

Town Hall Meeting - “The Effect of Coverage and Payment on Clinical Research Study Participation and Retention”

Thursday, September 20, 2007 1:00 pm EST to 4:00pm EST in the CMS Multipurpose Room

This announces a Town Hall Meeting. The meeting is being convened to allow interested parties to provide individual advice and recommendations to CMS about the important matters to consider regarding this issue to develop a white paper for dissemination to payers, providers, patients, and researchers. The issue the white paper will address is what the impact of health insurance coverage and payment for items and services in clinical research studies has on the generalizability and validity of study results and findings to guide decision making. This meeting will specifically discuss the following issues: (1) How do payment policies by CMS and other third-party payers affect enrollment into clinical trials? (2) How do payment policies by CMS and other third-party payers affect randomization and blinding within clinical trials? (3) What is the summary impact of this effect? (4) Does the timing of third-party payment in the clinical trial process impact the development of better evidence? (5) Do differing payment structures within clinical trials affect the resulting evidence? All interested parties are invited to attend or listen to the Session by teleconference. The session agenda includes an open forum discussion period to permit those in attendance as well as those on the telephone to participate. Written comments will be welcome from everyone. The perspectives expressed during this meeting and in writing will assist the Duke Center for Clinical Health Policy Research in writing the white paper.

Comments:

Written comments on the white paper to be developed by Duke Evidence-based Practice Center may be sent electronically CAGtownhall@cms.hhs.gov and must be received by COB September 10, 2007.

Call in instructions:

If you are unable to attend the Town Hall meeting you may call in to participate. The number to call in is 1-888-396-9924 and the pass code is Retention. Once you have told the operator the pass code the operator will ask for your name, organization, and phone number for the participant list.

Agenda:

An [agenda](#) will be posted on the CMS website at least one week prior to the meeting. We will provide the link to the [agenda](#) and notify the public at the time of the posting.

Registration:

If you are able to attend the Town Hall meeting, please email Maria Ellis at maria.ellis@cms.hhs.gov. Please provide Maria your name as it appears on your driver's license, address, organization, telephone and fax number, and email 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. This meeting is located on

Federal property; therefore, for security reasons, any individuals wishing to attend this meeting must register by 5 pm on September 13, 2007.

Security:

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 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.

Contact Information:

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