

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the HIT Policy Committee.

Date and Time: The meeting will be held on November 30, 2010, from 9 a.m. to 3 p.m./Eastern Time.

Location: The meeting will be conducted virtually only. Dial into the meeting: 1-877-705-6006; webcast: <http://altairum.adobeconnect.com/HITstandards>.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202-205-4528, Fax: 202-690-6079, e-mail: judy.sparrow@hhs.gov. Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups, including the Clinical Operations, Vocabulary Task Force, Implementation, and Enrollment Workgroups. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the

meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://healthit.hhs.gov>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 24, 2010. Oral comments from the public will be scheduled between approximately 2 and 3 p.m./Eastern Time. Time allotted for each presentation will be limited to three minutes each. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://healthit.hhs.gov> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. 2).

Dated: October 18, 2010.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0541]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 26, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0470. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Special Protocol Assessment—OMB Control Number 0910-0470—Extension

The "Guidance for Industry on Special Protocol Assessment" describes Agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the Agency to act on such requests. The guidance provides information on how the Agency interprets and applies provisions of the Food and Drug Administration