

costs. The Form CMS–2552–10 cost report is also used for rate setting and payment refinement activities, including developing a hospital market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospital cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the IPPS and OPSS, and to conduct additional analysis of the IPPS and OPSS. *Form Number:* CMS–2552–10 (OMB control number: 0938–0050); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other For-profit and Not-for-profit institutions), State, Local and Tribal Governments, Federal Government; *Number of Respondents:* 6,088; *Total Annual Responses:* 6,088; *Total Annual Hours:* 4,097,224. (For policy questions regarding this collection contact Gail Duncan at 410–786–7278.)

Dated: November 15, 2018.

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

Submission for OMB Review; Comment Request

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Reporting Form.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Office of Child Care, in collaboration with the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau, administers the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, as authorized by Title V, Section 511 of the Social Security Act. The Administration for Children and Families administers the Tribal MIECHV Program while HRSA administers the State/Territory MIECHV Program. Tribal MIECHV discretionary grants support 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; establish, measure, and report on progress toward meeting performance

measures in six legislatively-mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

The proposed data collection form is as follows: In order to continuously monitor, provide grant oversight, quality improvement guidance, and technical assistance to Tribal MIECHV grantees, ACF is seeking to collect services utilization data on a quarterly basis. The Tribal MIECHV Quarterly Data Performance Reporting Form, is made up of five categories of data—program capacity, place-based services, family engagement, staff recruitment and retention and staff vacancies. This form will be used by Tribal MIECHV grantees that receive grants under the Tribal MIECHV Program to collect data in order to determine the caseload capacity grantees are achieving, where services are being delivered, the retention and attrition of enrolled families, and the retention and attrition of program staff on a quarterly basis.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Managers. The information collection does not include direct interaction with individuals or families that receive the services.

ANNUAL BURDEN ESTIMATES

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Tribal MIECHV Grantees	Tribal MIECHV Quarterly Reporting Form.	25	4	24	2,400
Total	2,400

Estimated Total Annual Burden Hours: 2,400.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the

proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert A. Sargis,

Reports Clearance Officer.

[FR Doc. 2018–25214 Filed 11–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3017]

Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the establishment of a docket to solicit public comment on a proposed framework for regulating software applications disseminated by or on behalf of drug sponsors for use