

Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5020]

Notice to Public of Website Location of the Office of the Chief Scientist Proposed Guidance Development List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post a list of possible topics for future guidance document development or revision by the Office of the Chief Scientist (OCS) during the next year. In addition, FDA has established a docket where interested persons may provide comments that could benefit the OCS guidance program and its engagement with stakeholders, including comments on the priority of topics for guidance. This feedback is critical to the OCS guidance program as we consider feedback from stakeholders along with Agency resources and priorities.

ADDRESSES: You may submit either electronic or written comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-5020 for "Notice to Public of Website Location of OCS Proposed Guidance Development Agenda." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-4880 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

FDA welcomes comments on any or all of the topics for guidance documents on the list as explained in § 10.115(f)(5) (21 CFR 10.115(f)(5)). FDA has established Docket No. FDA-2023-N-5020 where comments on the list, drafts of proposed guidance documents on those or other topics, suggestions for new or different guidances within OCS's purview, and relative priority of listed guidance documents may be submitted and shared with the public (see **ADDRESSES**). FDA believes this docket is a valuable tool for receiving information from interested persons. FDA anticipates that feedback from interested persons will allow OCS to better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

Consistent with the Good Guidance Practices regulation at § 10.115(f)(4), OCS would appreciate suggestions that OCS revise or withdraw an already existing guidance document within OCS's purview. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.

II. Website Location of Guidance List

This notice announces the website location of the document that provides

the list of possible topics for future guidance document development or revision by OCS during the next year. The initial list covers calendar year (CY) 2024. To access the list, visit FDA's website at <https://www.fda.gov/about-fda/guidance-documents-office-chief-scientist/office-chief-scientist-guidance-documents-under-development>. We note that the topics on this list may be removed or modified based on current priorities, as well as comments received regarding this list. Furthermore, several factors may impact FDA's ability to issue a guidance, including, for example, new Administration priorities, emerging public health issues, or other extenuating circumstances. The Agency is not required to publish every guidance on the list if, for example, the resources needed would be to the detriment of meeting other Agency priorities and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on the list.

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Implement Maternal, Infant, and Early Childhood Home Visiting Program 2022 Legislative Changes: Assessment of Administrative Burden

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the

public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 20, 2024.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Implement Maternal, Infant, and Early Childhood Home Visiting Program 2022 Legislative Changes: Assessment of Administrative Burden, OMB No. 0906-xxxx-[New].

Abstract: The Consolidated Appropriations Act, 2023, Public Law 117-328, Section 6101, the Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022 (Section 6101 of the Consolidated Appropriations Act, 2023) extended funding for the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program for an additional 5 years and adopted new program requirements. This included a new requirement for the Secretary of Health and Human Services to assess and reduce burden on MIECHV funding recipients in administering the program by (1) eliminating duplication and streamlining reporting requirements; (2) analyzing ways, in consultation with administering agencies (*i.e.*, MIECHV funding recipients) to reduce the number of hours spent on complying with paperwork requirements by at least 15 percent; (3) reviewing paperwork and data collection requirements for tribal MIECHV funding recipients and exploring, in consultation with tribes and tribal organizations, ways to reduce administrative burden, respect sovereignty, and acknowledge the different focus points for tribal funding recipients; (4) collecting input from relevant state fiscal officials to align fiscal requirements and oversight for states and eligible entities to ensure

consistency with standards and guidelines for other federal formula grant programs; and (5) consulting with administering agencies and service delivery model representatives on needed and unneeded data elements regarding the dashboards provided for in newly added Social Security Act subsection 511(d)(1)(B), consistent with the data requirements of such subsection.

Through this ICR, HRSA aims to survey state, jurisdiction, and tribal MIECHV funding recipients to obtain feedback regarding potential ways to reduce administrative burden, as described above. Home visiting model developers will also be surveyed on potential ways to reduce administrative burden in their work to refine data collection requirements that align with MIECHV Program requirements.

Need and Proposed Use of the Information: Section 511(h)(6)(A) of the Social Security Act requires the Secretary of Health and Human Services to assess and reduce administrative burden on MIECHV funding recipients. Information gained from this information collection will inform recommendations to reduce administrative burden.

Likely Respondents: State and jurisdiction MIECHV Program funding recipients that are states, territories, and, where applicable, nonprofit organizations receiving MIECHV funding to provide home visiting services within states; tribal MIECHV Program funding recipients that are tribes and tribal organizations; and developers of home visiting models that are eligible for MIECHV funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.