

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT 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 a forthcoming meeting of a workgroup 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: Health IT Policy Committee's Governance Workgroup.

General Function of the Health IT Policy 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. Purpose of the Governance Workgroup: To draft a set of recommendations on the scope and process of governance for the nationwide health information network, including measures to ensure accountability and oversight. The charge to the Governance Workgroup is to draft a set of recommendations on the scope and process of governance for the nationwide health information network, including measures to ensure accountability and oversight.

DATE AND TIME: The meeting will be held on September 28, 2010, from 9 a.m. to 5 p.m. Eastern Time.

LOCATION: Washington Marriott Wardman Park Hotel, 2660 Woodley Road, NW., Washington, DC 20008. For up-to-date information, go to the ONC Web site, <http://healthit.hhs.gov>.

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 Workgroup will hear testimony from invited panelists on

information on governance of the nationwide health information network. 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, in writing, on issues identified by the Workgroup. Written submissions may be made to the contact person on or before September 24, 2010. Written comments are limited to 10 pages, and should be either mailed to the address above or e-mailed to judy.sparrow@hhs.gov, with the Subject Line: Responses for Governance Workgroup. The questions the Workgroup is interested in are as follows:

Panel 1: Governance Models in Other Domains

1. Please share your experiences in establishing governance requirements to ensure trust in the privacy and security of the information exchange, *e.g.*, to secure the data, to assure appropriate use of the data exchanged, to address responsibilities for obtaining consent, etcetera. Were governance requirements established to ensure a certain level of interoperability? What types of governance mechanisms and processes were established? What conditions, requirements, and processes facilitated the resolution of disputes between parties with differing interests?

2. Please describe whether and how you have included multiple stakeholders in governance? To what extent have consumers been engaged?

3. Please describe the relationship between the private sector parties and the government—was authority delegated from the government, did the government oversee either the governance process or the results of the process, was the government simply participating as a member of the group etc.? What changes, if any, would you recommend? Because the relationship between the government and the private sector may differ in governance mechanisms in technical and policy domains, please share your views as to how to determine and establish the most appropriate relationship.

4. In considering the question as to how to determine the most appropriate governance mechanism, please address: the costs and benefits involved in

delegation of authority from the government; the need for ensuring some degree of openness in the process of developing requirements when authority is delegated; and the most appropriate means available for determining compliance and enforcing any requirements that have been established through the governance mechanism.

Panels 2 and 3: Governance Experience of Implementers of Health Information Exchange

1. Please Provide an Introduction to Your Organization

- Describe the stakeholders that are governed by the governance process.
- Describe the group that executes the governance process.
- How is the authority of the governing body established (contract, law, other)?

2. Trust

- Please share your experiences in governance mechanisms for trust—what types of governance mechanisms and processes do you have in place (or are needed) to promote trust in the exchange?

- How have you addressed privacy and security obligations (*e.g.*, to safeguard information, to assure appropriate use of the data exchanged, to address responsibilities for obtaining consent, etc.) through governance?

- Please describe how you have included multiple stakeholders in governance (*e.g.*, how they were able to engage those stakeholders in effective participation? what challenges/enablers to engage in effective participation? To what extent have consumers been engaged?)

- Please identify issues, if any, that still need to be addressed. What types of governance mechanisms are needed to promote trust to facilitate exchange?

- What suggestions do you have for ONC for establishing governance in this area?

2. Interoperability

- Please share experiences in governance mechanisms for interoperability—what types of governance mechanisms and processes do you have in place (or are needed) to promote interoperability in the exchange?

- How are expectations for interoperability established and assured?

- What suggestions do you have for ONC for establishing governance in this area?

3. Accountability, Enforcement and Oversight

• Please share your experiences in establishing accountability, enforcement and oversight with regard to both trust and interoperability.

• What suggestions do you have for ONC for establishing governance in this area? Examples of specific issues include:

• How should organizations be vetted for participation?

• How should the exchange of information be monitored for appropriateness in a large volume/distributed environment?

• How should information be provided to a consumer regarding who accessed his/her information?

• How should consumer complaints be investigated?

• How should “bad actors” be disciplined?

Panel 4: Existing Governance Authorities

1. Please describe the scope and jurisdiction of your authority/authorities, with particular reference to areas that are/may be related to the exchange of health information over a network.

2. Please describe how your authorities are implemented.

3. Please offer suggestions to the Office of the National Coordinator for developing, implementing and coordinating governance.

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: September 13, 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

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: HRSA AIDS Drug Assistance Program Quarterly Report—(OMB No. 0915–0294)—Extension

HRSA’s AIDS Drug Assistance Program (ADAP) is funded through Part B of Title XXVI of the Public Health Service Act, the Ryan White HIV/AIDS Program, which provides grants to States and Territories. The ADAP provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 States, the District of Columbia, Puerto Rico, and several Territories receive ADAP grants. As part of the funding requirements, ADAP grantees submit quarterly reports that include information on patients served, pharmaceuticals prescribed, pricing, and other sources of support to provide AIDS medication treatment, eligibility requirements, cost data, and coordination with Medicaid. Each quarterly report requests updates from programs on number of patients served, type of pharmaceuticals prescribed, and prices paid to provide medication. The first quarterly report of each ADAP fiscal year (due in July of each year) also requests information that only changes annually (e.g., State funding, drug formulary, eligibility criteria for enrollment, and cost-saving strategies including coordinating with Medicaid).

The quarterly report represents the best method for HRSA to determine how ADAP grants are being expended and to provide answers to requests from Congress and other organizations.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
1st Quarterly Report	57	1	57	3	171
2nd, 3rd, & 4th Quarterly Reports	57	3	171	1.5	256.5
Total	57		228		427.5