respondent from making such representations unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of Part II, the proposed order defines “competent and reliable scientific evidence” as at least two randomized, double-blind, placebo-controlled human clinical studies that are conducted by independent, qualified researchers and that conform to acceptable designs and protocols, and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.

Part III of the proposed order prohibits respondent from making representations, other than representations covered under Parts I or II, about the health benefits of any drug, dietary supplement, or cosmetic, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of Part III, the proposed order defines “competent and reliable scientific evidence” as “tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.”

Part IV of the proposed order states that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the Food and Drug Administration (“FDA”), or under any new drug application approved by the FDA. This part of the proposed order also states that the order does not prohibit respondent from making representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part V of the proposed order requires respondent to pay nine hundred thousand dollars ($900,000) to the Commission to be used for equitable relief, including restitution, and any attendant expenses for the administration of such equitable relief. Parts VI, VII, VIII, and IX of the proposed order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2011–16739 Filed 7–1–11; 8:45 am]
meetings will be open to the public via dial-in access only.


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 HIT Standards Committee Workgroups will hold the following public meetings during July 2011: July 8th Vocabulary Task Force, 11 a.m. to 12 p.m./ET; and July 12th Implementation Workgroup, 12 to 1:30 p.m./ET.

Location: All workgroup meetings will be available via webcast; visit http://healthit.hhs.gov for instructions on how to listen via telephone or Web. Please check the ONC Web site for additional information as it becomes available. 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 these meetings. A notice in the Federal Register about last minute modifications that affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The workgroups will be discussing issues related to their specific subject matter, e.g., clinical operations vocabulary standards, clinical quality, implementation opportunities and challenges, and privacy and security standards activities. If background materials are associated with the workgroup meetings, they will be posted on ONC’s Web site prior to 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 workgroups. Written submissions may be made to the contact person on or before two days prior to the workgroup’s meeting date. Oral comments from the public will be scheduled at the conclusion of each workgroup 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 until close of business on that day.

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: June 24, 2011.

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

[FR Doc. 2011–16755 Filed 7–1–11; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HIT Policy Committee’s Workgroup Meetings; Notice of Meetings

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

ACTION: Notice of meetings.

This notice announces forthcoming subcommittee meetings of a Federal advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meetings will be open to the public via dial-in access only.

Name of Committees: HIT Policy Committee’s Workgroups: Meaningful Use, Privacy & Security Tiger Team, Quality Measures, Governance, Adoption/Certification, and Information Exchange workgroups.

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.

Date and Time: The HIT Policy Committee Workgroups will hold the following public meetings during July 2011: July 8th Privacy & Security Tiger Team, 2 to 4 p.m./ET; and July 22nd Privacy & Security Tiger Team, 2 to 4 p.m./ET.

Location: All workgroup meetings will be available via webcast; for instructions on how to listen via telephone or Web visit http://healthit.hhs.gov. Please check the ONC Web site for additional information or revised schedules as it becomes available.

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 these meetings. A notice in the Federal Register about last minute modifications that affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The workgroups will be discussing issues related to their specific subject matter, e.g., meaningful use, information exchange, privacy and security, quality measures, governance, or adoption/certification. If background materials are associated with the workgroup meetings, they will be posted on ONC’s Web site prior to 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 workgroups. Written submissions may be made to the contact person on or before two days prior to the workgroup’s meeting date. Oral comments from the public will be scheduled at the conclusion of each workgroup 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 until close of business on that day.

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. No. 92–463, 5 U.S.C., App. 2).

Dated: June 24, 2011.

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

[FR Doc. 2011–16749 Filed 7–1–11; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HIT Policy Committee Advisory Meeting; Notice of Meeting

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

ACTION: Notice of meeting.