- Description of the proposed pilot project, including, but not limited to, the goals, objectives, processes that will be studied, and evaluation methods

E. Initiation and Duration of Pilot Projects

The selected participants should be ready to start their pilot project within 4 months of receiving a letter of acceptance from FDA into the program. The duration of a pilot project should not exceed 6 months. FDA may consider a pilot project with a later start date or longer duration depending on the proposed goal(s) and objective(s). Each pilot project is expected to be completed within the proposed duration time period. This time period does not include an additional 30 days for completion of a final report (see Section II.G. Reports).

F. Participation in Pilot Projects

Each participant that is selected into the program will be responsible for conducting its pilot project. A group of entities (*e.g.,* members of the pharmaceutical distribution supply chain or other stakeholders, including trade associations) that partners to conduct a pilot project will be considered a single participant for purposes of the DSCSA Pilot Project Program. The participant will be responsible for the funding and resources necessary to conduct the pilot project, and for determining each partner's role and responsibility in its pilot project.

Prior to launch of a pilot project, FDA intends to hold a design strategy meeting with the selected pilot participant(s) to review the goal(s) and objective(s)s for the pilot project and discuss the project plans and other pertinent details. FDA also expects pilot project participants to submit reports on the progress of their pilot projects to FDA (see Section II.G. Reports). Participants should evaluate their pilot projects using the evaluation methods they identified during the pilot project design process.

G. Reports

Each pilot project is expected to be completed within the proposed duration time period, and FDA asks that all participants submit periodic progress reports to FDA while the pilot project is being conducted, in addition to submitting a final report after completing the pilot project. These reports will provide insight into the systems and process needed to comply with certain DSCSA requirements for enhanced drug distribution security.

1. Progress Report(s)

Each pilot project program participant is expected to provide reports on the progress of its pilot project to FDA. The progress reports are intended to capture the ongoing work during the pilot project, including but not limited to, status or results, changes, challenges, and/or lessons learned. FDA will work with participants to develop an appropriate schedule for the submission of progress reports based on the design and duration of the pilot project. Because the duration of a pilot project should not exceed 6 months, the frequency of progress reports will vary based on the length of the individual pilot project. Pilot projects of relatively shorter duration may result in shorter time intervals between progress reports. For example, FDA may ask for monthly progress reports for a 6-month pilot project, however for a 1-month pilot project, FDA may ask for weekly progress reports.

2. Final Report

Within 30 to 45 business days of completing a pilot project, each participant is expected to provide a final report to FDA that captures the description, objectives, methods, evaluation, costs and key findings, and lessons learned from the project. Timely completion of pilot projects and the final report will support FDA's DSCSA implementation, including the statutory requirements under section 582(j) of the FD&C Act to consider information from pilot projects in the development of guidances for unit-level tracing and standards for the interoperable data exchange in section 582(h)(3) and (4) of the FD&C Act. FDA may also request that the participants meet with the Agency upon the completion of their pilot project or the final report.

H. Final DSCSA Pilot Project Program Report

To ensure that all supply chain members benefit from the information generated by the DSCSA Pilot Project Program, FDA intends to make the following information about each pilot project of the program available to the public in a final program report: (1) The names and industry sector(s) of the pilot project participant(s); (2) the pilot project's objectives and evaluation methods; (3) the duration of the pilot project; and (4) the key findings and lessons learned from the pilot project. FDA intends to post the information related to the DSCSA Pilot Project Program and the final program report on FDA's website.

I. Recordkeeping

Any records generated by a participant while conducting a pilot project should be maintained in accordance with the participant's normal recordkeeping practices. For pilot projects that involve partnering entities, the partnering entities should decide who is responsible for the records generated in the course of conducting the pilot project. FDA recommends that participants maintain the progress reports and final report for its pilot project for at least 1 year after completion of the pilot project.

III. Paperwork Reduction Act of 1995

This notice contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this notice was approved under OMB control number 0910–0859.

Dated: February 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01561 Filed 2–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Both the *National HIV/AIDS Strategy* (NHAS) and the *National Viral Hepatitis Action Plan* (NVHAP) expire in 2020. The Department of Health and Human Services (HHS) Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), in collaboration with federal partners, is leading development of the next iterations of these two separate and distinct national strategies. To help inform the next iterations of the NHAS and NVHAP, HHS seeks input from external stakeholders for improving efficiency, effectiveness, coordination, and accountability of HIV and viral hepatitis prevention, care, treatment, and cure policies, services, and programs.

DATES: To be assured consideration, comments must be received at the

address provided below, no later than 5:00 p.m. ET on March 11, 2019.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to *HepHIVStrategies@hhs.gov.* Written responses should be addressed to: U.S. Department of Health and Human Services, Room L001, 330 C Street SW, Washington, DC 20024. Attention HIV/Viral Hepatitis RFI.

FOR FURTHER INFORMATION CONTACT: Nathan Fecik, MPH regarding HIV or Corinna Dan, RN, MPH regarding viral hepatitis, in the Office of HIV/AIDS and Infectious Disease Policy, (202) 795–7697.

SUPPLEMENTARY INFORMATION: The NHAS and NVHAP have served as roadmaps for the national response to HIV and viral hepatitis in the United States. They have been of great value in establishing and monitoring indicators of progress toward important national public health goals, setting expectations, identifying opportunities for stakeholder engagement across sectors, and improving transparency and accountability. As a nation, we have made significant progress toward achieving the goals for both strategies, but ongoing challenges and disparities remain.

The NHAS and the NVHAP were developed with input from nonfederal stakeholders who are committed to working toward shared national goals and aligning efforts across sectors. The strategies allow flexibility to adapt to: Scientific advances; changes in the needs of people with and at-risk for these infections; emerging threats to our progress toward eliminating HIV and viral hepatitis, such as the opioid crisis; and other factors including social determinants of health and stigma that affect the health of people with and at risk for these infections.

This request for information seeks public input on improving efficiency, effectiveness, coordination, and accountability of HIV and viral hepatitis prevention, care, treatment, and cure policies, services, and programs at all levels and for all types of stakeholders. The feedback received will inform the next edition of two separate strategies: (1) The National HIV/AIDS Strategy; and (2) the National Viral Hepatitis Action Plan. Please indicate the national strategy to which each comment applies. If submitting comments for both strategies please submit two separate responses. Topics of interest include, but are not limited to, the following:

(1a) What components of the NHAS do you think should be maintained? What changes should be made to the NHAS? This may include changes to the structure, goals, and indicators, key areas of focus and/or populations, and annual reporting processes by federal agencies. This may also include areas of the current strategy that should be scaled back or areas of the current strategy that should be expanded or scaled up.

(1b) What components of the NVHAP do you think should be maintained? What changes should be made to the NVHAP? This may include changes to the structure, goals, and indicators, key areas of focus and/or populations, and annual reporting processes by federal agencies. This may also include areas of the current strategy that should be scaled back or areas of the current strategy that should be expanded or scaled up.

(2a) Specific recommendations you think will improve the efficiency, effectiveness, accountability, and impact of the national response to HIV.

(2b) Specific recommendations you think will improve the efficiency, effectiveness, accountability, and impact of the national response to viral hepatitis.

(3a) What specific actions should the federal government and others take to improve the coordination of funding and delivery of HIV services?

(3b) What specific actions should the federal government and others take to improve the coordination of funding and delivery of viral hepatitis services?

(4a) What monitoring and evaluation strategies would further improve HIV prevention, care, and treatment?

(4b) What monitoring and evaluation strategies would further improve viral hepatitis prevention, care, and treatment?

Dated: January 29, 2019.

Tammy R. Beckham,

Director, Office of HIV/AIDS and Infectious Disease Policy.

[FR Doc. 2019–01695 Filed 2–7–19; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–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 March 11, 2019.

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 0937–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: SMARTool Pilot Replication Project.

Type of Collection: OMB No. 0937–NEW—Office of the Assistant Secretary for Health (OASH).

Abstract: The Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is requesting approval by OMB of a new information collection request. OASH is updating the Center for Relationship Education's Systematic Method for Assessing Risk-Avoidance Tool (SMARTool), a tool for sexual risk avoidance (SRA) curriculum developers and implementing organizations (IOs) to ensure that their SRA curricula are grounded in evidence. In an effort to assess the SMARTool's impact, OASH aims to conduct a formative evaluation to (1) provide preliminary evidence on the effectiveness of SRA curricula that are aligned with the SMARTool, (2) derive lessons learned to improve the implementation of SRA curricula, and (3) develop and test baseline and follow-up questionnaires that assess SRA program effects on the key SMARTool constructs. The evaluation will be conducted with an estimated four IOs. The evaluation will use quantitative and qualitative methods and will include both a process evaluation and an outcome evaluation.

Need and Proposed Use of the Information: To enhance the rigor of the evaluation, a comparison group will be identified for each IO, if possible. This