

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3283, Silver Spring, MD 20993-0002, 240-402-2246, or ELP Management, [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Additionally, CDRH assures patients and providers have timely and continued access to high-quality, safe and effective medical devices. Continuing our 2016 and 2017 priorities of Partnering with Patients and Promoting a Culture of Quality and Organizational Excellence, adding our 2018-2020 Strategic Priorities of Simplicity, Collaborative Communities and Employee Engagement, Opportunity, and Success, overlaid by our constant strive for patient safety and innovation highlights our need to understand the perspective of our stakeholders. The Center encourages applicants to consider including opportunities to discuss innovation, patient perspective, patient safety, incorporating quality system design and management, simplification principles, and utilization of collaborative communities in their proposal(s) as they contribute to the success of the device development life cycle.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH and other FDA staff with an opportunity to understand the laboratory and manufacturing practices, quality system management, patient perspective/input, simplification principles, and other challenges and how they impact the medical device development life cycle. ELP is a collaborative effort to enhance communication with our stakeholders to facilitate medical device reviews. The Center is committed to understanding current industry practices, innovative technologies, regulatory impacts and needs, and how patient perspective/input, safety and quality systems management advance the development and evaluation of medical devices, and

monitoring the performance of marketed devices.

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (e.g., compliance inspection), but rather, they are an opportunity to provide CDRH and other FDA staff a better understanding of the products they review, and how they are developed. Additionally, it is to understand challenges related to quality systems development and management and simplification in processes, patient preferences and safety, in the product life cycle, and how medical devices fit into the larger health care system. CDRH is formally requesting participation from industry, academia, and clinical facilities, medical device incubators and accelerators, health technology assessment groups, and those that have previously participated in the ELP or other FDA site visit programs.

Additional information regarding the CDRH ELP, including current areas of interest, submission dates, a sample site visit request, and an example of a site visit agenda, is available on CDRH's website at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

**II. CDRH ELP**

**A. Areas of Interest**

In the ELP training program, groups of CDRH and other FDA staff will observe operations in the areas of research, device development, Digital Health, incorporating patient information and reimbursement, manufacturing, quality management principles, and health care facilities. The areas of interest for visits include various topics identified by managers at CDRH and other areas within FDA. These areas of interest are listed on the ELP website and are intended to be updated quarterly.

To submit a proposal addressing one of the Center's areas of interest, visit the link for the table of areas of interest at: <https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/UCM380676.htm>.

Once you have determined an area of interest to address in your ELP proposal, follow the instructions in section III to complete the site visit request template and agenda provided at: <https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf> and at: <https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf>.

Submit all proposals at [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov) within the dates provided at

the ELP website at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

**B. Site Selection**

CDRH and FDA will be responsible for its own staff travel expenses associated with the site visits. CDRH and FDA will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH and FDA's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding (if applicable). If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history, and must be listed in the proposal along with a Facility Establishment Identifier number, if applicable.

**III. Request To Participate**

Information regarding the CDRH ELP, including a sample request and an example of a site visit agenda, and submission dates is available on CDRH's website at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>. Proposals to participate should be submitted at [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov), within the dates provided at the ELP website at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

Dated: July 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of Meeting of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030**

**AGENCY:** Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) announces the next meeting of the

Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee). The meeting is open to the public and will be held in the Washington, DC metropolitan area. The Committee is working to accomplish its mission to provide independent advice to the Secretary of the U.S. Department of Health and Human Services or a designated representative for the implementation of *Healthy People 2030*.

**DATES:** The Committee will meet on September 6, 2018, from 8:30 a.m. to 5:00 p.m. Eastern Time (ET), and September 7, 2018, from 8:30 a.m. to 3:00 p.m. ET.

**ADDRESSES:** The meeting will be held at the 20 F Street Conference Center, located at 20th F Street NW, Washington, DC 20001. To register to attend the meeting, please visit the Healthy People website at <https://www.healthypeople.gov>.

**FOR FURTHER INFORMATION CONTACT:** Emmeline Ochiai, Designated Federal Officer, Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Room LL-100, Rockville, MD 20852, (240) 453-8255 (telephone), (240) 453-8281 (fax). Additional information is available on the Healthy People website at <https://www.healthypeople.gov>.

**SUPPLEMENTARY INFORMATION:**

*Appointed Committee Members:* The names and biographies of the appointed Committee members are available at <https://www.healthypeople.gov/2020/about/history-development/healthy-people-2030-advisory-committee>.

*Purpose of Meeting:* In accordance with Federal Advisory Committee Act and to promote transparency of the process, deliberations of the Committee will occur in a public forum. At this meeting, the Committee will continue its deliberations from the last public meeting.

*Background:* The Committee, a federal advisory committee, is charged with issuing recommendations for the Secretary regarding the implementation of national health promotion and disease prevention objectives for 2030. The Committee will discuss the nation's health promotion and disease prevention objectives and will provide recommendations to improve health status and reduce health risks for the nation by the year 2030. The Committee will develop recommendations for

implementing Healthy People 2030, including recommendations for engaging stakeholders in the implementation and achievement of the objectives. Through the Healthy People initiative, HHS leverages scientific insights and lessons from the past decade and new knowledge of current data, trends, and innovations to develop the next iteration of national health promotion and disease prevention objectives to improve the health of the nation. Healthy People provides science-based, 10-year national objectives for promoting health and preventing disease. Since 1979, Healthy People has set and monitored national health objectives that meet a broad range of health needs, encourage collaboration across sectors, guide individuals toward making informed health decisions, and measure the impact of our prevention and health promotion activities.

*Meeting Agenda:* The meeting agenda is available at the Healthy People website at <http://www.healthypeople.gov>. The Committee will develop further its recommendations regarding: Stakeholder engagement; the roles of health equity, complex systems science and modeling, and summary measures in Healthy People 2030; and activities for implementing Healthy People 2030.

*Public Participation at Meeting:* Members of the public are invited to attend the Committee meeting. There will be no opportunity for oral public comments during the Committee meeting. However, written comments are welcome throughout the entire development process of the national health promotion and disease prevention objectives for 2030 and may be emailed to [HP2030@hhs.gov](mailto:HP2030@hhs.gov). To attend the Committee meeting, individuals must pre-register at the Healthy People website at <http://www.healthypeople.gov>. Registrations must be completed by 5:00 p.m. E.T., on August 31, 2018. Space for the meeting is limited and registration will be accepted until maximum room capacity is reached. A waiting list will be maintained should registrations exceed room capacity. Individuals on the waiting list will be contacted as additional space for the meeting becomes available. Registration questions may be directed to [HealthyPeople@norc.org](mailto:HealthyPeople@norc.org).

*Authority:* 42 U.S.C. 217a. The Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C.,

App.) which sets forth standards for the formation and use of federal advisory committees.

Dated: July 25, 2018.

**Donald Wright,**

*Deputy Assistant Secretary for Health, (Disease Prevention and Health Promotion).*

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-7006-N-13]

**60-Day Notice of Proposed Information Collection: Voucher Management System (VMS), Section 8 Budget and Financial Forms**

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* September 28, 2018.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410-5000; telephone 202-402-3400 (this is not a toll-free number) or email at [Colette.Pollard@hud.gov](mailto:Colette.Pollard@hud.gov) for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

**FOR FURTHER INFORMATION CONTACT:** Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW, (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202-402-4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877-