

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be neither an E.O. 14192 regulatory action nor an E.O. 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.2 and 601.12 for biologics license applications and supplemental applications have been approved under OMB control number 0910–0338. The collections of information in Form FDA 2253 have been approved under OMB control number 0910–0001. The collections of information for prescription drug product labeling requirements in 21 CFR 201.56 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 202.1 for prescription drug advertisements have been approved under OMB control number 0910–0686.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21516 Filed 10–20–26; 8:45 am]

BILLING CODE 4164–01–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; Information Collection Request Title: 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 November 20, 2026.

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: 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.

Abstract: The Title V Maternal and Child Health (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 Maternal and*

Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report (Guidance). This Guidance is used annually by the 50 states and nine jurisdictions (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 U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands; 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 for this 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. Updates to this edition of the Guidance are editorial and technical revisions based on feedback from the states in using the Guidance and Forms since January 2024, and by comments received from State Title V program leadership, national MCH leaders, other MCH stakeholders, and the public.

A 60-day notice published in the **Federal Register** on May 19, 2026, vol. 91, No. 96; pp. 29140–41 (91 FR 29140). The 60-day **Federal Register** Notice (FRN) stated that minor editorial corrections and clarifications were made to Form 7, Form 10, Form 12 instructions and the Glossary, and that updates were made to the short and long titles of the National Performance Measures to improve title accuracy and fulfill Government Accountability Office recommendations and align National Performance Measures with other HRSA program measures. However, the reference to Form 12 instructions in the 60-day FRN was a technical error; instead, the FRN should have referred to Form 11, to which additional minor clarifications were made.

HRSA received comments from five respondents (state Title V programs and other MCH stakeholders) on the proposed updates to the eleventh edition of the Guidance. The submitted responses included multiple comments. Of the five respondents, four respondents provided comments related to implementation of the guidance or the Title V Information System (TVIS) that would be addressed most effectively in the form of technical assistance, rather than adjusting the guidance instructions. Two respondents recommended expanding the definitions of budget-related glossary terms to

include additional examples for each category. HRSA considered all public comments as part of its deliberative process in finalizing updates to the eleventh edition of the *Title V Maternal and Child Health 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) Organization and Structure of the Application/Annual Report Guidance.

Comments: Some respondents expressed support for the Application/Annual Report Guidance reporting structure that was implemented as part of the tenth edition and maintained through this edition. Respondents provided additional comments related to combining various sections of the Application/Annual Report, such as: (1) Systems and Services for Children with Special Health Care Needs with Relationship with Medicaid; (2) Title V Purpose and Design, Organizational Structure, Impact of Organizational Structure, and Impact of Agency Capacity; (3) System of Care for Mothers, Infants, and Families with Systems and Services for Children with Special Health Care Needs; (4) How Title V Funds Support MCH Efforts and the Expenditures and Budget Narratives; (5) MCH Population Health and Wellbeing and State Description; (6) Impact of Organizational Structure, Impact of Agency Capacity, and Title V Workforce Capacity and Workforce Development; and (7) Title V Partnerships, Collaboration, and Coordination and Family and Community Partnerships.

HRSA Response: HRSA will not adopt the recommendation to consolidate the identified sections, as each section requests distinct types of information or fulfills a legislative requirement.

Consolidating sections increases the risk that important information may be left out or overlooked. HRSA also sought to minimize revisions in the eleventh edition of the guidance to provide State Title V programs sufficient time to implement and adjust to the Application/Annual Report reporting structure that was introduced in the tenth edition. HRSA wants State Title V programs to have sufficient opportunities to fully implement and assess the revised structure before making a significant number of revisions to the TVIS reporting structure.

(2) TVIS Functionality.

Comments: Some respondents provided comments regarding the

character limits in the Executive Summary section and requested that HRSA increase the character limits to allow states to provide additional detail, including more comprehensive descriptions of program successes (*i.e.*, success stories). Respondents also requested an increase in character limits for the Relationship with Medicaid section, to allow states to more fully describe relevant program activities and efforts.

HRSA Response: HRSA will not adopt the recommendation related to character limits in the Executive Summary section but will adopt the recommendation related to the increase in character count for the Relationship with Medicaid Section. The Executive Summary is intended to be a standalone document that enables the reader to acquire a clear understanding of the state's Title V program without having to read the entire MCH Block Grant Application/Annual Report. The Executive Summary also serves as the narrative portion of the TVIS State Snapshot, serving as a quick point of reference for MCH stakeholders and other interested parties. Character limits for the Executive Summary are established in TVIS to support these purposes. The Relationship with Medicaid section character limits are established within TVIS and related to the functionality of the data entry system, rather than to requirements contained in the Guidance. HRSA will increase the character limit for the Relationship with Medicaid section, which will be implemented as part of system updates to TVIS. Additionally, HRSA will communicate any relevant changes to states through skills-building training or technical assistance provided prior to the release of the data entry system.

(3) Guidance Implementation and Technical Assistance.

Comments: Some respondents requested additional support related to Interim Needs Assessment reporting and data entry for Form 5 and Form 10.

HRSA Response: HRSA recognizes the importance of providing technical assistance to support states in their submission of the Application/Annual Report. For Forms 5 and 10, HRSA provides dedicated Learning Labs that include presentations from states on their approaches to completing and reporting on these forms. HRSA will also provide technical assistance on the interim Needs Assessment Reporting.

(4) Statutory Requirement Clarification.

Comments: Two respondents recommended incorporating the Public Input section into the Family and

Community Engagement (*i.e.*, Family and Community Partnerships) section, stating that community input is centered on engagement in program planning, implementation, and evaluation, rather than on the formal application process itself. The respondents also questioned whether a separate Public Input section is statutorily required.

HRSA Response: While public input may include family and community engagement activities, the two sections serve distinct purposes. Section 505(a) of Title V of the Social Security Act requires states to make the Application/Annual Report available for public comment during its development and after its transmittal. Maintaining a separate Public Input section provides a clear and consistent mechanism for states to annually document compliance with this statutory requirement. The Family and Community Partnerships section addresses ongoing engagement activities with families, individuals, and family-led organizations and is only required to be updated every 5 years. As a result, HRSA will not adopt this recommendation and will provide technical assistance to the states through group webinars and one-on-one calls, as appropriate.

(5) Expanded Definitions of Budget-Related Glossary Terms.

Comments: Two respondents requested an expansion of budget-related glossary terms.

HRSA Response: HRSA agrees that additional examples would improve the clarity of the budget-related glossary terms. HRSA will revise the definitions of local, program income, and other funds to include additional examples.

(6) State General Revenue Funds Delineation.

Comments: Two respondents recommended revising the guidance to require states to report on the specific delineation of the percent of undesignated state general revenue funds used for non-federal Title V funding.

HRSA Response: HRSA will not adopt this recommendation. Requiring states to provide this additional information would increase the reporting burden associated with the Application/Annual Report. However, states may elect to include this information in the financial narrative at their discretion.

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 HRSA (Sections 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 Guidance.

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. States will use the updated edition of the Guidance to prepare and submit the fiscal year (FY) 2028, FY 2029, and FY 2030 Applications/FY 2026, FY 2027, and FY 2028 Annual Reports, which will not contain the 5-Year Needs Assessment Summary. States will submit the next 5-Year Needs Assessment Summary in 2030, as part of the FY 2031 Application/FY 2029 Annual Report.

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 Five-Year Needs Assessment Summary	59	1	59	116	6,844
Total	59		59		6,844

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026–21519 Filed 10–20–26; 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; Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System, OMB No. 0915–0298—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.

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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: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System.

OMB No. 0915–0298—Revision

Abstract: HRSA is requesting OMB approval to revise the Maternal and Child Health Bureau (MCHB) Performance Measures for the Discretionary Grant Information System (DGIS). The revision updates terminology across five forms—replacing “underserved” with “medically underserved” on the Engaging Families and Other Individuals (formerly Engagement of Persons With Lived Experience) form; Training Forms 07, 08, 09; and Former Long-Term Trainees—and eliminates

two forms (Training 03/Healthy Tomorrows and Training 04/Maternal and Child Health (MCH) Training Program) whose data is now captured through the Partnership and Collaboration form. The remaining 42 forms carry forward unchanged from the currently approved package.

A 60-day notice published in the **Federal Register** on July 13, 2026, vol. 91, No. 132; pp. 42967–42969. HRSA received one out-of-scope comment regarding drug testing, which this information collection does not cover.

Need and Proposed Use of the Information: The performance data collected through the DGIS supports grantee monitoring, program planning, and performance reporting, and helps demonstrate alignment between MCHB discretionary programs and the Title V MCH Services Block Grant program.

Likely Respondents: The grantees for MCHB Discretionary Grant Programs.

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