DATE: October 14, 2020

TO: Paul Ray
Administrator, OIRA

FROM: Lee Fleisher, MD
Director, CCSQ

SUBJECT: Request for Emergency Clearance for the Information Collection Request Related to SARS-CoV-2 Test Results Reporting

Emergency Justification

The Centers for Medicare & Medicaid Services (CMS) is requesting that a new information collection request associated with the CMS-3401-IFC be processed as an Emergency in accordance with the implementing regulations of the Paperwork Reduction Act of 1995 at 5 CFR 1320.13(a)(2)(i). The CLIA information collection request is related to SARS-CoV-2 Test Results Reporting, which is associated with the COVID-19 Public Health Emergency (PHE). CMS will be unable to assess laboratory compliance with CLIA SARS-CoV-2 CLIA reporting requirements if the normal, non-emergency clearance procedures are followed. Laboratories will need to develop a mechanism to track, collect, and report SARS-CoV-2 test results. CMS' needs to have the ability to collect the SARS-CoV-2 test result reporting information from laboratories in order to determine compliance. This collection is of utmost importance in order to meet the Administration's priorities.

CMS will not be able to assure a rapid and thorough public health response to the COVID-19 pandemic unless we have complete and comprehensive laboratory testing data that can improve both the response to SARS-CoV-2 and treatment of COVID-19. These data can contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. We believe that public harm is reasonably likely to result if normal clearance procedures are followed.

Specifically, we are requesting emergency approval for information collection requirements (ICRs) related to SARS-Co-V-2 test result reporting requirements (42 CFR 493.41, 42 CFR 493.555 and 42 CFR 493.1100(a)). In accordance with 5 CFR 1320.13(a)(2)(ii), we believe that the unanticipated public health emergency (PHE) justifies the requirements for CLIA-certified laboratories and Accreditation Organizations (AOs) to collect this information.

Background

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." Consistent with the CARES Act laboratory reporting requirements, CMS has made modifications to the CLIA regulations. 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. These regulatory changes update the Clinical Laboratory Improvement Amendments laboratory requirements to meet the SARS-CoV-2 test result reporting provisions related to the Secretary's Public Health Emergency declaration with respect to COVID-19.

All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report, regardless of the type of laboratory (type of CLIA certificate) performing the testing. All negative and positive SARS-CoV-2 results must be reported irrespective of the method (e.g., molecular, lateral flow) used.

The regulatory amendments at §§ 493.41 and 493.1100(a) require all CLIA-certified laboratories, including those holding a Certificate of Waiver (CoW) and Certificate for Provider Performed Microscopy (PPM), to report SARS-CoV-2 test results to the Secretary for the duration of the PHE for COVID-19, and, that failure to do so will result in a condition level violation of the CLIA regulations. If a laboratory does not report required SARSCoV-2 test results, CMS will impose a CMP as required under §§ 493.1804 and 493.1834.
The Exempt States (ESs) (i.e., Washington and New York (partial exemption) are generally approved by CMS to operate their own oversight programs so we would expect that the ESs would report those laboratories that fail to report SARS-CoV-2 test results as required to CMS. In this case, the ES would impose the CMPs based on their updated CMS-approved standards. We would expect ESs to have an equivalent CMP imposition structure to CMS.

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 implemention and CMS monitoring of compliance with the CMS-3401-IFC CLIA-certified laboratory reporting requirements.

Timeline

October 15, 2020

- Emergency Information Collection Request formally submitted to OMB.

October 20, 2020

- OMB approval received.

October 22, 2020

- 15-day FR notice submitted to the Office of the Federal Register (OFR) for publication.

October 27, 2020

- Target publication date for 15-day FR notice to initiate standard OMB approval process.
- Start of the 15-day public comment period.
- PRA package posted for public review on the CMS PRA web site.

November 10, 2020

- End of 15-day comment period.
- CMS reviews and responds to comments, as needed.
- PRA package revised as needed.

November 17, 2020

- OMB approval received.