

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:

James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993-0002, 301-796-3156, james.hunter@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 23, 2021 (86 FR 39038), FDA published a notice entitled "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F-MDMB-BICA (4F-MDMB-BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut" that requested comments for consideration in preparing a response from the United States to the WHO regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. To allow interested persons additional time to submit comments, FDA is reopening the comment period until August 24, 2021.

Dated: August 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-17498 Filed 8-11-21; 4:15 pm]

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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 HRSA Community-Based Outreach Reporting Module, OMB # 0906-0064, Extension

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

ACTION: Notice.

SUMMARY: HRSA requests an extension to continue data collection for the Community-Based Workforce for COVID-19 Vaccine Outreach Programs (CBO Programs) (OMB # 0906-0064). 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 October 15, 2021.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443-1984.

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

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

Abstract: HRSA requests approval of an extension of 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.

Need and Proposed Use of the Information: HRSA is requesting approval from OMB for an extension of the current emergency data collection module to support HRSA's Healthcare Systems Bureau and Office of Planning, Analysis, and Evaluation 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 has awarded nearly \$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 June and July, under the CBO Programs, HRSA awarded funding to over 140 local and national organizations. 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, the vaccine outreach activities performed by this workforce, and the individuals who received vaccinations by this workforce in a manner that assesses equitable access to vaccine services and that 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.	14 cooperative agreement awards for HRSA-21-136 and 127 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 hours	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 hours	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 hours	466,667.
Grand Total	8,003,000 (est.)			8,003,000 (est.)		934,134.

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. 2021-17495 Filed 8-13-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0430, 0431, 0432, 0433, 0434]

Agency Information Collection Request; 60-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 proposed extensions of collections for public comment.

DATES: Comments on the ICR must be received on or before October 15, 2021.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795-7714 the Reports Clearance Officer.

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.