



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10633 and CMS-10744]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 (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 **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail 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 N. 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-10633 QIC Demonstration Evaluation Contractor (QDEC): Analyze Medicare Appeals to Conduct Formal Discussions and Reopening's with DME Suppliers and Part A Providers

CMS-10744 Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program – Contracting Forms

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:* Revision with change of a currently approved collection; *Title of Information Collection:* QIC Demonstration Evaluation Contractor (QDEC): Analyze Medicare Appeals to Conduct Formal Discussions and Reopening's with DME Suppliers and Part A Providers; *Use:* The Formal Telephone Discussion Demonstration and Reopening's Process is authorized under Section 402(a)(1)(F), U.S.C. 1395-1(a)(1)(F), of the Social Security Amendments of 1967. Primary and secondary data are needed to understand the effectiveness of the Demonstration in improving DME suppliers' and Part A providers' understanding of claims denial during Level 2 of the appeals process and facilitating more accurate

claim submission over time. Primary data are necessary to determine, from the perspective of participating DME suppliers and Part A providers, the quality of the formal telephone discussions, satisfaction with the formal telephone discussion process, and the effect of the formal telephone discussions on submitting accurate claims. These data will inform an evaluation of the demonstration's effectiveness in achieving more accurate claims submissions, and thus reducing the number of claims CMS must process each year.

All information collected through the evaluation of the Formal Telephone Demonstration and Reopening's Process will be used by CMS through the QDEC (IMPAQ International and its partner, Palmetto GBA) to conduct analyses of satisfaction with the formal telephone discussions, and determine whether further engagement with the QIC improves understanding of the reasons for claim denials.

CMS will use the results of the evaluation to make informed policy decisions regarding the effectiveness of this demonstration and whether or not the demonstration should become a permanent part of the appeals process. Ultimately, if the information shows that DME suppliers and Part A providers were able to submit more accurate claims on the first pass, and a reduced number of claims are put through the appeals process, the Federal Government could realize cost savings.

Form Number: CMS-10633 (OMB control number: 0938-1348); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 5,288; *Total Annual Responses:* 5,288; *Total Annual Hours:* 949.7. (For policy questions regarding this collection contact Lynnsie G. Kelley at 410-786-1155.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program – Contracting Forms; *Use:* The

Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“Medicare Modernization Act” or “MMA”). Section 302 of the MMA amended Section 1847 of the Social Security Act (the Act) to establish the competitive acquisition program and define program requirements.

Under the MMA, the DMEPOS Competitive Bidding Program was to be phased in so that competition under the program would first occur in 10 areas in 2007. The Centers for Medicare & Medicaid Services (CMS) completed the rulemaking process for the competitive acquisition of DMEPOS items and services in 42 CFR parts 411 and 414 published in the Federal Register Volume 72 on April 10, 2007. CMS conducted the Round 1 competition in 10 areas and for 10 DMEPOS product categories, and implemented the program on July 1, 2008. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted on July 15, 2008, made limited changes to the Competitive Bidding Program, including termination of existing contracts that were in effect and a requirement to re-bid Round 1.

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 metropolitan statistical areas (MSAs), bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a competition for National Mail Order (NMO) of diabetes testing supplies at the same time as Round 2. The Round 2 and NMO contracts and prices were implemented on July 1, 2013.

The MMA requires the Secretary to re-compete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except mail-order diabetes

testing supplies expired on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetes testing supplies ended on December 31, 2012.) The competition for the Round 1 Recompete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Recompete contract period expires on December 31, 2016. Round 1 2017 contracts will become effective on January 1, 2017 through December 31, 2018. Round 2 and NMO contracts and prices expired on June 30, 2016. Round 2 Recompete and the NMO Recompete contracts became effective on July 1, 2016, and expired on December 31, 2018. CMS will be implementing a consolidated round of competition to include all Round 1 2017 and Round 2 Recompete competitive bidding areas, referred to as Round 2021. Round 2021 will not include NMO, which will be competed again in future rounds of the program.

The forms included in this ICR were previously included in the ICR currently approved under 0938-1016. Due to the temporary gap in the DMEPOS Competitive Bidding Program, which started on January 1, 2019, we do not currently have any active PRA package for this specific collection of information (Form C, Subcontracting, Change of Ownerships, and Grandfathering). We are now seeking approval of a PRA package based on estimates from previous rounds of the program (specifically Round 2 Recompete and Round 1 2017) and without reference to changes in burden *Form Number:* CMS-10744 (OMB control number: 0938-New); *Frequency:* Occasionally (varies by form); *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 2,984; *Total Annual Responses:* 271,597; *Total Annual Hours:* 31,121. (For policy questions regarding this collection contact Julia Howard at 410-786-8645.)

Dated: June 25, 2020.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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