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.

[FR Doc. 2020–24442 Filed 11–3–20; 8:45 am]

BILLING CODE 4120–01–P

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

collection contact Sarah Bennett at 410–786–3354.)

Dated: October 30, 2020.

William N. Parham, III,

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

[FR Doc. 2020–24435 Filed 11–3–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9126–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2020, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I. CMS Manual Instructions	Ismael Torres	(410) 786–1864
II. Regulation Documents Published in the FEDERAL REGISTER	Terri Plumb	(410) 786–4481
III. CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV. Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V. FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI. Collections of Information	William Parham	(410) 786–4669
VII. Medicare—Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII. American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX. Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X. One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI. National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786–3365
XIII. Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV. Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV. Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for