section 103(b)(2) and Section 103(e) of the Indian Self-Determination and Education Assistance Act, Public Law 93-638, as amended. This program is described at 93.228 in the Catalog of Federal Domestic Assistance (CFDA).

The TMG Program is a national competitive discretionary grant program pursuant to 45 CFR part 75 and 45 CFR part 92 established to assist Federally-recognized Tribes and Tribally-

<sup>1</sup> FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.