21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 601.12 have been approved under OMB control numbers 0910–0338, and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27589 Filed 12–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 22, 2018.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: I Can Do It, You Can Do It! Program Evaluation.

Type of Collection: New.

OMB No. 0990—NEW—Office within OS—President's Council on Fitness, Sports & Nutrition (PCFSN), Office of the Assistant Secretary for Health.

Abstract: Approximately 56 million children and adults living in the United States have some level of disability. Despite physical activity and good nutrition being the cornerstones of evidence-based health promotion interventions for reducing the risk of comorbidities (*e.g.,* diabetes, heart disease, and stroke), many people with a disability or caregivers who have a child with a disability experience substantial difficulty accessing these programs. Benefits of physical activity and good nutrition have been well documented for individuals with and without a disability, including: reducing the risk of developing chronic diseases and medical conditions. Studies also show that one-on-one mentoring through healthy eating, physical activity, and sport participation can support the development of social skills, improve positive self-esteem, and increase self-confidence among children and adults with a disability. I Can Do It, You Can Do It! partners with K–12 schools and school districts, colleges and universities, and other community-based entities to provide access and opportunities for children and adults with a wide range of physical and cognitive disabilities to lead healthy, active lives. PCFSN plans to conduct a rigorous evaluation of I Can Do It, You Can Do It! The evaluation will assess the impact of the program on mentee level outcomes (impact evaluation) as well as barriers and facilitators to program implementation (process evaluation). Evaluation activities will take place in 10 sites between summer 2018 and fall 2019. The I Can Do It, You Can Do It! sites recruited to participate in the evaluation will be identified from a list of schools and community organizations that have signed up to be program sites. The aims of the process evaluation are to determine what parts of the program were successful, the usefulness of program materials, and what changes are necessary to improve the administration of the program. The aims of the impact evaluation are to examine how ICDI impacts Mentee physical activity and healthy eating behaviors. The information collected for the I Can Do It, You Can Do It! Program Evaluation will allow the OPCFSN and partners to assess the impact of the program and gather critical information for improvement. OMB approval is requested for three years. Participation in I Can Do It, You Can Do It! is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Respondents	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Site Application	Site Coordinator	10	1	7/60	1
Partner Application	National Partner Organizations	50	1	15/60	12
Site Annual Follow-Up Survey	Site Coordinator	10	1	5/60	1
End of Wave 1 Interview	Site Coordinator	10	1	30/60	5
End of Wave 1 Feedback Survey	Site Coordinator	10	1	11/60	2
End of Wave 2 Interview	Site Coordinator	10	1	30/60	5
End of Wave 2 Feedback Survey	Site Coordinator	10	1	6/60	1
Technical Assistance Assessment	Site Coordinator	10	1	10/60	2
Mentee Pre-Assessment	Mentee/Program Participant	700	1	20/60	233
Mentee Post-Assessment	Mentee/Program Participant	700	1	25/60	292
Mentor Feedback Survey	Mentor	700	1	8/60	94
Weekly Goal-Setting Guide	Mentor	700	8	10/60	936
Total			19		1,584

Dated: December 12, 2017.

Darius Taylor,

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

[FR Doc. 2017–27559 Filed 12–21–17; 8:45 am]

BILLING CODE 4150–35–P

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.