

Dated: December 12, 2017.

Darius Taylor,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Health Information Technology Advisory Committee

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

ACTION: Notice of establishment meeting dates of the Health Information Technology Advisory Committee.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) is established in accordance with section 4003(e) of the 21st Century Cures Act and the Federal Advisory Committee Act. The Health Information Technology Advisory Committee, among other things, shall identify priorities for standards adoption and make recommendations to the National Coordinator of Health Information Technology (National Coordinator) on a policy framework to advance an interoperable health information technology infrastructure. The HITAC will hold public meetings throughout 2018 with its first public meeting scheduled for January 18, 2018, from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: Lauren Richie, Designated Federal Officer, at Lauren.Richie@hhs.gov.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114-255) establishes the Health Information Technology Advisory Committee (referred to as the "HITAC"). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition

The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;
- 3 members are appointed by the HHS Secretary

- 1 of whom shall be appointed to represent the Department of Health and Human Services and

- 1 of whom shall be a public health official;

- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives; and
- Other members are appointed by the Comptroller General of the United States.

Introductory members will serve for one-, two-, or three-year terms. All members may be reappointed for subsequent three-year terms. Each member is limited to two three-year terms, not to exceed six years of service. After establishment, members shall be appointed for a three year term. Members serve without pay, but will be provided per-diem and travel costs for committee services.

Recommendations

The HITAC shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing following target areas: (1) Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information; (2) the promotion and protection of privacy and security of health information in health information technology; (3) the facilitation of secure access by an individual to such individual's protected health information; and (4) any other target area that the HITAC identifies as an appropriate target area to be considered. Such policy framework shall seek to prioritize achieving advancements in these target areas and may incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

Public Meetings

The first public meeting of the HITAC will be held on January 18, 2018, from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008. Subsequently, the remainder of the meetings to be held in 2018 is scheduled as follows:

- February 21, 2018 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)

- March 21, 2018 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- April 18, 2018 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- May 16, 2018 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- June 20, 2018 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- September 5, 2018 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- October 17, 2018 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- November 14, 2018 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time (virtual meeting)

All meetings are open to the public. For web conference instructions and the most up-to-date information, please visit the HITAC calendar on the ONC website, <http://www.healthit.gov/FACAS/calendar>.

Contact Person for Meetings: Lauren Richie, lauren.richie@hhs.gov. 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. Please email Lauren Richie for the most current information about meetings.

Agenda: The committee will take care of administrative matters and hear reports from ONC. 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 website 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 website after the meeting, at <http://www.healthit.gov/hitac>.

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. An oral public comment period will be scheduled at 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 public comment period, ONC will take written comments after the meeting.

Persons attending ONC's HITAC 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 HITAC 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 Lauren Richie at least seven (7) days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App. 2).

Dated: December 13, 2017.

Lauren Richie,

Office of Policy, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Tawanda Abdelmouti, Assistant Project Officer, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland, 20892, call non-toll-free number (301) 435-0978 or Email your request, including your address to: abdelmot@

mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 0925-0648, Expiration date 3/31/2018 EXTENSION, National Institutes of Health (NIH).

Need and Use of Information Collection: We are not requesting changes for this submission. The proposed information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions. This information, however, is not statistical surveys that yield quantitative results, which can be generalized to the population of study. This feedback will provide information about the NIH's customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the NIH and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of

service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the NIH's services will be unavailable.

The NIH will only submit a collection for approval under this generic clearance if it meets the following:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally Identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and

- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to