CMS Open Door Forum:
Guidance Documents on the National Coverage Determination Process

Thursday, March 10, 2005
2:00 – 4:00 PM (Eastern Time)

The Centers for Medicare & Medicaid Services (CMS) is holding a Special Open Door Forum to engage stakeholders in a public dialogue to assist in the development of the first three of a series of draft guidance documents associated with the National Coverage Determination (NCD) process. These first documents describe factors that CMS considers when: 1) initiating a Medicare NCD; 2) determining when to commission an external health technology assessment (HTA) to evaluate a new health care technology; and 3) referring issues to the Medicare Coverage Advisory Committee (MCAC) for independent, expert advice and public input on specific clinical topics.

This will be an opportunity for the public to provide comments on the three guidance documents. Discussion topics may include:

- *Initiating a Medicare NCD:*
  Is there ample opportunity for transparency and public participation in the NCD development process?
  Are the requirements for initiating an NCD by an outside party clear?
- *Referring issues to the Medicare Coverage Advisory Committee:*
  Are instances in which CMS may request an issue be reviewed by the MCAC sufficiently explained?
  Are there additional instances when an issue should go to the MCAC?
- *Requesting an external health technology assessment (HTA):*
  Is the process for external HTAs appropriate?
  Are there other factors that should be considered in requesting a TA?

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 Sean Tunis, MD, the director of the Office of Clinical Standards and Quality.

For more information on the CTI, please refer to the CTI webpage:
http://www.cms.hhs.gov/providers/cti.

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: **4028132**

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 Tuesday, March 8, 2005 to SpecialODF@cms.hhs.gov.
Please include the words "**CTI**" 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:
ADDRESS:
    CMS Single Site Building
    Room C-112
    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 # **4028132**

The recording begins on Monday, March 14, 2005 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.