

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
<b>Investigational Food Additive Files</b>					
570.17 Moderate Category .....	6	1	6	1,500	9,000
570.17 Complex Category .....	7	1	7	5,000	35,000
<b>Color Additives</b>					
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification .....	3,120	0.8292	2,587	* 0.25	647
Total Hours .....					119,147

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

\* (15 minutes).

For the purpose of this consolidation, we base our estimate of the total annual responses on submissions received during fiscal years 2019 and 2020. We base our estimate of the hours per response on our experience with the labeling, food additive petition, and filing processes.

The information collection reflects a net decrease of 70,453 hours (189,600 OMB approved hours—119,147 estimated hours). We also experienced a net increase of 2,587 responses from 35 OMB approved annual responses to 2,616 estimated annual responses. These changes were due to the consolidating of the information collection covered by OMB control number 0910–0721 and due to estimated changes of the number of respondents for food additive petitions and investigational food additive files.

**Section 571.1(c) Moderate Category:** The estimated time requirement per food additive petition remains at approximately 3,000 hours; however, we now estimate that the number of annual respondents has decreased from 12 to 6 respondents for a total of 18,000 hours.

**Section 571.1(c) Complex Category:** The estimated time requirement per food additive petition remains at approximately 10,000 hours; however, we now estimate that the number of annual respondents has decreased from 12 to 5 respondents for a total of 50,000 hours.

**Section 571.6 Amendment of Petition:** We estimated that the number of annual respondents that will submit an amendment has increased from two to five respondents who will each submit one amendment for a total of 6,500 hours. This is an increase of three respondents and 3,900 hours from the burden approved by OMB.

**Section 570.17 Moderate Category:** We estimated that the number of annual

respondents for investigational food additive files has increased from four to six respondents who will each submit one file for a total of 9,000 hours. This is an increase of two respondents and 3,000 hours from the burden approved by OMB.

**Section 570.17 Complex Category:** We estimated that the number of annual respondents for investigational food additive files has increased from five to seven respondents who will each submit one such file, for a total of 35,000 hours. This is an increase of 10,000 hour from the burden approved by OMB.

**Section 501.22(k) Labeling of Color Additive or Lake of Color Additive; Labeling of Color Additives Not Subject to Certification:** The information collection reflects an adjustment in burden by 647 hours and 2,587 responses. We attribute this adjustment due to the consolidation of OMB control number 0910–0546 and OMB control number 0910–0721.

Dated: October 1, 2021.

**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; Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report, OMB No. 0906–0016, 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 should be received no later than November 8, 2021.

**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 HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-9094.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report, OMB No. 0906-0016, Revision.

*Abstract:* This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Quarterly Performance Report. The MIECHV Program, administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities.

A 60-Day notice was published in the **Federal Register**, 86 FR 35809 (July 7, 2021). There were two public comments. These comments expressed support for proposed updates to definitions of key terms and provided suggestions to improve clarity and reduce reporting burden related to

quarterly information reporting. HRSA appreciates these comments and suggestions to the information collection. Comments also raised questions about existing guidance that do not appear to require amendments to the guidance and that HRSA therefore intends to address through technical assistance. After taking these comments into consideration, HRSA intends the following proposed revisions to Form 4:

- Form 4, Reporting guidance: Revise reporting instructions and links to reflect updated reporting requirements.
- Form 4, Definition of Key Terms: Update definitions for Table A.1.
- Form 4, Definition of Key Terms: Add definitions for Table A.2.
- Form 4, Due date: The due date will be revised to 45 days after the end of each reporting period.

HRSA requests approval to expand the use of Form 4 in order to collect quarterly performance data from awardees who receive MIECHV funding appropriated by section 9101 of the American Rescue Plan Act (Pub. L. 117-2).

*Need and Proposed Use of the Information:* HRSA uses quarterly performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state,

and local level. HRSA seeks to revise reporting instructions and definitions of key terms and to expand the use of Form 4 in order to collect distinct quarterly performance data related to the use of American Rescue Plan Act funds. This notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, information can be collected in a timely manner.

*Likely Respondents:* MIECHV Program awardees are states, jurisdictions, and, where applicable, nonprofit organizations receiving MIECHV funding to provide home visiting services within states.

*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
Form 4: Section A—Quarterly Performance Report .....	56	8	448	24	10,752
Form 4: Section B—Quarterly Benchmark Performance Measures .....	10	4	40	200	8,000
<b>Total</b> .....	<b>156</b>	.....	<b>488</b>	.....	<b>18,752</b>

<sup>1</sup> The 10 responses for Section B are a sub-set of 56 total awardees funded through the MIECHV Program.

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.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; 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.,