

documents pertaining to an adverse event report have been assembled and filed in accordance with MoCRA, we expect the records retention burden to be minimal, as we believe most responsible persons would normally keep this kind of record for at least several years after creating the document, as a matter of usual and customary business practice.

Dated: September 13, 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: Submission to OMB for Review and Approval; Public Comment Request; Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report, OMB No. 0915–0172—Revision

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 October 18, 2023.

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: Title V Maternal and Child Health (MCH) Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915–0172—Revision

Abstract: The Title V MCH Services Block Grant to States Program is authorized by Sections 501–509 of Title V of the Social Security Act (42 U.S.C. 701–709). HRSA is updating the *Title V MCH Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* (“Guidance”). The updated edition will be the tenth edition of the Guidance. This Guidance is used annually by the 50 states and nine jurisdictions¹ (hereafter referred to as “state”) in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. The updates being proposed by HRSA's Maternal and Child Health Bureau for the tenth edition of the Guidance continue to support the federal-state partnership that is supported by the Title V MCH Services Block Grant and the state's role in developing a 5-Year Action Plan that addresses its individual priority needs. These proposed updates build on and further refine the reporting structure and vision that was outlined in the previous ninth edition. As such, they are intended to enable a state to articulate a comprehensive description of its Title V program activities and its leadership efforts in advancing and assuring a public health system that serves the MCH population. HRSA's proposed updates to the tenth edition of the Guidance were informed by consultation with State Title V MCH agencies, and by comments received from State Title V program leadership, national MCH leaders, other MCH stakeholders, and the public. A 60-day notice was published in the **Federal Register** on May 5, 2023, vol. 88, No. 87; pp. 29135–37 FR 29135–37. HRSA received 170 comments on the proposed updates to the tenth edition of the Guidance, from a variety of responders, including state Title V Programs, other state agencies, public health organizations, universities, members of the community, and other stakeholders.

¹ The following nine jurisdictions receive Title V Maternal and Child Health Block Grant Program funding: the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, the Commonwealth of Puerto Rico, the US Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Of the 170 comments, 80 requested that stillbirth be addressed in the Guidance, and 71 requested that the oral health performance measures be retained as a national performance measure. The remainder of 19 comments included suggestions for clarifying instructions in certain sections of the Guidance, including examples of partnership with non-governmental organizations and family organizations, or responding to reporting burden on the universal performance measures. HRSA considered all public comments as part of its deliberative process in finalizing updates to the tenth edition of the *Title V MCH Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*.

A discussion of the public comments received during the 60-day comment period and HRSA's response to the comments is set below:

(1) *Revised Approach for Interim-Year Reporting:* States and diverse stakeholders expressed strong support for the proposed approach that would allow states to decide whether updates are needed to numerous sections of the guidance during interim years 2 through 5, following submission of the 5-year Needs Assessment in year 1. In response to these comments, HRSA will maintain this approach in the tenth edition of the Guidance.

(2) *Streamlining and Reorganizing of the Guidance:* States and diverse stakeholders expressed strong support for the proposed approach of streamlining and reorganizing the requirements for state narrative reporting, in order to eliminate duplication. In response to these comments, HRSA will maintain this approach in the tenth edition of the Guidance.

(3) *Family and Community Partnership:* HRSA received comments related to clarifying expectations on reporting about family and community partnerships. In response to these comments, expectations around state Title V reporting on family and community partnerships will be clarified, such as reporting on partnership with HRSA's Family-to-Family Health Information Centers, discussion on the impact these partnerships have on the MCH population, and their value in improving outcomes.

(4) *Health Equity:* Comments received from states and stakeholders support the stronger emphasis on health equity, including it being a guiding principle of the Title V Program. In response to these comments, HRSA will maintain this approach in the tenth edition of the Guidance.

(5) *Children and Youth With Special Health Care Needs*: Several commenters provided suggestions to enhance the instructions related to the children with special health care needs (CSHCN) domain, with a focus on the *Blueprint for Change: A National Framework for a System of Services for Children and Youth with Special Health Care Needs*, family engagement, and the six core outcomes for a CSHCN system of care. In response to these comments, HRSA will clarify the instructions in the tenth edition of the Guidance for describing the CSHCN system of care and the Annual Report and Application narrative for the CSHCN population domain.

(6) *Oral Health Performance Measure*: HRSA received comments from stakeholders that requested to retain the preventive dental visit as a National Performance Measure (NPM), rather than classify it as a Standardized Measure as proposed during the 60-day comment period. Based on comments received from stakeholders and members of the community, HRSA will retain the preventive dental visit as an NPM.

(7) *Reporting on Stillbirth*: Comments were received during the 60-day comment period that requested a change to National Outcome Measure 6 from “perinatal mortality rate per 1,000 live births plus fetal deaths” to a stillbirth-focused measure. HRSA will maintain the perinatal mortality measure as defined; however, based on these comments received from stakeholders and members of the community, HRSA will add a National Outcome Measure for stillbirth rate defined as, “number of fetal deaths at 20 or more weeks gestation per 1,000 live births plus fetal deaths.” In addition, HRSA will update the narrative in the tenth edition of the Guidance to revise the last sentence of III.B.3.a System of Care for Mothers, Children, and Families to include bereavement and stillbirth, as follows: “In describing the state’s system of care for mothers, infants, and children, the role of the Title V program in addressing key MCH issues, which may include access to quality services, prenatal and postpartum care, maternal morbidity and mortality, stillbirth, newborn screening, infant mortality, preventive and primary care services for children and adolescents, immunizations, injury prevention, oral health, behavioral and mental health, bereavement, and/or substance use, should be clearly identified.” HRSA also added an example for Form 5b, pregnant women, around health promotion campaigns that address stillbirth and postpartum depression. Comments were also

received suggesting updates to the Healthy People 2030 objective for stillbirth, although this was not proposed in the 60-day notice. These comments were not accepted, as HRSA does not have the authority to modify Healthy People 2030 objectives.

(8) *Universal Measures*: A few states commented that the requirement of reporting on the two universal measures increased burden to the states, when the universal measures do not align with state priorities. The Title V statute authorizes the Secretary of Health and Human Services to identify priorities of national significance and require reporting on those priorities. The two selected universal measures, Postpartum Visit and Medical Home, are selected as national priorities because of their focus on access and quality of essential primary and preventive care for mothers and children, including children with special health care needs. To help reduce burden, instructions will clarify that only one Evidence-based or -informed Strategy Measure is required for Medical Home. HRSA has removed the requirement to discuss Medical Home in the Adolescent Health Domain, emphasizing reporting in the Child Health Domain. States may optionally report on Medical Home in the Adolescent Health Domain in addition to the required Child Health and CSHCN domains. HRSA did not receive specific comments on the Postpartum Visit universal measure.

(9) *Standardized Measures*: No comments were submitted in response to the proposal to update the Guidance with a new set of Standardized Measures to select as State Performance Measures. Accordingly, HRSA will retain this update to the tenth edition of the Guidance.

(10) *Form 7 Title V Program Workforce*: HRSA received comments requesting clarifications to the instructions and data fields in Form 7: Title V Program Workforce. In response to comments received from state Title V programs and stakeholders, Form 7 instructions will be clarified to better define what is a full-time employee, the relationship between the data fields, and the data being collected about positions lost over the past 12 months.

(11) *Technical Revisions*: Several commenters suggested technical revisions to the Guidance, which included edits to terminology, provided examples of possible revisions, and clarifications to the narrative reporting instructions. In response to these comments, HRSA will modify the tenth edition of the Guidance to incorporate these revisions to terminology,

examples, and clarifications to instructions. Revisions will include:

a. Part One: Background and Administrative Information:

i. IV.B: Update Figure 2 to better display the performance measure framework.

b. Part Two: Application/Annual Report Instructions.

i. II: Clarify instructions concerning the use of State Performance Measures to address a priority need.

ii. II: Clarify instructions on the option to select a priority population, in addition to an NPM overall.

iii. III.B.3.b: Include the definition of a well-functioning system of care.

iv. III.B.3.c: Include Medicaid Core Set measures as part of the list of what to include in the state’s narrative that describes areas of coordination between the state Title V program and Medicaid, and expanded examples of health care financing.

v. III.C.1.b.ii.c: Expand the workforce narrative to include the number of parents and family members, including CSHCN and families, who are on a state’s Title V program staff.

vi. III.C.1.c: Include narrative on the ways stakeholders, including families, constituents, and family-led organizations, were involved in identifying priority needs.

vii. III.E: Reorder the columns of the State Action Plan Table to the following order: Priority Needs, 5-Year Objectives, Strategies, Evidence-based or -Informed Strategy Measures, National and State Performance Measures, and National and State Outcome Measures.

c. Part Three: Reporting Forms.

i. Form 10: Use consistent terms to describe “annual objective”.

Need and Proposed Use of the Information: Each year, all states are required to submit an Application/Annual Report for federal funds for their Title V MCH Services Block Grant to States Program to the HRSA’s MCHB (Section 505(a) and 506(a)(1) of Title V of the Social Security Act). In addition, the State MCH Services Block Grant programs are required to conduct a state-wide, comprehensive Needs Assessment every 5 years. The information and instructions for the preparation and submission of this Application/Annual Report are contained in the *Title V Maternal and Child Health Services Block Grant to State Program: Guidance and Forms for the Title V Application/Annual Report*.

Likely Respondents: Likely respondents are state MCH agencies and other MCH stakeholders.

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
Application and Annual Report without 5-Year Needs Assessment Summary	59	1	59	115	6,785
Application and Annual Report with 5-Year Needs Assessment Summary	59	1	59	181	10,679
Total	59	59	17,464

Maria G. Button,

Director, Executive Secretariat.

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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: Maternal Health Portfolio Evaluation Design, OMB No. 0906-0059, Revision

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 November 17, 2023.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Maternal Health Portfolio Evaluation Design OMB No. 0906-0059—Revision.

Abstract: HRSA programs provide health care to people who are geographically isolated, economically, or medically vulnerable. HRSA programs help those in need of high quality primary health care, such as pregnant women and mothers. Improving maternal health outcomes and access to quality maternity care services is a key component of the HRSA mission. HRSA’s Maternal and Child Health Bureau provides funding to address some of the most urgent issues influencing the high rates of maternal mortality. With this emphasis on improving maternal health across the life course and promoting optimal health for all mothers, HRSA is employing a multipronged strategy to address maternal mortality and severe maternal morbidity through the following programs:

1. The State Maternal Health Innovation Program,
2. The Alliance for Innovation on Maternal Health Program,
3. The Alliance for Innovation on Maternal Health—Community Care Initiative,
4. The Rural Maternity and Obstetrics Management Strategies Program, and
5. The Supporting Maternal Health Innovation Program.

HRSA is conducting a portfolio-wide evaluation of HRSA-supported Maternal Health Programs with a primary focus

on reducing maternal mortality. Through this evaluation, HRSA seeks to identify individual and/or collective strategies, interrelated activities, and common themes within and across the Maternal Health Programs that may be contributing to or driving improvements in key maternal health outcomes. HRSA seeks to ascertain which components should be elevated and replicated to the national level, as well as inform future investments to reduce rates of maternal mortality and severe maternal morbidity.

Need and Proposed Use of the Information: HRSA seeks to understand the impact of HRSA’s investments into maternal health programs. These five HRSA maternal health programs represent a total of 12 state-based grantees and three grantees with the potential for national reach. In understanding the strategies that are most effective in reducing maternal morbidity and mortality, HRSA will be able to determine which program elements could be replicated and/or scaled up nationally.

Likely Respondents: Likely respondents are recipients of the cooperative agreements mentioned above (State Maternal Health Innovation Program, Alliance for Innovation on Maternal Health Program, Alliance for Innovation on Maternal Health—Community Care Initiative, and Supporting Maternal Health Innovation Program) which include state health agencies, national organizations, and academic organizations.

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