

approved collection; *Title:* Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program—Contracting Forms; *Use:* Since 1989, Medicare has been paying for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) (other than customized items) using fee schedule amounts that are calculated for each item or category of DMEPOS identified by a Healthcare Common Procedure Coding System (HCPCS) code. Payments are based on the average DMEPOS supplier charges on Medicare claims from 1986 and 1987 and are updated annually on a factor legislated by Congress. For many years, the Government Accountability Office (GAO) and the Office of Inspector General (OIG) of the United States (U.S.) Department of Health and Human Services (HHS) have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DMEPOS. Due to reports of Medicare overpayment of DMEPOS, Congress required that the Centers for Medicare & Medicaid Services (CMS) conduct a competitive bidding demonstration project for these items. Accordingly, CMS implemented a demonstration project for this program from 1999–2002 which produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. Shortly after the successful competitive bidding demonstrations, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and mandated a phased-in approach to implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). This statute specifically required the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the U.S. for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the Medicare DMEPOS Competitive Bidding Program (the Program).

CMS conducted its first round of bidding, Round 1, for the Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor (CBIC). CMS published a Request for Bids (RFB) and instructions for DMEPOS suppliers to submit their bids to participate in the Program. During this first round of bidding, DMEPOS suppliers from across the U.S.

submitted bids to furnish competitively bid item(s) to Medicare beneficiaries residing or traveling to Round 1 CBAs. CMS evaluated these bids and contracted with those bidders that met all program requirements. Round 1 was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed the Program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the Program which included, but was not limited to: a delay of Round 1 (competition to begin in 2009) and Round 2 of the Program (competition to begin in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy from Round 1 and Group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to bidders regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of MIPPA specified that the competition for national mail-order (NMO) items and services may be phased in after 2010. This section of MIPPA also specified that competitions to phase-in additional areas could occur after 2011. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011. The Affordable Care Act (ACA), enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a NMO competition for diabetes testing supplies (DTS) at the same time as Round 2. The Round 2 and NMO DTS contracts and prices were implemented on July 1, 2013.

The MMA requires the Secretary to recompetete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except NMO DTS expired on December 31, 2013. (Round 1 Rebid contracts for NMO DTS ended on December 31, 2012.) The competition for the Round 1 Recompetete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Recompetete contract period expired on December 31, 2016. Round 1 2017 contracts were effective on January 1, 2017, and expired on December 31, 2018. Round 2 and NMO DTS contracts and prices expired on June 30, 2016. Round 2 Recompetete and the NMO DTS Recompetete contracts became effective

on July 1, 2016, and expired on December 31, 2018.

On October 31, 2018, CMS issued a final rule (CMS–1691–F) requiring changes to bidding and pricing methodologies to be implemented under the next round of the Program. As a result, starting January 1, 2019, there was a temporary gap in the entire Program that lasted two years until December 31, 2020. When the program resumed in January 2021, CMS implemented a consolidated round of competition to include most Round 1 2017 and Round 2 Recompetete CBAs for Round 2021. However, due to the 2019 novel coronavirus (COVID–19) pandemic, and the unexpected bid evaluation results, CMS only awarded Round 2021 contracts for two product categories: Off-The-Shelf (OTS) Back and OTS Knee Braces. As a result, this Paperwork Reduction Act (PRA) package reflects a significant reduction in burden, compared to previous packages, for Round 2021 which was implemented on January 1, 2021, and will conclude on December 31, 2023. This iteration of the package currently approved under OMB control number 0938–1408 is based on data from the first year of Round 2021 (January 1, 2021–December 31, 2021). *Form Number:* CMS–10744 (OMB control number: 0938–1408); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for profits and Not-for-profit institutions); *Number of Respondents:* 179; *Total Annual Responses:* 121,407; *Total Annual Hours:* 97,069. (For policy questions regarding this collection contact Joe Bryson at 410–786–2986.)

Dated: December 27, 2022.

**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

#### Submission for Office of Management and Budget Review; Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting an Annual Report to the Secretary (Office of Management and Budget #0970–0409)

**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 revisions to the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal MIECHV) Guidance for Submitting Reports to the Secretary (Office of Management and Budget (OMB) #0970–0409; expiration September 30, 2024). Guidance under this OMB number includes that for an annual report and that for a final report. This request is for review of the final report guidance. There are no changes proposed to the guidance for the annual report.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about 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.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed 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 MIECHV Program for states and jurisdictions submit an annual and a final 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.

ECD, 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 annual and final report guidance specifies that grantees must address the following:

- Update and reflections on meeting Home Visiting Program Goals and Objectives
- Update and reflections on Home Visiting Programs in Targeted Community(ies)
- Update and reflections on meeting Legislatively Mandated Benchmark Requirements
- Update and reflections on Rigorous Evaluation Activities
- Update and reflections on Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Update and reflections on Dissemination Activities
- Update and reflections on Administration of Home Visiting Program
- Update and reflections on Technical Assistance Needs

Previously, the guidance included information about both the annual and the final reports from grantees. In 2021, ECD separated out the annual report guidance and received OMB approval for that in September 2021. ECD is now requesting review of guidance specific to the final report.

*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 .....	30	1	25	750
Final Report to the Secretary .....	30	*.33	25	248

\* Note that this is estimated to be .33 because grantees provide one final report over the three-year approval period.

*Estimated Total Annual Burden Hours:* 998.

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

Mary B. Jones,  
ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Temporary Assistance for Needy Families (TANF) Financial Report, ACF–196T (OMB #0970–0345)**

**AGENCY:** Office of Family Assistance, 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) is requesting a 3-year extension of the Temporary Assistance for Needy Families (TANF) Financial Report, Form ACF–196T (Office of Management and Budget (OMB) #0970–0345, expiration April 30, 2023). ACF is proposing minor