information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare prescription drug plans and Medicare Advantage plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information. The Balanced Budget Act of 1997 also requires the collection of information about fee-for-service plans.

The primary purpose of the Medicare CAHPS surveys is to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. Survey results are reported by CMS in the Medicare & You Handbook published each fall and on the Medicare Plan Finder website. Beneficiaries can compare CAHPS scores for each health and drug plan as well as compare MA and FFS scores when making enrollment decisions. The Medicare CAHPS also provides data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. CAHPS data are included in the Medicare Part C & D Star Ratings and used to calculate MA Quality Bonus Payments. *Form Number:* CMS–R–246 (OMB control number: 0938- 0732); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 794,500; *Total Annual Responses:* 794,500; *Total Annual Hours:* 192,265. (For policy questions regarding this collection contact Lauren Fuentes at 410–786–2290).

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* The Balanced Budget Act of 1997 required that the CMS publicly report two years of disenrollment rates on all Medicare + Choice (M+C) organizations. Disenrollment rates are a useful measure of beneficiary dissatisfaction with a plan; this information is even more useful when reasons for disenrollment are provided to consumers, insurers, and other stakeholders. Advocacy organizations agree that CMS needs to report disenrollment reasons so that disenrollment rates can be interpreted correctly.

Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding the PDP and MA contracts pursuant to section 1860D–4(d). Plan disenrollment is generally believed to be a broad indicator of beneficiary dissatisfaction with some aspect of plan services, such as access to care, customer service, cost of the plan, services, benefits provided, or quality of care.

The information generated from the disenrollment survey supports CMS' ongoing efforts to assess plan performance and provide oversight to the functioning of Medicare Advantage (Part C) and PDP (Part D) plans, which provide health care services to millions of Medicare beneficiaries (*i.e.,* 28 million for Part C coverage and 49 million for Part D coverage).

Beneficiary experiences of care (as measured in the MCAHPS survey) and dissatisfaction (as measured in the disenrollment survey) with plan performance are both important sources of information for plan monitoring and oversight. The disenrollment survey assesses different aspects of dissatisfaction (*i.e.,* reasons why beneficiaries voluntarily left a plan), which can identify problems with plan operations; performance areas evaluated include access to care, customer service, cost, coverage, benefits provided, and quality of care. Understanding how well plans perform on these dimensions of care and service helps CMS understand whether beneficiaries are satisfied with the care they are receiving from contracted plans. When and if plans are found to be performing poorly against an array of performance measures, including beneficiary disenrollment, CMS may take corrective action. *Form Number:* CMS–10316 (OMB control number: 0938–1113); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 32,750; *Total Annual Responses:* 32,750; *Total Annual Hours:* 7,055. (For policy questions regarding this collection contact Beth Simons at 415–744–3780).

Dated: February 2, 2023.

William N. Parham, III,

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

[FR Doc. 2023–02580 Filed 2–6–23; 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 Implementation Plan Guidance for Development and Implementation and Implementation and Expansion Grantees

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

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Early Childhood Development (ECD) is requesting Office of Management and Budget (OMB) approval of Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Implementation Plan Guidance for Tribal Home Visiting Development and Implementation Grants (DIG) and Tribal Home Visiting Implementation and Expansion Grants (IEG).

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) 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(e)(8)(A) of title V of the Social Security Act requires that grantees under the Tribal MIECHV program, in the first year of their grants, submit an implementation plan on how they will meet the requirements of the program. 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.

The ACF Office of Early Childhood Development, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program 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.

During the first grant year, Tribal Home Visiting grantees must comply with the requirement to submit an implementation plan that should feature planned activities to be carried out under the program in years 2–5 of their cooperative agreements. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their plans. The DIG and IEG guidance specify that grantees must provide a plan to address the following areas:

- Community Needs and Readiness Assessment
- Program Design
- Program Blueprint
- Plan for Data Collection, Management and Performance Measurement
- Fidelity Monitoring and Quality Assurance

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

TOTAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Implementation Plan Guidance for Development and Implementation Grantees	13	1	1,000	13,000
Implementation Plan Guidance for Implementation and Expansion Grantees	35	1	1,000	35,000
Estimated Total Annual Burden Hours:				48,000

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. 2023–02543 Filed 2–6–23; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–5658 and FDA–2019–E–5659]

Determination of Regulatory Review Period for Purposes of Patent Extension; YUPELRI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for YUPELRI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by April 10, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 7, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 April 10, 2023. 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.*
- 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