

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total .....	.....	.....	.....	.....	1,287

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**Estimated Annual Recordkeeping Burden**

*510(k) reviews:* The 3PROs should retain copies of all 510(k) reviews and associated correspondence. Based on FDA’s recent experience with this program, we estimate the number of 510(k)s submitted for 3P510k review to be 126 annually; approximately 14 annual reviews for each of the 9 3PROs. We estimate the average burden per recordkeeping to be 10 hours.

*Records regarding qualifications to receive FDA recognition as a 3PRO:* Under section 704(f) of the FD&C Act (21 U.S.C. 374(f)), a 3PRO must maintain records that support their initial and continuing qualifications to receive FDA recognition, including documentation of the training and qualifications of the 3PRO and its personnel; the procedures used by the 3P510k review organization for handling confidential information; the compensation arrangements made by the 3PRO; and the procedures used by the 3PRO to identify and avoid conflicts of interest. Additionally, the guidance states that 3PROs should retain information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k) submission and other relevant records. Because most of the burden of compiling the records is expressed in the reporting burden for requests for accreditation, we estimate the maintenance of such records to be 1 hour per recordkeeping annually.

*Recordkeeping system regarding complaints:* Section 523(b)(3)(F)(iv) of the FD&C Act requires 3PROs to agree in writing that they will promptly respond and attempt to resolve complaints regarding their activities. The guidance recommends that 3PROs establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved. Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours annually.

Based on our experience with the program since our last request for OMB approval, we have adjusted our burden estimate, which has resulted in a

decrease to the currently approved burden.

Dated: October 21, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–23377 Filed 10–26–22; 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: Evaluation of the Maternal and Child Health Bureau Pediatric Mental Health Care Access Program and the Screening and Treatment for Maternal Depression and Related Behavioral Disorders Program**

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

**ACTION:** Notice.

**SUMMARY:** 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 28, 2022.

**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](http://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 Samantha Miller, the acting HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–9094.

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

*Information Collection Request Title:* Evaluation of the Maternal and Child Health Bureau Pediatric Mental Health Care Access Program and the Screening and Treatment for Maternal Depression and Related Behavioral Disorders Program, OMB No. 0906–xxxx–New.

*Abstract:* This notice describes information collection requests for two of HRSA’s Maternal and Child Health programs: the Pediatric Mental Health Care Access (PMHCA) program and the Screening and Treatment for Maternal Depression and Related Behavioral Disorders (MDRBD) program. Both of these programs aim to increase identification of behavioral health conditions by providing support for screening of specified populations (e.g., children, adolescents, young adults, and pregnant and postpartum women, especially those living in rural, isolated, and/or underserved areas); providing clinical behavioral health consultation, care coordination support (i.e., communication/collaboration, accessing resources, referral services), and training to health professionals (HP); <sup>1</sup> and increasing access to clinical interventions, including by telehealth. HP education and training will support the knowledge and skills acquisition needed to accomplish this goal.

The information will be collected with recipients of awards that were issued in 2018 (PMHCA and MDRBD), 2019 (PMHCA), and 2021 (PMHCA). The 2018, 2019, and 2021 PMHCA programs are authorized by 42 U.S.C § 254c–19 (§ 330M of the Public Health Service Act), using Section 2712 of the American Rescue Plan Act of 2021 (P.L. 117–2) for 2021 awardees. The 2018 MDRBD program is authorized by 42 U.S.C. 247b–13a (§ 317L–1 of the Public

<sup>1</sup> HPs may include pediatricians, family physicians, physician assistants, advanced practice nurses/nurse practitioners, licensed practical nurses, registered nurses, counselors, social workers, medical assistants, patient care navigators.

Health Service Act). To evaluate progress made toward the programs' goals, this data collection will use eight instruments: the HP Survey, Practice-Level Survey, Program Implementation Survey, Program Implementation Semi-Structured Interview (SSI), Champion SSI, Champion Focus Group Discussion (FGD), Community Resources SSI, and Care Coordinator SSI.

A 60-day Notice published in the **Federal Register**, Vol. 87, No. 127, FR pp. 39841–42 (July 5, 2022). There was one public comment.

*Need and Proposed Use of the Information:* HRSA needs this information to evaluate the PMHCA and MDRBD programs and guide future policy decisions regarding increasing HPs' capacity to address patients' behavioral health and access to behavioral health services. Specifically, data collected for the evaluation will be used to study the efforts of awardee programs to achieve key awardee outcomes (e.g., increase in access to behavioral health services; health professionals trained; available community-based resources, including counselors or family service providers) and to measure whether and to what extent awardee programs are associated with changes in these outcomes. The evaluation will also examine changes over time, within a state, political

subdivision of a state, Indian tribe, or tribal organization, and/or across the PMHCA and MDRBD programs, with regard to (1) enrolled health professionals/practices related to screening, referral, and care coordination support for behavioral health conditions; (2) provision of behavioral health services for mental illness and substance use in primary care settings; (3) use of consultative services; and (4) provision of access to behavioral health services for mental illness and substance use.

*Likely Respondents:* Likely respondents include:

- *HP Surveys (2021 PMHCA only):* Pediatricians, family physicians, physician assistants, advanced practice nurses/nurse practitioners, licensed practical nurses, registered nurses, counselors, social workers, medical assistants, patient care navigators.
- *Practice-Level Surveys (2021 PMHCA only):* Practice managers (e.g., office managers, office leadership, nurse champions).
- *Program Implementation Survey and SSI (2021 PMHCA only):* 2021 PMHCA cooperative agreement-funded project directors/principal investigators.
- *Champion SSI or FGD (all awardees):* PMHCA and MDRBD program champions, who may include

HPs, community and social service specialists, and others.

- *Community Resources SSI (all awardees):* PMHCA and MDRBD program-level community resource partner representatives, who may include counselors, social workers, other community and social service specialists, other HPs/support workers (e.g., patient care navigators, medical assistants), and practice/organization managers.

- *Care Coordinator SSI (all awardees):* PMHCA and MDRBD program-level care coordinators.

*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 <sup>2</sup>	Total responses	Average burden per response (in hours)	Total burden hours
2021 PMHCA HP Survey .....	8,029	3	24,087	.25	6,021.75
2021 PMHCA Practice-Level Survey .....	2,950	3	8,850	.25	2,212.50
2021 PMHCA Program Implementation Survey .....	24	3	72	.33	23.76
2021 PMHCA Program Implementation SSI .....	24	1	24	1.00	24.00
2021 PMHCA Champion SSI .....	48	1	48	.50	24.00
2021 PMHCA Champion FGD .....	24	1	24	1.00	24.00
2021 PMHCA Community Resources SSI <sup>3</sup> .....	50	1	50	.50	25.00
2021 PMHCA Care Coordinator SSI .....	24	2	48	.50	24.00
2018/2019 PMHCA and 2018 MDRBD Champion SSI .....	56	1	56	.50	28.00
2018/2019 PMHCA and 2018 MDRBD Champion FGD .....	28	1	28	1.00	28.00
2018/2019 PMHCA and 2018 MDRBD Community Resources SSI <sup>3</sup> .....	50	1	50	.50	25.00
2018/2019 PMHCA and 2018 MDRBD Care Coordinator SSI .....	28	1	28	.50	14.00

<sup>2</sup> The HP, practice-level, and program implementation surveys will be administered with enrolled/participating HPs, office managers/ leadership of enrolled/participating practices, and project directors/principal investigators of the 2021 PMHCA cooperative agreement-funded programs three times during the project period (2023, 2024, and 2025) for a total of up to three responses per respondent. The 2021 PMHCA Program Implementation SSIs and the Champion SSIs and FGDs will be administered to 2021 PMHCA cooperative agreement-funded project directors/principal investigators and program champions once at the end of the data collection period. The 2021 PMHCA Care Coordinator SSI will be

administered twice, once at the beginning of the data collection period and once at the end. The number of responses per respondent varies for the Care Coordinator SSI between the 2018 and 2019 PMHCA and 2018 MDRBD cooperative agreement-funded programs and the 2021 PMHCA cooperative agreement-funded program because the 2018 and 2019 cooperative agreement programs will end in 2023 whereas the 2021 PMHCA cooperative agreement-funded programs will end in 2026.

<sup>3</sup> The Community Resources SSI will be a case study with (1) up to five awardees who have identified up to five formal (i.e., there is a formal agreement, Memorandum of Understanding, Memorandum of Agreement, or letter of support)

community partnerships and (2) up to five awardees who have identified up to five informal (i.e., there is no formal agreement, Memorandum of Understanding, Memorandum of Agreement, or letter of support) community partnerships. There will be up to 25 respondents for each group (i.e., formal, informal) for a total N=50. The Community Resource SSIs will be administered for the 2018 and 2019 PMHCA and 2018 MDRBD cooperative agreement-funded programs at the end of the data collection period in spring 2023 and for 2021 PMHCA cooperative agreement-funded program at the end of the data collection period in fall 2025.

## TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent <sup>2</sup>	Total responses	Average burden per response (in hours)	Total burden hours
Total .....	11,335	.....	33,365	.....	8,474.01

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. 2022-23394 Filed 10-26-22; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2022-0341; OMB Control Number 1625-0104]

#### Collection of Information Under Review by Office of Management and Budget

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0104, Barges Carrying Bulk Hazardous Materials; without change.

Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** You may submit comments to the Coast Guard and OIRA on or before November 28, 2022.

**ADDRESSES:** Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket

number [USCG-2022-0341]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://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.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:** A.L. Craig, Office of Privacy Management, telephone 202-475-3528, or fax 202-372-8405, for questions on these documents.

#### SUPPLEMENTARY INFORMATION:

##### Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These

comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG-2022-0341], and must be received by November 28, 2022.

#### Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-0104.

#### Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (87 FR 44415, July 26, 2022) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments.