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FDA tentatively concludes that this draft guidance contains no collection of information.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 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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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: March 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06985 Filed 4–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Assessing Strategies To Promote Children's Engagement and Active Participation in Virtual Visits

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing Strategies to Promote Children's Engagement and Active Participation in Virtual Home Visits OMB No. 0915–xxxx—[NEW]

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, title V, section 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies to provide home visiting services to eligible families in at-risk communities.

This information collection is part of the Assessing and Describing Practice Transitions Among Evidence-Based Home Visiting Programs in Response to the COVID–19 Public Health Emergency Study, which aims to identify and study practices implemented in response to the COVID–19 public health emergency that support evidence-based practice and have the potential to enhance home visiting programming. One of the practices the study identified is strategies home visitors use to engage children and promote their active engagement during virtual visits. The purpose of this information collection is to better understand, through rapid cycle learning, how MIECHV-funded home visiting programs can implement virtual strategies improve child engagement and how home visitors can apply these strategies during in-person service delivery.

Information will be collected in four phases designed to (1) identify virtual child engagement strategies (co-definition phase); (2) pilot test and identify refinements to improve the implementation of strategies (installation phase); (3) iteratively test the strategies with refinements to their implementation (refinement phase); and (4) assess the potential of these child engagement strategies to improve service delivery and promote family engagement and family satisfaction with home visiting programs in both virtual and in-person settings (summary phase). Data collection activities include focus groups, online questionnaires, and review of documents and administrative data.

A 60-day notice published in the **Federal Register** on December 5, 2023, 88 FR 84340–41. There were no public comments. One home visiting model developer requested copies of the information collection forms.

Need and Proposed Use of the Information: With the end of the COVID–19 public health emergency, most MIECHV-funded home visiting programs have transitioned back to some level of in-person service delivery. However, many continue to offer occasional virtual home visits if warranted and appropriate, such as during inclement weather or due to family and staff health concerns. Understanding the virtual strategies that home visitors used or are using to address the challenges of engaging children during virtual home visits, how these strategies can be implemented, how these strategies and learned lessons can be applied to in-person settings, and how children and families respond to these strategies will be valuable to the field. HRSA intends to use collected information to share evidence-informed resources and strategies that MIECHV awardees can use to optimize children's engagement and active participation and strengthen their home visiting services.

Likely Respondents: Respondents include (1) families who receive home visiting services and (2) MIECHV-funded home visiting program staff, which may include program directors, managers, supervisors, and home visitors.

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
Program Eligibility Protocol	16	1	16	1.00	16.0
Program Staff Focus Group Protocol 1 (Co-definition Phase)	24	1	24	1.50	36.0
Program Staff Focus Group Protocol 2 (Co-definition Phase)	24	1	24	1.50	36.0
Program Staff Focus Group Protocol (Installation & Refinement Phases)	24	3	72	1.00	72.0
Program Staff Focus Group Protocol (Summary Phase)	24	1	24	1.00	24.0
Family Focus Group Protocol (Co-definition & Summary Phases)	48	1	48	1.00	48.0
Home Visitor Questionnaire (Installation & Refinement Phases)	40	9	360	0.17	61.2
Family Post-Visit Questionnaire (Refinement Phase)	48	6	288	0.08	23.0
Focus Group Participant Characteristics Form (All Phases)	120	1	120	0.08	9.6
Total	368		976		325.8

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. 2024–07066 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Alliance for Innovation on Maternal Health Biannual Survey

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

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