duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This notice sets forth the amounts of States' final FY 2007 allotments for payment of Medicare Part B premiums for qualifying individuals determined in accordance with existing statutory and regulatory provisions. Because this notice merely redistributes allotments that have already been made, it has no impact. As a result, it does not reach the economic threshold of being considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

As indicated previously, this notice is applicable only to States. Moreover, the total amount of Federal funds available during a Federal fiscal year and the formula for determining individual State allotments are specified in the law. We have applied the statutory formula for the State allotments. Because the data specified in the law were not initially available, we used comparable data from the U.S. Census Bureau on the number of possible qualifying individuals in the States. *The existing statute and regulations* permit, in a specific circumstance, reallocation of funds to enable enrollment of all eligible individuals to the extent of the available funding.

We believe that the final FY 2007 allotments set forth in this notice will have a positive effect on States and individuals. Federal funding at the 100 percent matching rate is available for Medicare cost-sharing for Medicare Part B premium payments for qualifying individuals and, with the reallocation of the State allotments, a greater number of low-income Medicare beneficiaries will be eligible to have their Medicare Part B premiums paid under Medicaid. The changes in allotments will not result in fewer individuals receiving the QI benefit in any State. The FY 2007 costs for this provision have been included in the FY 2007 President's Budget.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. The analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Core-Based Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined and certify that this notice will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (URMA) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1902(a)(10), 1933 of the Social Security Act (42 U.S.C. 1396a), and Pub. L. 105–33.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: November 20, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 3, 2007.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on March 18, 2008.

[FR Doc. E8–5748 Filed 3–31–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

CMS–3197–N

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—May 21, 2008

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, May 21, 2008. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. This meeting will focus on the design and methodological issues that challenge clinical research regarding innovative neurorehabilitation techniques. The meeting will discuss the various kinds of evidence that are useful to support requests for Medicare coverage in this field. 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 7:30 a.m. until 4:30 p.m., d.s.t. on Wednesday, May 21, 2008.

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 April 21, 2008. Once submitted, comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker, and to submit materials and writings that will be used in support of an oral presentation, is 5 p.m., d.s.t. on Monday, April 21, 2008. 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, May 14, 2008.

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* 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 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*.

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.