

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: May 31, 2018.

Leslie Kux,

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; The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906-0017—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 has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. A 60-day **Federal Register** Notice was published in the **Federal Register** on February 9, 2018 (83 FR 5791). There were 23 public comments. 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.

DATES: Comments on this ICR should be received no later than July 5, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

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 or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early

Childhood Home Visiting Program Performance Measurement Information System.

OMB No. 0906-0017—Revision.

Abstract: This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System. 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. After taking into consideration public comments in response to the 60-day Notice published in the **Federal Register** on February 9, 2018 (83 FR 5791), HRSA is proposing final revisions to the data collection forms for the MIECHV Program by making the following changes:

- *Form 1:* Update Tables 4-14, 16, and 18-20 to include specific guidance to account for and report missing data.
- *Form 1, Tables 1 and 2:* Update table titles to reflect “participants served by MIECHV.”
- *Form 1, Table 5:* Update to reflect correct age categories of “<1 year,” “1-2 years,” “3-4 years,” “5-6 years,” and “Unknown/Did not Report.”
- *Form 1, Table 8:* Revise the category of “Never Married” to read “Never Married (excluding not married but living together with partner).”
- *Form 1, Table 10:* Delete.
- *Form 1, Table 18:* Delete.
- *Form 1, Table 22:* Revise to only include children greater than or equal to 12 months of age. Title will be updated to “Index Children (≥12 months of age) by Usual Source of Dental Care.”
- *Form 1, Notes:* Revise to include Table-specific notes.
- *Form 1, Definition of Key Terms:* Update definitions for Tables 1, 3, 5, 12, 13, 15, 20, 21, and 22.
- *Form 2:* Update all measures to include specific guidance to account for and report missing data.
- *Form 2, Measure 3:* Update denominator to reflect correct inclusion criteria.
- *Form 2, Measure 7:* Update numerator to read “. . . without bed sharing and without soft bedding.”
- *Form 2, Measure 8:* Update numerator to clarify that nonfatal injury-related visits to the ED must have occurred within the reporting period.

- *Form 2, Measure 9:* Update numerator to clarify that investigated cases of maltreatment must have occurred within the reporting period.

- *Form 2, Measure 13:* Update numerator and denominator to clarify that only postnatal home visits should be included.

- *Form 2, Measure 14:* Update measure to reflect current terminology and the timing within which screenings should be reported.

- *Form 2, Measure 15:* Update measure and numerator to include primary caregivers enrolled in middle school.

- *Form 2, Measure 17:* Update denominator to reflect correct inclusion criteria.

- *Form 2, Measure 19:* Update denominator to reflect correct inclusion criteria.

- *Form 2, Definitions of Key Terms:* Update definitions for measures 1, 2, 4, 5, 18, and 19.

HRSA is also requesting an extension of this information collection request through November 30, 2021.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability with legislative and programmatic requirements 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 is seeking to revise demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services. In addition, HRSA will collect a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas.

In the future, HRSA anticipates that MIECHV funding decisions may be allocated, in part, based on awardee performance, including on benchmark performance areas.

Likely Respondents: MIECHV Program awardees.

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 1: Demographic, Service Utilization, and Select Clinical Indicators	56	1	56	560	31,360
Form 2: Performance Indicators and Systems Outcome Measures	56	1	56	200	11,200
Total	56	56	42,560

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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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; Office of the Advancement of Telehealth Outcome Measures, OMB No. 0915-0311—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 has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. This proposed information collection was previously published in the **Federal Register** on January 10, 2018 (83 FR 1264), and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. 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.

DATES: Comments on this ICR should be received no later than July 5, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Office for the Advancement of Telehealth Outcome Measures, OMB No. 0915-0311—Revision.

Abstract: In order to help carry out its mission, the Office for the Advancement of Telehealth (OAT) created a set of performance measures that grantees can use to evaluate the effectiveness of their services programs and monitor their progress through the use of performance reporting data.

Need and Proposed Use of the Information: As required by the Government Performance and Results Act of 1993, all federal agencies must develop strategic plans describing their overall goal and objectives. OAT has worked with its grantees to develop performance measures used to evaluate

and monitor the progress of the grantees. Grantee goals are to improve access to needed services, reduce rural practitioner isolation, improve health system productivity and efficiency, and improve patient outcomes.

In each of these categories, specific indicators were designed to be reported through a performance monitoring website. New measures are being added to the Telehealth Network Grant Program and all measures speak to OAT's progress toward meeting the goals, specifically telehealth services delivered through rural schools.

Likely Respondents: Telehealth Network Grantees.

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
Performance Improvement Measurement System (PIMS) ..	21	1	21	7	147
Total	21	21	147