DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10516 and CMS–10561]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by September 10, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

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 *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule II; *Use:* The original approved ICR affiliated with this final rule was titled Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014; Final Rule II and was approved on 8/26/2015. This request serves as the formal request for renewal of the clearance. This ICR includes some of the ICRs from the previously approved final rule. The program integrity data collections and third-party disclosure requirements will assist HHS in determining Exchange compliance with Federal standards. The data collection and third-party disclosure requirements will also assist HHS in monitoring QHP issuers in FFEs for compliance with Federal QHP issuer standards. The data collected by health insurance issuers and Exchanges will help to inform HHS, Exchanges, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange, and SHOP. *Form Number:* CMS–10516 (OMB Control Number: 0938–1277); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 1,915; *Number of Responses:* 1,915; *Total Annual Hours:* 48,732. (For questions regarding this collection, contact Leigha Basini at (301) 492–4380.)

2. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Essential Community Provider Data Collection to Support QHP Certification for PYs 2021–2023; *Use:* For plan years beginning on or after January 1, 2021, Health and Human Services (HHS) intends to continue collecting more complete provider data for inclusion on the HHS Essential Community Provider (ECP) list to ensure a more accurate reflection of the universe of qualified available ECPs in a given service area that can be counted toward an issuer's satisfaction of the ECP standard. HHS intends to continue collecting these data on qualified and available ECPs directly from providers through the online ECP petition. Providers will submit an ECP petition to be added to the HHS ECP list or update required data fields to remain on the list. *Form Number:* CMS–10561 (OMB control number: 0938–1295); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit Institutions); *Number of Respondents:* 14,260; *Total Annual Responses:* 14,260; *Total Annual Hours:* 7,468. (For policy questions regarding this collection contact Deborah Hunter at (202) 309–1098).

Dated: August 7, 2018.

William N. Parham, III,

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

[FR Doc. 2018–17190 Filed 8–9–18; 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: Multi-site Implementation Evaluation of Tribal Home Visiting (MUSE).

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services has launched a national multi-site evaluation of Tribal Maternal, Infant, and Early Childhood Home Visiting (TMIECHV) programs. MUSE is the first multi-site, multi-model study that will systematically explore how home visiting programs are operating across diverse tribal contexts and identify factors that lead to programs' success. The evaluation will provide information that will help the federal government design and support federal home visiting initiatives in tribal communities and similar populations. Evaluation findings will also assist programs with improving home visiting services for children and families. The aims of MUSE are to (1) identify and describe the primary influences shaping tribal home visiting program planning; (2) identify and describe how home visiting programs are being implemented; and (3) explore supports to home visiting implementation in tribal communities. To address these aims, the evaluation will gather data about participating home visiting programs from program staff and parent program participants and utilize administrative program data.

The current Notice is specific to data collection efforts needed to address the MUSE aims. Quantitative and qualitative data will be collected from program staff and parent program participants at each program site. Program sites will also submit local administrative data to the evaluation team. After obtaining informed consent from all respondents, data collection will include: (1) A Caregiver Enrollment Form, (2) a survey of caregivers receiving home visiting services at enrollment (baseline), (3) a follow-up survey of caregivers receiving home visiting services at 6 and 12 months, (4) a Rapid Reflect self-completed questionnaire completed by caregivers after selected home visits; (5) a Rapid Reflect self-completed questionnaire completed by home visitors after selected home visits; (6) a one-time survey of home visitors; (7) a one-time survey of program coordinators/managers; (8) a one-time survey of program directors; (9) a one-time survey of local program evaluators; (10) a one-time survey for program managers on program implementation, (11) qualitative interviews of home visitors at each site; (12) qualitative interviews of program coordinators/managers and program directors at each site; (13) qualitative interviews of local program evaluators at each site; (14) qualitative interviews of caregivers receiving home visiting services; (15) a log of implementation activities completed by program coordinators/managers on training, family group activities, and supervision; and 156 electronic compilation and submission of administrative program data.

All data collection will be used to generate information about how tribal home visiting program services are planned and delivered, and about what individual, organizational, community, and external factors support successful program implementation.

Respondents: Caregivers enrolled in TMIECHV programs and TMIECHV program staff (program directors, program coordinators/managers, home visitors, and local program evaluators).

Annual Burden Estimates: We will request approval for three years, which will accommodate an approximate 27 month data collection period and any potential delays in the data collection timeline.

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Caregiver Enrollment Form	93	31	14	.08	35
Caregiver Survey—Baseline	565	188	1	.25	47
Caregiver Survey—6 & 12 Month Follow-up	380	127	2	.50	127
Rapid Reflect Self-Completed Home Visit Questionnaire for Caregivers	1,136	[1] 568	6	.08	273
Rapid Reflect Self Completed Home Visit Questionnaire for Home Visitors	93	[1] 47	66	.2	620
Home Visitor Survey	81	27	1	1.17	32
Program Coordinator/Manager Survey	21	7	1	1	7
Program Director Survey	21	7	1	.75	5
Local Program Evaluator Survey	30	10	1	.5	5
Program Implementation Survey	34	11	1	.25	3
Qualitative Interviews of Home Visitors	42	14	1	2	28
Qualitative Interviews of Program Coordinators/Managers and Program Directors	34	11	1	1.5	17
Qualitative Interviews of Local Program Evaluators	30	10	1	1.5	15
Qualitative Interviews of Caregivers	51	17	1	1	17
Implementation Logs	17	[1] 9	24	.67	145
Administrative Program Data	17	[1] 9	4	24	864

[1] The annual number of respondents is annualized over 2 years for instruments that are completed by respondents on an ongoing basis.

Estimated Total Annual Burden Hours: 2,240.

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, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@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.

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–17121 Filed 8–9–18; 8:45 am]

BILLING CODE 4184–74–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects

Title: Supplemental Nutrition Assistance Program (SNAP) Matching Program Performance Outcomes.

OMB No. 0970–0464.

Description: State agencies administering the Supplemental Nutrition Assistance Program (SNAP) are mandated to participate in a computer matching program with the federal Office of Child Support Enforcement (OCSE). The matching program compares SNAP applicant and recipient information with employment and wage information maintained in the National Directory of New Hires (NDNH). The outcomes of the compared information help state SNAP agencies with administering the program and verifying and determining an individual's benefit eligibility. To receive NDNH information, state agencies enter into a computer matching agreement and adhere to its terms and conditions, including providing OCSE with annual performance outcomes attributable to the use of NDNH information.

The Office of Management and Budget (OMB) requires OCSE to periodically report performance measurements demonstrating how the use of information in the NDNH supports OCSE's strategic mission, goals, and objectives. OCSE will provide the annual SNAP performance outcomes to OMB.

The information collection activities for the SNAP performance outcomes reports are authorized by: (1) Subsection 453(j)(10) of the Social Security Act (42 U.S.C. 653(j)(10)), which allows the Secretary of the U.S. Department of Health and Human Services to disclose information maintained in the NDNH to state agencies administering SNAP under the Nutrition Act of 2008, as amended by the Agriculture Act of 2014; (2) the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), which sets forth the terms and conditions of a computer matching program; and, (3) the Government Performance and Results Modernization Act of 2010 (Pub. L. 111–352), which requires agencies to report program performance outcomes to the Office of Management and Budget and for the reports to be available to the public.

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

Information collection title	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SNAP Matching Program Performance Outcomes	53	1	1.92	101.76

Estimated Total Annual Burden Hours: 101.76.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 330 C Street SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

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 Sargis,

Reports Clearance Officer.

[FR Doc. 2018–17152 Filed 8–9–18; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2582]

Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the following 1-day public workshop entitled ''Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation.'' The purpose of the public workshop is to provide a forum to discuss the current state and future directions of the collection of human data on the potential skin toxicity with the use of medications applied topically. The workshop will review current approaches to the collection of human data during the clinical development of topical drug products. The workshop will also address the impact of human skin toxicity studies on drug labeling and consider alternative approaches to providing information about skin toxicity.

DATES: The public workshop will be held on September 10, 2018, from 8:30 a.m. to 4 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by October 10, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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 October 10, 2018. The