

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket Nos. FDA–2020–N–0908; FDA–2010–N–0583; FDA–2020–N–0257; FDA–2008–N–0490; FDA–2011–N–0017; FDA–2011–N–0144; FDA–2015–D–3327; FDA–2020–N–1207]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB

under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions, and Electronic Submission Using FDA Form 3503 .....	0910–0016	09/30/2023
Radioactive Drug Research Committees .....	0910–0053	09/30/2023
Rapid Response Surveys .....	0910–0500	09/30/2023
Cosmetic Labeling and Voluntary Cosmetic Registration .....	0910–0599	09/30/2023
Voluntary National Retail Food Regulatory Program Standards .....	0910–0621	09/30/2023
FDA's Voluntary Qualified Importer Program; Guidance for Industry .....	0910–0840	09/30/2023
GFI: E6(R2) Good Clinical Practice; International Council for Harmonisation .....	0910–0843	09/30/2023
List of US Manufacturers of Specific CVM-Regulated Products with Interest in Exporting Covered Products to China .....	0910–0884	09/30/2023

Dated: November 5, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–25022 Filed 11–10–20; 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 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 must be received no later than December 14, 2020.

**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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

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

*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:** 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*. This Guidance is used annually by the 50 states and nine jurisdictions (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 (MCHB) for this edition of the Guidance continue to honor the federal-state partnership that is supported by the Title V Maternal and Child Health Services Block Grant and reinforce the state's role in developing a Five-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 edition. As such, they are intended to enable a state to provide an articulate and comprehensive description of its Title V program activities and its leadership efforts in advancing and assuring a public health system that serves the Maternal and Child Health population. HRSA's proposed updates

to this edition of the Guidance were informed by comments received from State Title V program leadership, national Maternal and Child Health leaders and other stakeholders. Publication of a 60-day **Federal Register** Notice on June 15, 2020 (85 FR 36217) generated comments on proposed changes to the narrative instructions, reporting forms, and appendices.

While retaining the current organizational structure, performance measure framework and focus on family partnership, specific updates to this 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* include the following:

(1) Add clarifying language/instructions for completing the reporting forms and updating the Glossary of terms, references and citations, as needed.

(2) Revise the content of the National Outcome/Performance Measure Detail Sheets to include the 2030 *Healthy People* Objectives and to provide clear links to evidence-based and-informed strategies, federally available/state-reported data and data notes.

(3) Revise the format for Form #10e, which serves as the detail sheet for the state-specific measures (*i.e.*, Evidence-based and -Informed Strategy Measures (ESM), State Performance Measures (SPM), and State Outcome Measures (SOM)). Implement a staggered approach that requires states to use the revised form for all newly established state-specific measures and allows states to transition existing measures to the new form by the end of the five-year reporting cycle.

(4) Provide continued emphasis on family partnership and engagement at the systems level and include the Family Engagement in Systems Assessment Tool and Toolkit (FESAT) as one possible tool for State Title V programs to consider.

(5) Share background information, resources, state examples/metrics and definitions to assist states in their efforts to advance population health strategies for children with special health care needs (CSHCN).

(6) Expand Form 5 to include infants in the state's reporting on the number (5a) and percent (5b) of CSHCN served by Title V, *i.e.*, update the reporting to include infants and children with special health care needs (0–21 years).

(7) Enhance the narrative and performance reporting on State Title V efforts to build or expand program capacity related to Maternal and Child Health data access and cross-program data linkages, Maternal and Child

Health workforce development/training, and emergency planning/preparedness.

a. Integrate key aspects of the annual performance and progress reporting for the State Systems Development Initiative (SSDI) grant into the Title V Maternal and Child Health Services Block Grant Application/Annual Report to allow for more focused narrative reporting on SSDI program goals and activities relative to the State Title V Maternal and Child Health program and provide an annual assessment of the state's progress in building/expanding Maternal and Child Health data capacity through an added reporting form.

b. Enhance the annual narrative reporting to include a more robust description of the State Title V workforce capacity (*e.g.*, number/types of Full-Time Equivalents, trends/shifts in Maternal and Child Health workforce, and key external partners) and professional development efforts, while providing resources to assist State Title V programs in their ongoing assessment of Maternal and Child Health workforce and training needs.

c. Expand the annual narrative reporting to include a descriptive analysis of the

Title V program's role in the state's emergency planning and preparedness efforts, with the intended purpose of enabling each State Title V program to better assess capacity within the state for responding to emerging public health threats and disasters that could potentially impact the Maternal and Child Health population.

(8) Expand and enhance the Appendices to include supportive background information, examples, resources and tools.

In consideration of the increasing demands that are being placed on State Title V programs at this time due to the COVID–19 emergency and given that no major changes to the reporting requirements are being proposed, the burden estimates presented in the table below are based on the previous burden estimates for completion of the Title V Maternal and Child Health Services Block Grant Application/Annual Report. These estimates were developed based on prior estimates and consultations with a few States. When the COVID–19 emergency subsides, HRSA can solicit additional information from states to derive more accurate burden estimates.

The addition of clarifying instructions, state examples, reformatted Glossary, expanded background information and supportive resources and tools, where possible, is expected to assist State Title V programs in responding to the reporting requirements. It is anticipated that

further reductions in burden will be realized through the proposed revisions to the National Outcome/Performance Measure detail sheets and to Form #10e. These reductions in burden will be partially offset by the addition of one reporting form (formerly part of the state's annual performance reporting for the SSDI grant). This reporting will be coupled with expanded narrative reporting on the state's SSDI grant activities, along with other capacity-building efforts that relate to the Maternal and Child Health workforce and emergency planning and preparedness.

A 60-day notice published in the **Federal Register** on June 15, 2020, vol. 85, No. 115; pp. 36217–18. There were 10 public comments.

*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 Maternal and Child Health Services Block Grant to States Program to the HRSA's MCHB (Section 505(a) of Title V of the Social Security Act). In addition, the State Maternal and Child Health Services Block Grant programs are required to conduct a state-wide, comprehensive Needs Assessment every five 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 States Program: Guidance and Forms for the Title V Application/Annual Report*.

*Likely Respondents:* By legislation (Section 505(a) of Title V of the Social Security Act), the Maternal and Child Health Services Block Grant Application/Annual Report must be developed by, or in consultation with, the State Maternal and Child Health agency.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This estimate 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 Information Collection Request are summarized in the table below.

## TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Burden per response (in hours)	Total burden hours
Application and Annual Report without Five-Year Needs Assessment Summary .....	59	1	59	120	7,080
Average Total Annual Burden .....	59	.....	59	.....	7,080

States will use the updated 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* to prepare and submit the fiscal year (FY) 2022, FY 2023 and FY 2024 Applications/FY 2020, FY 2021 and FY 2022 Annual Reports, which will not contain the Five-Year Needs Assessment Summary. States will submit the next Five-Year Needs Assessment Summary in 2025, as part of the FY 2026 Application/FY 2024 Annual Report. Instructions for preparing the FY 2025, FY 2026 and FY 2027 Applications/FY 2023, FY 2024 and FY 2025 Annual Reports will be provided in the subsequent edition of the Application/Annual Report Guidance.

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. 2020-25031 Filed 11-10-20; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Review Subcommittee Member Conflict Panel.

*Date:* December 2, 2020.

*Time:* 10:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892, 301-443-4032, [anna.ghambaryan@nih.gov](mailto:anna.ghambaryan@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: November 4, 2020.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-24985 Filed 11-10-20; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; NIMH HIV/AIDS Training Review (R25, T32, K99).

*Date:* December 4, 2020.

*Time:* 12:00 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, [steinerr@mail.nih.gov](mailto:steinerr@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel NIMH HIV/AIDS Review (P30).

*Date:* December 9, 2020.

*Time:* 11:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Jasenka Borzan, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Mental Health, 6001 Executive Blvd., Neuroscience Center, Room 6150, Bethesda, MD 20892, 301-435-1260, [jasenka.borzan@nih.gov](mailto:jasenka.borzan@nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 4, 2020.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-24980 Filed 11-10-20; 8:45 am]

**BILLING CODE 4140-01-P**