limit only for relevant studies newly published between the application deadline and the virtual public meeting date, in which case, we request a copy of the complete publication be emailed as soon as possible to *HCPCS_Level_II_Code_Applications@cms.hhs.gov.* This exception applies only to the page limit and not the submission deadline.

Fifteen minutes is the total time interval for the presentation. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to the primary speaker.

Every primary speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

On the day of the virtual meeting, before the end of the meeting, all primary speakers must email a brief written summary of their comments and conclusions to *HCPCS_Level_II_Code_Applications@cms.hhs.gov.*

2. 5-Minute Speakers

The deadline for registering to be a 5-minute speaker is noted in the **DATES** section of this notice. Individuals must provide their name, company name and address, and contact information as specified in the instructions for remote participation, and identify the specific agenda item that they will address. Based on the number of items on the agenda and the progress of the meeting, a determination will be made by the meeting coordinator and the meeting moderator regarding how many 5-minute speakers can be accommodated and whether the 5-minute allocation would be reduced to accommodate the number of speakers.

Every 5-minute speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

On the day of the virtual meeting, before the end of the meeting, all 5-minute speakers must email a brief written summary of their comments and conclusions to *HCPCS_Level_II_Code_Applications@cms.hhs.gov.*

C. Additional Virtual Meeting/Registration Information

Prior to registering to attend a virtual public meeting, all participants are advised to review the public meeting agendas at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* which identify our preliminary coding recommendations, and the dates each item will be discussed. All participants and other stakeholders are encouraged to regularly check CMS' official HCPCS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* for publication of draft agendas, including a summary of each request and our preliminary recommendations.

CMS' official HCPCS website *will include a*dditional details regarding the public meeting process for new revisions to the HCPCS code set, including information on how to join the meeting remotely, and guidelines for an effective presentation. Individuals who intend to provide a presentation at a virtual public meeting are encouraged to familiarize themselves with the HCPCS website and the valuable information it provides to prospective registrants. The HCPCS website also contains a document titled ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' which is a description of the HCPCS coding process, including a detailed explanation of the procedures CMS uses to make coding determinations for the items and services that are coded in the HCPCS.

III. Written Comments From Meeting Attendees

As part of CMS' response to the COVID–19 PHE, written comments from the general public and meeting registrants will *only* be accepted when emailed to *HCPCS_Level_II_Code_Applications@cms.hhs.gov* before 5 p.m., e.d.t., on the date of the virtual public meeting at which a request is discussed.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: June 9, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–12453 Filed 6–11–21; 8:45 am]

BILLING CODE 4120–01–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: Guidance for Submitting an Annual Report to the Secretary (OMB #0970–0409)

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

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Care (OCC) is requesting a 3-year extension of the Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program: Guidance for Submitting an Annual Report to the Secretary (OMB #0970–0409; expiration 9/30/2021). There are minor updates to the annual guidance which reflects a change in timing for the due date of the final report.

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: 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: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the MIECHV program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further

states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

OCC, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program (Tribal Home Visiting) to 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.

After the first grant year, Tribal Home Visiting grantees must comply with the requirement to submit an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period, and a final report to the Secretary during the final year of their grant. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their reports. The guidance specifies that grantees must address the following:

- Update on Home Visiting Program Goals and Objectives
- Update on the Implementation of Home Visiting Program in Targeted Community(ies)
- Progress toward Meeting Legislatively Mandated Benchmark Requirements
- Update on Rigorous Evaluation Activities
- Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Update on dissemination activities
- Administration of Home Visiting Program
- Technical Assistance Needs

Previously, the guidance included information about both the annual and the final reports from grantees. This extension request includes updates to the guidance to make it specific to just the annual reports. Guidance specific to the final report will be submitted for review and approval by OMB in the future. A comment period will accompany that request.

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Report to the Secretary	23	1	25	575

Estimated Total Annual Burden Hours: 575.

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: Title V of the Social Security Act, sections 511(e)(8)(A) and 511(h)(2)(A).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–12464 Filed 6–14–21; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2319]

Evaluation of Study Data Exchange Standards for Submission of Study Data to the Center for Veterinary Medicine; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments on the use of study data exchange standards from persons involved in study conduct, data collection, data management, and submission of animal study data intended to support the approval of new animal drug applications, abbreviated new animal drug applications, or applications for conditional approval.

DATES: Submit either electronic or written comments on the notice by September 13, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 13, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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.*