use of RWE to: (1) Help to support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)); and (2) help to support or satisfy postapproval study requirements. This section also requires that FDA use the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for the collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to the goal of publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions.

FDA is issuing the draft guidance as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI goal. The RWE Program will cover clinical studies that use real-world data sources, such as information from routine clinical practice, to derive RWE.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21315 Filed 9–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Advisory Committee on Infant Mortality has been renamed the Advisory Committee on Infant and Maternal Mortality (ACIMM) and has been renewed.

DATES: The effective date of the charter renewal is September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, HRSA, Maternal and Child Health Bureau, 5600 Fishers Lane, 18N84, Rockville, Maryland 20857; (301) 443–0543; or *VLee1@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees. ACIMM advises the Secretary of HHS on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how best to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, and maternal health, as well as influence similar efforts in the private and voluntary sectors. ACIMM provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The charter renewal and name change for ACIMM was approved on September 30, 2021, which will also stand as the filing date. Renewal of the ACIMM charter gives authorization for the ACIMM committee to operate until September 30, 2023.

A copy of the ACIMM charter is available on the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–21277 Filed 9–29–21; 8:45 am]

BILLING CODE 4165–15–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: The HRSA Community-Based Outreach Reporting Module, OMB #0906–0064, Revision

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

ACTION: Notice.

SUMMARY: HRSA at the U.S. Department of Health and Human Services (HHS) requests a revision to the data collection for the Community-Based Workforce for COVID–19 Vaccine Outreach Programs (CBO Programs) (OMB # 0906–0064). In compliance with of the Paperwork Reduction Act of 1995, HRSA has 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 November 1, 2021.

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 30-day 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 Samantha Miller, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The HRSA Community-Based Outreach Reporting Module, OMB # 0906–0064, Revision.

Abstract: HRSA requests approval of a revision to the current emergency ICR to continue data collection for the Community-Based Workforce for COVID–19 Vaccine Outreach Programs (CBO Programs), which support nonprofit private or public organizations to establish, expand, and sustain a public health workforce to prevent, prepare for, and respond to COVID–19. This data is needed to comply with requirements to monitor funds distributed under the American Rescue Plan Act of 2021 and in accordance with OMB Memorandum M–21–20.

A 60-day Notice was published in the **Federal Register** (vol. 86, FR pp. 45739 (August 16, 2021)). There were no public comments.

Need and Proposed Use of the Information: HRSA is requesting approval from OMB for a revision to the current emergency data collection module to support the HRSA Health Systems Bureau (HSB) and Office of Planning, Analysis, and Evaluation (OPAE) requirements to monitor and report on funds distributed. As part of the American Rescue Plan Act of 2021, signed into law on March 11, 2021 (Pub. L. 117–2), HRSA will award $250 million to develop and support a community-based workforce that will engage in locally tailored efforts to build vaccine confidence and bolster COVID–19 vaccinations in underserved communities. In July and August 2021, under the CBO Programs HRSA expects to award funding to over 100 organizations, including those comprising community health workers, patient navigators, and social support specialists. These organizations are responsible for educating and assisting individuals in accessing and receiving COVID–19 vaccinations. This includes activities such as conducting direct face-to-face outreach and other forms of direct outreach to community members to educate them about the vaccine, assisting individuals in making a vaccine appointment, providing resources to find convenient vaccine locations, and assisting individuals with transportation or other needs to get to a vaccination site. The program will address persistent health disparities by offering support and resources to vulnerable and medically underserved communities, including racial and ethnic minority groups and individuals living in areas of high social vulnerability.

HRSA is proposing a new data reporting module—the Community-Based Vaccine Outreach Program Reporting Module—to collect information on CBO Program-funded activities. The CBO Program will collect monthly progress report data from funded organizations. This data will be related to the public health workforce developed, the vaccine outreach performed by this workforce, including the distribution of vaccine booster shots (a new addition to the data collection plan since the 60-day notice was released), and the vaccination rate by this workforce in a manner that assesses equitable access to vaccine services and whether the most vulnerable populations and communities are reached. This data will allow HRSA to clearly identify how the funds are being used and monitored throughout the period of performance and to ensure that high-need populations are being reached and vaccinated. Responses to some data requirements are only reported during the initial reporting cycle (*e.g.,* the name, location, affiliation, etc. of the individual supporting community outreach), though respondents may update the data should any of that change during the duration of the reporting period.

Likely Respondents: Respondents are community outreach workers employed by entities supported by HRSA grant funding over a period of either 6 months (HRSA–21–136) or 12 months (HRSA–21–140).

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 unique organizations funded through the two programs	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Community outreach worker profile form.	10 cooperative agreement awards for HRSA–21–136 and 121 grant awards for HRSA–21–136.	Total number of Community outreach workers deployed through the work of the two programs.	One response per respondent.	Reported once across the duration of the programs (the period of performance for HRSA–21–136 is 6 months, and for HRSA–21–140 is 12 months).	Sampled response times of approximately 15 minutes per response.	Total hours spent on responses for all funded organizations over a 2-year period.
	131 (est.)	3,000 (est.)	1	3,000	0.27	800.
Form name	Number of community outreach workers	Number of respondents over the period of the programs	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Vaccine-site data—outreach to community members form.	Number of community outreach workers deployed for 6 months (HRSA–21–136) or 12 months (HRSA–21–140) of support.	Number of community members in contact with community outreach workers.	One response per respondent or less (e.g., one response from the audience of a group outreach event).	Reported once across the duration of the programs (the period of performance for HRSA–21–136 is 6 months, and for HRSA–21–140 is 12 months).	Sampled response times of approximately 6 minutes per response.	Total hours spent on responses for all funded organizations over a 2-year period.
	3,000 (est.)	4,000,000 (est.)	1	4,000,000	0.12	466,667.
General outreach activities for community members form.	Number of community outreach workers deployed for 6 months (HRSA–21–136) or 12 months (HRSA–21–140) of support.	Number of community members in contact with community outreach workers.	One response per respondent or less (e.g., one response from the audience of a group outreach event).	Reported once across the duration of the programs (the period of performance for HRSA–21–136 is 6 months, and for HRSA–21–140 is 12 months).	Sampled response times of approximately 6 minutes per response.	Total hours spent on responses for all funded organizations over a 2-year period.
	3,000 (est.)	4,000,000 (est.)	1	4,000,000	0.12	466,667.
Vaccine-site data—outreach to community members form—booster shots only.	Number of community outreach workers deployed for 6 months (HRSA–21–136) or 12 months (HRSA–21–140) of support.	Number of community members in contact with community outreach workers.	One response per respondent or less (e.g., one response from the audience of a group outreach event).	Reported once across the duration of the programs (the period of performance for HRSA–21–136 is 6 months, and for HRSA–21–140 is 12 months).	Sampled response times of approximately 6 minutes per response.	Total hours spent on responses for all funded organizations over a 2-year period.
	3,000 (est.)	4,000,000 (est.)	1	4,000,000	0.12	466,667.
Grand Total	12,003,000 (est.)			12,003,000 (est.)		1,400,801.

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. 2021–21207 Filed 9–29–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 72nd full Council meeting utilizing virtual technology on Monday, November, 15 and Wednesday, November, 17, 2021 from 1:00–5:00 p.m. (ET) on both days. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required to provide public comment during the meeting. To pre-register to attend or to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, November 8, 2021. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement