incidence and higher mortality rates from TBI than do residents of urban areas, and that the prevalence of TBI-related disability in rural geographical areas is higher than in urban and suburban areas. The obstacles healthcare providers and patients face in rural areas are vastly different from those in urban areas. There is little published research specifically related to the challenges rural providers face in TBI diagnosis and treatment, and even less examination into effective ways to address gaps in service and improve TBI outcomes. The National Center for Injury Prevention and Control at the CDC, in a 2015 ''Report to Congress on TBI in the United States,'' determined that certain population groups, including residents of rural geographic areas, require special consideration when it comes to researching TBI.

This is a New Information Collection Request for two years to collect information on challenges that rural healthcare providers face in diagnosing, treating, and managing TBI of all severities and developing a knowledge base upon which we can begin to address gaps in services to improve clinical care and TBI outcomes in rural communities. The target population for the data collection effort includes physicians, nurse practitioners (NPs), and physician assistants (PAs) in selected specialties (general or family practice, emergency medicine, pediatrics) working in direct patient care in rural and urban areas. The focus of the study is rural healthcare providers; urban healthcare providers will be included in this study to allow for comparison in identifying the distinct challenges and opportunities for rural healthcare providers. This study has two data collection methods. A web survey to gather quantitative data on the unique challenges faced by rural clinicians, and focus groups to gain deeper insight into the context supporting and/or inhibiting access to comprehensive TBI evaluation and treatment, the study will collect qualitative data through focus groups with rural clinicians.

The total estimated annualized burden hours are 200. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Health care providers (Primary Care Physician, Emergency Physician, Nurse Practitioner and Physician Assistant).	TBI Provider Survey	600	1	15/60
	Focus group screener	36	1	5/60
	Focus group consent and questionnaire.	31	1	5/60
	Focus group discussion guide	31	1	85/60

Jeffrey M. Zirger,

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

[FR Doc. 2018–25274 Filed 11–19–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10511, CMS–10575, and CMS–2552–10]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 22, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More

detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10511 Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies-Revision of Medicare Coverage

CMS–10575 Generic Clearance for the Health Care Payment Learning and Action Network

CMS–2552–10 Hospitals and Health Care Complex Cost Report

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement; *Title of Information Collection:* Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage; *Use:* Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201–405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. *Form Number:* CMS–10511 (OMB control number: 0938–1250); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 200. (For policy questions regarding this collection contact Cheryl Gilbreath at 410–786–5919.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Generic Clearance for the Health Care Payment Learning and Action Network; *Use:* The Center for Medicare and Medicaid Services (CMS), through the Center for Medicare and Medicaid Innovation, develops and tests innovative new payment and service delivery models in accordance with the requirements of section 1115A and in consideration of the opportunities and factors set forth in section 1115A(b)(2) of the Act. To date, CMS has built a portfolio of models (in operation or already announced) that have attracted participation from a broad array of health care providers, states, payers, and other stakeholders. During the development of models, CMS builds on ideas received from stakeholders—consulting with clinical and analytical experts, as well as with representatives of relevant federal and state agencies.

CMS will continue to partner with stakeholders across the health care system to catalyze transformation through the use of alternative payment models. To this end, CMS launched the Health Care Payment Learning and Action Network, an effort to accelerate the transition to alternative payment models, identify best practices in their implementation, collaborate with payers, providers, consumers, purchasers, and other stakeholders, and monitor the adoption of value-based alternative payment models across the health care system. A system wide transition to alternative payment models will strengthen the ability of CMS to implement existing models and design new models that improve quality and decrease costs for CMS beneficiaries.

The information collected from LAN participants will be used by the CMS Innovation Center to potentially inform the design, selection, testing, modification, and expansion of innovative payment and service delivery models in accordance with the requirements of section 1115A, while monitoring the percentage of payments tied to alternative payment models across the U.S. health care system. In addition, the requested information will be made publically available so that LAN participants (payers, providers, consumers, employers, state agencies, and patients) can use the information to inform decision making and better understand market dynamics in relation to alternative payment models. *Form Number:* CMS–10575 (OMB control number: 0938–1297); *Frequency:* Occasionally; *Affected Public:* Individuals; Private Sector (Business or other For-profit and Not-for-profit institutions), State, Local and Tribal Governments; *Number of Respondents:* 30,110; *Total Annual Responses:* 23,110; *Total Annual Hours:* 25,917. (For policy questions regarding this collection contact Dustin Allison at 410–786–8830.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospitals and Health Care Complex Cost Report; *Use:* Under the authority of sections 1815(a) and 1833(e) of the Act, CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. The Form CMS–2552–10 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and calculate the hospital settlement amounts. These providers, paid under the inpatient prospective payment system (IPPS) and the outpatient prospective payment system (OPPS), may receive reimbursement outside of the PPS for hospital-specific adjustments such as Medicare reimbursable bad debts, disproportionate share, uncompensated care, direct and indirect medical education costs, and organ acquisition

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 OPPS, and to conduct additional analysis of the IPPS and OPPS. *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.

[FR Doc. 2018–25312 Filed 11–19–18; 8:45 am]

BILLING CODE 4120–01–P

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]

BILLING CODE 4184–01–P

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