

section 503A because they are not the subject of an applicable USP or NF monograph, components of FDA-approved drug products, or on the 503A bulks list. One of those conditions is that the bulk drug substance appears in Category 1. If the 2023 503A Interim Policy Draft Guidance is finalized in its current form, a substance nominated on or after the date of publication of that final guidance would not be categorized and would not be within the scope of the policy for substances that appear in Category 1.¹ However, FDA would consider the substance for inclusion on the 503A bulks list in accordance with the process and criteria established in the FD&C Act and FDA regulations (see section 503A(b)(1)(A) of the FD&C Act and 21 CFR 216.23(c)). Substances that already appear in Category 1 (including substances nominated with adequate supporting information prior to the date of publication of the final guidance) may continue to be eligible for the policy that applies to Category 1 substances, as described in the final guidance, until FDA promulgates a final rule determining whether they will be placed on the 503A bulks list in accordance with section 503A(b)(1)(A)(i)(III) of the FD&C Act or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

FDA encourages interested parties to focus their comments on the limited revisions to the interim policy included, for public comment, in the 2023 503A Interim Policy Draft Guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under

¹ FDA recognizes that some compounders and other stakeholders may currently be in the process of compiling a nomination for the 503A bulks list for submission to the Agency. FDA intends to categorize nominations of bulk drug substances received prior to the date in which FDA announces the availability of the final guidance. FDA believes that this will provide a sufficient amount of time in which to submit nominations that are currently in progress.

the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 1, 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: The Alliance for Innovation on Maternal Health Biannual Survey, OMB No. 0915-xxxx—New

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 5, 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: The Alliance for Innovation on Maternal Health Biannual Survey, OMB No. 0915-xxxx—New.

Abstract: The Alliance for Innovation on Maternal Health (AIM) program is administered by HRSA and authorized by 42 U.S.C. 254c-21 (Public Health Service Act, title III section 330O), as added by the Consolidated Appropriations Act, 2022 (Pub. L. 117-103).

The AIM program supports the identification, development, implementation, and dissemination of maternal (patient) safety bundles to promote safe care for every U.S. birth and assist with addressing the complex problem of high maternal mortality and severe maternal morbidity rates within the U.S. The mission of AIM is to support best practices that make birth safer, improve the quality of maternal health care and outcomes, and save lives. Maternal patient safety bundles address topics commonly associated with health complications or risks related to prenatal, labor and delivery, and postpartum care.

The AIM program consists of two components: The AIM Capacity program and the AIM Technical Assistance (TA) Center. The AIM Capacity awards began in fiscal year 2023 and directly fund 28 States and jurisdictions (including U.S. Territories and the District of Columbia) to implement AIM maternal patient safety bundles. The second component, the AIM TA Center, is funded through a cooperative agreement to provide TA to all 50 States, the District of Columbia, jurisdictions, U.S. Territories, Tribal communities, and birthing facilities who participate in the AIM program. The TA Center builds data capacity for participating entities to track progress on bundle implementation and support improvement of data collection.

The funding amount for the AIM program was increased in fiscal year 2023, which allowed HRSA to directly fund States and Territories to support AIM bundle implementation. Previously, HRSA supported AIM through one cooperative agreement to develop maternal patient safety bundles, provide TA on bundle implementation, and enroll States and Territories in the program. The shift to directly fund States and jurisdictions for the work makes the collection of information about the reach of the program, participation by birthing facilities, and TA needs necessary. The AIM Biannual Survey will be administered to AIM State Teams (the State-or jurisdiction-level entity leading AIM implementation) twice a year in all States and jurisdictions enrolled in

AIM. Respondents will include AIM State Teams that receive HRSA funding through the AIM Capacity program, as well as AIM State Teams that do not receive HRSA funding to implement AIM, to gauge the full reach of the program.

Need and Proposed Use of the Information: The information will be used by the HRSA program team to understand and report on AIM program reach and potential growth regarding participating birthing facilities and patient safety bundles implemented, inform development of resources and types of TA offered, and develop program targets. In addition,

information on the number of participating birthing facilities and patient safety bundles being implemented is shared on the HRSA and ACOG AIM websites. The biannual survey is the only place this information is collected.

Likely Respondents: Respondents are AIM State Teams in all States and jurisdictions enrolled in AIM, including AIM Capacity award recipients and AIM State Teams that do not receive direct funding from HRSA.

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.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
AIM Biannual Survey	52	1 per survey; 2 surveys per year	104	1	104
Total	52	1 per survey; 2 surveys per year	104	1	104

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023-26902 Filed 12-6-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Advancing Translational Sciences Advisory Council, January 18, 2024, 11:00 a.m. to January 19, 2024, 6:00 p.m., National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on November 03, 2023, FR Doc. 2023-24224, 88 FR 75295.

This notice is being amended to change the meeting date from January 18, 2024, to January 19, 2024. The meeting times and location remain the

same as stated above. This meeting is partially closed to the public.

Dated: December 4, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-26903 Filed 12-6-23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0013]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Application for Travel Document

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort, and

resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until February 5, 2024.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0013 in the body of the letter, the agency name and Docket ID USCIS-2007-0045. Comments must be submitted in English, or an English translation must be provided. Submit comments via the Federal eRulemaking Portal website at <http://www.regulations.gov> under e-Docket ID number USCIS-2007-0045.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721-3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <https://www.uscis.gov>, or call the USCIS Contact Center at 800-375-5283 (TTY 800-767-1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the