

Dated: July 2, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3193-N]

Town Hall Meeting Regarding the Effect of Coverage and Payment on Clinical Research Study Participation and Retention, September 20, 2007

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

ACTION: Notice of Town Hall Meeting.

SUMMARY: This notice announces a Town Hall meeting to allow interested parties to provide individual advice and recommendations to Centers for Medicare and Medicaid Services (CMS) regarding the impacts of health insurance coverage, and payment for items, and services in clinical research studies on the generalizability and validity of study results and findings to guide decision-making.

DATES: *Meeting Date:* The public meeting will be held on September 20, 2007 from 1 p.m. until 4 p.m., D.S.T.

Registration and Special Accommodations Deadlines: For security reasons, individuals wishing to attend this meeting must register by 5 p.m., D.S.T. on September 13, 2007. Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify Michelle Atkinson as specified in the **FOR FURTHER INFORMATION CONTACT** section, by 5 p.m. D.S.T. on September 13, 2007.

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.

Registration: Register by contacting Maria Ellis (410-786-0309; Maria.Ellis@cms.hhs.gov; Centers for Medicare & Medicaid Services, OCSQ-Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244). You may access up-to-date information on this meeting at <http://www.cms.hhs.gov/center/coverage.asp>. Please use this site to access the system that will permit you to submit written comments.

FOR FURTHER INFORMATION CONTACT:

Michelle Atkinson, 410-786-2881; Michelle.Atkinson@cms.hhs.gov; Centers for Medicare & Medicaid Services, OCSQ-Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION:

I. Meeting Topic

In May 2007, CMS entered into an interagency agreement with the Agency for Healthcare Research and Quality (AHRQ) to work with the Duke Evidence-Based Practice Center to develop a White Paper that will assist CMS in our decisions regarding payment policy, especially the timing of initiating coverage, for new therapeutic agents. The Duke Evidence-Based Practice Center has assembled a panel for this project. The agenda for the town hall meeting is as follows:

- Review the planned methodology.
- Advise the investigators at the Duke Center for Clinical Health Policy Research regarding key informants.
- Provide critical input on content of the conference calls, topics for discussion, and direction for the literature search.

Background information about this topic, including instructions for submitting written comments, is available on the Internet at <http://www.cms.hhs.gov/center/coverage.asp>. This meeting will specifically discuss the following issues:

- How do payment policies by CMS and other third-party payers affect enrollment into clinical trials?
- How do payment policies by CMS and other third-party payers affect randomization and blinding within clinical trials?
- What is the summary impact of this effect?
- Does the timing of third-party payment in the clinical trial process impact the development of better evidence?
- Do differing payment structures within clinical trials affect the resulting evidence?

All interested parties are invited to attend or participate via teleconference. The perspectives expressed during this meeting and in writing will assist the Duke Center for Clinical Health Policy Research in drafting the White Paper.

II. Registration Instructions

The CMS Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. Register by contacting Maria Ellis at the address by the dates specified in the **ADDRESSES** and **DATES**

sections of the notice, respectively. Please provide your name, address, organization, telephone and fax numbers, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

III. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security.

In order to gain access to the building and grounds, individuals must present photographic identification to the Federal Protective Service or Guard Service personnel before being allowed entrance. Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all individuals entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, 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 demonstration or to support a demonstration.

Parking permits and instructions will be issued upon arrival.

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: Medicare—Supplementary Medical Insurance Program.

Dated: August 9, 2007.

Herb B. Kuhn,

Acting Deputy Administrator, Centers for Medicare & Medicaid Services.

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