

based on which state issued the driver's license. For detailed information, please refer to the Department of Homeland Security (DHS) website: At <http://www.dhs.gov>. When planning a visit to a federal facility, visitors who have further questions about acceptable forms of identification are encouraged to contact the facility to determine acceptable identification.

Participants will also be subject to a vehicle security inspection before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on federal property include but are not limited to, alcoholic beverages, illegal narcotics, explosives, firearms or other dangerous weapons (including pocket knives), dogs or other animals except service animals. Once cleared for entry to the complex participants will be directed to visitor parking by a security officer.

To ensure expedited entry into the building it is recommended that participants have their ID and a copy of their written meeting registration confirmation readily available and that they do not bring large/bulky items into the building. Participants are reminded that photography on the CMS complex is prohibited. We have also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The invited guests may not enter the building earlier than 45 minutes before the convening of the meeting each day.

Guest access to the complex is limited to the meeting area, the main entrance lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted off of the premises. Also be mindful that there will be an opportunity for everyone to speak and we request that everyone waits for the appropriate time to present their product or opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at any time. Additionally, our staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required at least 2 weeks prior to each public meeting to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

Foreign National Visitors are defined as Non-US Citizens, and non-lawful permanent residents, non-resident aliens or non-green-card holders.

Attendees that are foreign nationals must identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Building to Visit/Destination.
- Visit start date, start time, end date, end time.
- Visitor full name.
- Gender.
- Visitor Title.
- Visitor Organization/Employer.
- Citizenship.
- Birth Place (City, Country).
- Date of Birth.
- ID Type (Passport or State Department ID).
- Passport issued by Country.
- ID (passport) Number.
- ID (passport) issue date.
- ID (passport) expiration date.
- Visa Type.
- Visa Number.
- Purpose of Visit.

Dated: February 21, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-70, CMS-R-72, CMS-1557, and CMS-10185]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 April 30, 2018.

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 <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: William Parham 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-R-70 Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations

CMS-R-72 Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals

CMS-1557 Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations

CMS-10185 Medicare Part D Reporting Requirements and Supporting Regulations

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:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: Obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment. *Form Number:* CMS-R-70 (OMB control number: 0938-0426); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profits; *Number of Respondents:* 400; *Total Annual Responses:* 21,200; *Total Annual Hours:* 42,400. (For policy questions regarding this collection contact Tennille Coombs at 410-786-3472.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. *Form Number:* CMS-R-72 (OMB control number: 0938-0443); *Frequency:* Reporting—On

occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 2,590; *Total Annual Responses:* 5,228; *Total Annual Hours:* 2,822. (For policy questions regarding this collection contact Tennille Coombs at 410-786-3472).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations; *Use:* The form is used to report surveyor findings during a CLIA survey. For each type of survey conducted (*i.e.*, initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. *Form Number:* CMS-1557 (OMB control number: 0938-0544); *Frequency:* Biennially; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions, State, Local or Tribal Governments and Federal Government); *Number of Respondents:* 19,183; *Total Annual Responses:* 9,592; *Total Annual Hours:* 4,796. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385).

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* Data collected via Medicare Part D Reporting Requirements is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Each section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, *e.g.* Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

For CY2019 Reporting Requirements, the following 6 reporting sections will be reported and collected at the

Contract-level or Plan-level: (1) Enrollment and Disenrollment—to evaluate sponsors’ processing of enrollment, disenrollment, and reinstatement requests in accordance with CMS requirements. (2) Medication Therapy Management (MTM) Programs—to evaluate Part D MTM programs, and sponsors’ adherence to CMS requirements. (3) Grievances—to assess sponsors’ compliance with timely and appropriate resolution of grievances filed by their enrollees. (4) Improving Drug Utilization Review Controls—to determine the impact of formulary-level edits at point of sale in sponsors’ processing of opioid prescriptions. (5) Coverage Determinations and Redeterminations—to assess sponsors’ compliance with appropriate resolution of coverage determinations and redeterminations requested by their enrollees. (6) Employer/Union Sponsored Sponsors—to ensure PDPs and the employer groups that contract with the PDPs properly utilize appropriate waivers and modifications.

Form Number: CMS–10185 (OMB control number: 0938–0992); *Frequency:* Annually and semi-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 627; *Total Annual Responses:* 13,603; *Total Annual Hours:* 14,748. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008.)

Dated: February 23, 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

Proposed Information Collection Activity; 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 survey of parent program participants at enrollment (baseline), (2) a follow-up survey of parent program participants at 6 and 12 months, (3) the MUSE Family Resources Check-in administered to parent program participants at baseline and 12 months (4) a Rapid Reflect self-completed questionnaire completed by parent program participants 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) qualitative interviews of home visitors at each site; (11) qualitative interviews of program coordinators/managers and program directors at each site; (12) qualitative interviews of local program evaluators at each site; (13) qualitative interviews of program participants; (14) a log of implementation activities completed by program coordinators/managers on staffing, training, family group activities, and supervision; and (15) 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: Parent participants 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 two-year 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
Participant Survey—Baseline	423	141	1	.25	35
Participant Survey—6 & 12 Month Follow-up	312	104	2	.50	104
Family Resources Check-in—Baseline and 12 Month Follow-up	354	118	2	.25	59
Rapid Reflect Self-Completed Home Visit Questionnaire for Participants	1,394	1,697	12	.08	669
Rapid Reflect Self Completed Home Visit Questionnaire for Home Visitors	93	147	180	.2	1,692
Home Visitor Survey	81	27	1	1.17	32
Program Coordinator/Manager Survey	21	7	1	1	7
Program Director Survey	21	7	1	1	7