

Generic Information Collections

1. *Title of Information Collection:* Managed Care Rate Setting Guidance; *Type of Information Collection Request:* Revision of an existing generic information collection request; *Use:* In accordance with 42 CFR 438.7, states must submit to CMS for review and approval all rate certifications for managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs). The rate certification itself is prepared by a state's actuary who certifies the managed care program's capitation rates as actuarially sound for a specific time period, and documents the rate development process and final certified capitation rates.

Our Medicaid Managed Care Rate Development Guide (otherwise referred to as the "rate guide") outlines the rate development standards and CMS' expectations for documentation included in rate certifications such as descriptions of base data used, trend factors to base data, projected benefit and non-benefit costs, and any other considerations or adjustments used when setting capitation rates. The information outlined in the rate guide must be included within the rate certification in adequate detail to allow CMS to determine compliance with applicable provisions of 42 CFR part 438, including that the data, assumptions, and methodologies used for rate development are consistent with generally accepted actuarial principles and practices and that the capitation rates are appropriate for the populations and services to be covered. There is no required template that states' actuaries must utilize for the rate certification, but the guidance outlined in the rate guide serves as a resource for states and their actuaries. Adherence by states and their actuaries to the rate development standards and documentation expectations outlined in the rate guide, will aid in ensuring compliance with the regulations and support CMS's review and approval of actuarially sound capitation rates and associated federal financial participation. *Form Number:* CMS-10398 (#37) (OMB control number: 0938-1148); *Frequency:* Annual; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 46; *Total Annual Responses:* 135; *Total Annual Hours:* 743. For policy questions regarding this collection contact Rebecca Burch-Mack at 303-844-7355.

Dated: April 5, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program Data Reports: Demographic and Service Utilization, Grantee Performance Measures and Quarterly Performance Reports

AGENCY: Office of Early Childhood Development; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a new information collection for the Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Tribal Home Visiting Program Data Reports: Demographic and Service Utilization, Grantee Performance Measures and Quarterly Performance Reports.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511 of Title V of the Social Security Act created the MIECHV Program and authorizes the Secretary of the United States Department of Health and Human Services (HHS) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 6 percent of the total MIECHV program appropriation for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to

states and jurisdictions and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The ACF Office of Early Childhood Development (ECD), in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, awards grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs assessments, plan for and implement high-quality, culturally grounded, evidence-based home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

In Year 1 of the cooperative agreement, grantees must (1) conduct a comprehensive community needs and readiness assessment and (2) develop a plan to respond to identified needs. Following each year that Tribal MIECHV grantees implement home visiting services; they must comply with the requirement to submit demographic and service utilization data once they begin to provide services, and then on an annual basis. Grantees also begin to report quarterly on caseloads and family and staff retention and submit performance data in years 2-5 of their cooperative agreements. Tribal MIECHV Program data are used to help ACF better understand the population receiving services from Tribal MIECHV grantees, the degree to which they are using services, as well as staffing data to better understand the Tribal MIECHV workforce. This includes demographic and service utilization data on the number of newly enrolled and continuing participants, educational level and poverty status of participants, education level of staff, number of home visits and grantee caseload capacity and retention of families and staff. Performance reporting on the six legislatively mandated areas (referred to as "benchmark areas") will document grantee improvement in the benchmark areas over time and will allow new cohorts of grantees to reflect on their performance to make program improvements or to document implementation of services successfully that encompass the major goals of the program.

ACF will use Tribal Home Visiting Data Reports to:

- Collect demographic and service utilization that provides vital information on the families being served under the Tribal MIECHV Program;

- Collect the number of newly enrolled and continuing families being served;
- Number of home visits;
- Track and improve the quality of benchmark measures data submitted by the tribal grantees;
- Improve program monitoring and oversight;
- Improve rigorous data analyses that help to assess the effectiveness of the

- programs and enable ACF to better monitor projects;
- Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including Congress and members of the public; and
 - Collect data on caseload capacity, retention and attrition of enrolled

families and the retention and attrition of program staff on a quarterly basis.

Overall, this information collection will provide valuable information to HHS that will guide understanding of the Tribal MIECHV Program and the provision of technical assistance to Tribal MIECHV Program grantees.

Respondents: Tribal MIECHV Program Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal MIECHV Demographic and Service Utilization Data Form	55	1	317	17,435
Tribal MIECHV Performance Measures Form	55	1	288	15,840
Tribal MIECHV Quarterly Performance Report	55	4	2.5	550

Estimated Total Annual Burden Hours: 33,825.

Comments: HHS specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 511 of Title V of the Social Security Act

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1157]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information which allows the submission of individual generic requests for obtaining qualitative data to support social and behavioral research for food, dietary supplements, cosmetics, and animal food and feed.

DATES: Either electronic or written comments on the collection of information must be submitted by June 9, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2023-N-1157 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Generic