

CMS Special Open Door Forum:

Draft Guidance Document on Coverage with Evidence Development (CED)

Monday, May 9, 2005

2:00-4:00 pm [ET]

The Centers for Medicare & Medicaid Services (CMS) is holding this Special Open Door Forum to engage stakeholders in a public dialogue to assist the agency in developing guidance to improve the process for making Medicare national coverage decisions involving additional evidence development. The draft guidance document was issued April 7, 2005 and posted on the CMS website at www.cms.hhs.gov/coverage/guidance.asp.

CED is intended to be limited to only those items and services that would normally be covered under the NCD process. For example, the NCD process does not generally apply to self-administered drugs or outpatient prescription drugs payable under Part D.

CED will only be used in those instances where an NCD has been opened and the evidence is less convincing and would have resulted in non-coverage. Rather than waiting for the completion of definitive studies that address all key questions about whether a technology is reasonable and necessary in every specific circumstance, CMS would provide coverage by collecting the appropriate data to ensure the item or service is reasonable and necessary for those specific Medicare beneficiaries receiving care.

This will be an opportunity for the public to provide comments and address questions posed in the draft guidance document. Presentations and topics for discussion are:

- An overview of the guidance document
- A summary of comments received
- Questions raised in the draft guidance document about:
 - Factors to consider in applying CED
 - Process for deciding when and how to apply CED
 - Evidence development methods
 - Process for study design and implementation

This effort is being led by the Agency's Council for Technology and Innovation (CTI). The CTI is charged with leading improvements in the coordination of coverage, coding, and payment processes with respect to new technologies and procedures (including new drug therapies). The CTI will additionally serve in facilitating the exchange of information between CMS and other entities, both public and private, that are faced with making similar decisions. This council replaces the previous Medicare Technology Council and consists of cross-cutting members of the agency's senior staff and is co-chaired by the Director of the Center for Medicare Management, Herb Kuhn, who is designated the Council's executive Coordinator, and Barry M. Straube, M.D., the Acting Chief Medical Officer and Acting Director of the Office of Clinical Standards and Quality.

Open Door Participation Instructions:

There are 2 ways to participate, by phone or "in-person".

1. To participate by phone:

Dial: 1-800-837-1935 & Reference Conference ID 5394065

Persons participating by phone do not need to RSVP.

Note: TTY Communications Relay Services are available for the Hearing Impaired.

For TTY services dial 7-1-1 or 1-800-855-2880 and for Internet Relay services click here <http://www.consumer.att.com/relay/which/index.html>.

A Relay Communications Assistant will help.

2. To participate in-person:

If you intend to participate in person, **RSVP is required:**

Please send a reply to this email by close of business Thursday, May 5th, to

SpecialODF@cms.hhs.gov.

Please include the word "CTI ODF" in the subject line of your message, and send us the following information:

- a) Your full name
- b) Your organization or representation
- c) Your contact information (phone and email)
- d) Special needs information

Location information:

Photo identification is required at security points. Please arrive with enough time to both park and pass through security checkpoints. (This may take about 30 minutes.)

ADDRESS:

CMS Single Site Building

7500 Security Boulevard

Baltimore, MD 21244

Map & Directions:

<http://cmsnet.cms.hhs.gov/hpages/ocsq/cmsdirections-north.htm>

ENCORE: 1-800-642-1687

"Encore" is a recording of this call that can be accessed by dialing 1-800-642-1687 and entering the Conf. ID # 5394065.

The recording begins the following Monday, and expires after 4 business days.

For automatic emails of Open Door Forum [schedule updates](#) (Listserv registration) and to view Frequently Asked Questions please visit our website at:

www.cms.hhs.gov/opendoor.