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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10744]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 December 4, 2020.

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. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

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 website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT:
William Parham at (410) 786–4669.

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:

1. *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 recompete 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: October 30, 2020.

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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10757]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On March 13, 2020, the President declared a national emergency in response to the public health emergency (PHE) caused by the SARS-CoV-2 virus, otherwise known as COVID-19. The CARES Act was published in response to the PHE that requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test.” The September 2, 2020 interim final rule with comment (CMS-3401-IFC) requires laboratories to report SARS-CoV-2 test results in a manner and frequency specified by the Secretary. Consistent with the CARES Act laboratory reporting requirements, CMS made modifications to the CLIA regulations to meet the SARS-CoV-2 test result reporting provisions related to the Secretary’s Public Health Emergency declaration with respect to COVID-19.

DATES: Comments must be received by November 19, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted within 15 days 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 <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR 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.

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS-10757 CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting

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. 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting; *Use:* In order to be in compliance with the new CLIA mandatory SARS-CoV-2 test results reporting requirements, laboratories will need to develop a mechanism to track, collect, and report test results as well as update policies and procedures. In addition, Accreditation Organizations (AOs) and Exempt States (ESs) will need to update laboratory standards to reflect the reporting requirements and update policies and procedures related to reporting laboratories that do not report test results as required.

The CDC has an information collection request (OMB Control Number 0920-1299) in order to collect laboratory data related to the COVID-19 Pandemic Response. The CMS package (ICR) is for laboratory implementation and CMS monitoring of compliance with the CMS-3401-IFC CLIA-certified laboratory reporting requirements.

The information collected by the Centers for Medicare and Medicaid Services (CMS) or its designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections will be used to determine a laboratory’s compliance with the CLIA SARS-CoV-2 test result reporting requirements. During an on-site survey, the Condition-level laboratory requirement at 42 CFR 493.41 and 493.1100(a) are assessed for compliance. The information is used by CMS in determining appropriate Civil Money Penalties (CMPs) when laboratories fail to report as required. *Form Number:* CMS-10757 (OMB control number: 0938-NEW); *Frequency:* Daily; *Affected Public:* Private Sector Not-for-profit institutions and State, Local and Tribal Governments; *Number of Respondents:* 77,033; *Total Annual Responses:* 308,114; *Total Annual Hours:* 1,386,873 (For policy questions regarding this