approval to conduct a new information collection entitled Evaluation of the DP18–1801 Healthy Schools Program. The DP18–1801 Healthy Schools Program builds upon previous CDC efforts designed to enhance the capacity of state education agencies (SEAs) to adopt and implement evidence-based policies, practices, and programs that support health among the nation's youth. The purpose of the DP18–1801 Healthy Schools Program is to: (1) Increase the number of students who consume nutritious food and beverages (*i.e.,* those aligned with the *Dietary Guidelines for Americans*); (2) increase the number of students who participate in daily physical education and physical activity; and (3) increase the number of students who can effectively manage their chronic health conditions. The evaluation approach is a multisite, embedded case study design, consisting of both process and outcome components, focusing on three 1801 state grantees and a subset of their targeted LEAs and schools. The process component will assess implementation of strategies and activities at the state, local, and school levels and their integration across levels; fidelity of implementation; implementation facilitators and barriers; and contributions of national and state level TA towards program achievements. Three primary data collection methods will be used: (1) Key informant interviews (KII) conducted during in-person site visits or by phone, (2) Web-based surveys, and (3) review of secondary data sources. CDC is requesting approval for an estimated 265 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
SEA staff	Web-Survey	3	1	75/60
	Key-Informant Interview	9	1	75/60
LEA staff	Web-Survey	30	1	75/60
	Key-Informant Interview	12	1	75/60
School staff	Web-Survey	210	1	75/60
	Key-Informant Interview	54	1	75/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program Form 2: Grantee Performance Measures (OMB #0970–0500)

AGENCY: Office of Child Care; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the ACF-Tribal Maternal, Infant, and Early Childhood Home Visiting (Tribal MIECHV) Program Form 2: Grantee Performance Measures (OMB #0970–0500; Expiration date 8/31/2020). There are no changes requested to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) authorizes the Secretary of HHS (in Section 511(h)(2)(A)) 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 3 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 Child Care, 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 relevant, evidence-based home visiting programs in at-risk tribal communities; collect and report on performance measures; and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

Specifically, the MIECHV legislation requires that State and Tribal MIECHV grantees collect performance data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program. These include:

1. Improved maternal and newborn health;
2. Prevention of child injuries, child abuse, neglect, or maltreatment, and reduction in emergency department visits;
3. Improvement in school readiness and achievement;
4. Reduction in crime or domestic violence;
5. Improvement in family economic self-sufficiency; and
6. Improvement in the coordination and referrals for other community resources and supports.

Tribal MIECHV grantees are required to propose a plan for meeting the benchmark requirements specified in the legislation and must report on

improvement on constructs under each benchmark area. The Tribal Home Visiting (HV) Form 2 provides a template for Tribal MIECHV grantees to report data on their progress in improving performance under the six benchmark areas, as stipulated in the legislation.

ACF will continue to use Tribal HV Form 2 to:

- 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; and
- Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including Congress and members of the public.

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 Form 2	25	1	500	12,500

Estimated Total Annual Burden Hours: 12,500.

Comments: The Department 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: Public Law 115–123, Section 511(h)(2)(A) 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–2016–N–2544]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by December 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Current Good Manufacturing Practice Quality System Regulation—21 CFR Part 820

OMB Control Number 0910–0073—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device, but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice (CGMP), as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the FD&C Act.

The CGMP quality system (QS) regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the FD&C Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies requirements for product acceptance activities, quality data evaluations, and corrections of nonconforming product/quality problems.

Requirements are compatible with specifications in the international standards ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.'' The CGMP/QS information collections will assist FDA inspections of manufacturers for compliance with QS requirements encompassing design, production, installation, and servicing processes.