Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Gemma Kuijpers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5374, Silver Spring, MD 20993–0002, 301–796–1243.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment.'' This draft guidance provides recommendations to industry for designing a nonclinical development program to support approval of drugs to treat osteoporosis. In addition to the pharmacology and toxicology studies required to support development of a new drug or biologic, long-term nonclinical studies to evaluate effects on bone quality in adequate animal models and including bone-specific pharmacologic and toxicologic endpoints are needed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on nonclinical evaluation of drugs intended for the treatment of osteoporosis. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–13988 Filed 6–13–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health IT 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 updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings are open to the public.

*Name of Committee:* Health IT 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 Health IT Policy Committee.

**2016 Meeting Dates and Times**

- May 17, 2016, from 9:00 a.m. to 3:00 p.m./Eastern Time
  - This will be an in-person meeting at the Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC 20008
- June 8, 2016, from 9:30 a.m. to 12:00 p.m./Eastern Time
  - This will be a virtual meeting
- June 23, 2016, from 9:00 a.m. to 3:00 p.m./Eastern Time
  - This will be an in-person meeting at the Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202
- July 27, 2016 from 10:00 a.m. to 1:00 p.m./Eastern Time (replacing the formerly announced July 13 and August 7 meetings)
  - This will be a virtual meeting

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, *http://www.healthit.gov/FACAS/calendar.*

*Contact Person:* Michelle Consolazio, email: *michelle.consolazio@hhs.gov.* Please email Michelle Consolazio for the most current information about meetings. 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/task forces

and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. 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://www.healthit.gov/facas/health-it-standards-committee.*

*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 prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing wireless access or 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 Michelle Consolazio 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: June 2, 2016.

**Michelle Consolazio,**

*FACA Program Director, Office of Policy, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 2016–13997 Filed 6–13–16; 8:45 am]

**BILLING CODE 4150–45–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health IT Policy Committee Advisory Meeting; Notice of Meeting

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

**ACTION:** Notice of meeting.

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

*Name of Committee:* Health IT Policy Committee.

*General Function of the Committee:* To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

**2016 Meeting Dates and Times**

- May 17, 2016, from 9:00 a.m. to 3:00 p.m./Eastern Time
  - This will be an in-person meeting at the Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC 20008
- June 8, 2016, from 10:00 a.m. to 1:00 p.m./Eastern Time (replacing the June 7, 2016 meeting)
  - This will be a virtual meeting
- June 23, 2016, from 9:00 a.m. to 3:00 p.m./Eastern Time
  - This will be an in-person meeting at the Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202
- July 27, 2016 from 9:30 a.m. to 1:00 p.m./Eastern Time (replacing the formerly announced July 12 and August 9 meetings)
  - This will be a virtual meeting

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, *http://www.healthit.gov/FACAS/calendar*

*Contact Person:* Michelle Consolazio, email: *michelle.consolazio@hhs.gov.* Please email Michelle Consolazio for the most current information about meetings. 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/task forces and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. 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://www.healthit.gov/FACAS/health-it-policy-committee.*

*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 prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

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

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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: June 1, 2016.

**Michelle Consolazio,**

*FACA Program Director, Office of Policy, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 2016–13998 Filed 6–13–16; 8:45 am]

**BILLING CODE 4150–45–P**