DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-37-CLIA, NH

DATE: **August 26, 2020**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency**

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, an interim final rule with comment period (IFC) went on display at the Federal Register.
- CLIA regulations have been updated to require all laboratories to report SARS-CoV-2 test results in a standardized format and at a frequency specified by the Secretary.
- Failure to report SARS-CoV-2 test results will result in a condition level violation of the CLIA regulation and may result the imposition of a Civil Money Penalty (CMP) as required under §§ 493.1804 and 493.1834.
- Long-Term Care (LTC) Enforcement requirements at 42 CFR part 488 have been revised to include requirements specific to the imposition of a CMP for nursing homes that fail to report requisite COVID-19 related data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) per §483.80(g)(1) and (2).
- LTC Facility Testing Requirements for Staff and Residents- Facilities are required to test staff and to offer testing to all nursing home residents.

Background

On March 13, 2020, the President declared a national emergency, retroactive to March 1, 2020, in response to the unprecedented public health emergency (PHE) caused by the SARS–CoV–2 virus, otherwise known as COVID-19. CMS has remained committed to controlling and preventing the transmission of COVID-19 by taking swift actions to address this PHE and its impact on all Medicare/Medicaid beneficiaries receiving care from all CMS certified

provider/supplier types. In addition, Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act[1] 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, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration with respect to COVID-19." The Secretary's guidance calls for a rapid and thorough public health response to the COVID-19 pandemic, which necessitates reporting of all SARS-CoV-2 test results.

Consistent with the CARES Act laboratory reporting requirements, CMS has made modifications to the CLIA regulations. The August 25, 2020 interim final rule with comment requires laboratories to report SARS-CoV-2 test results in a manner and frequency specified by the Secretary. These regulatory changes are intended to 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. On June 4, 2020, the Secretary of HHS published reporting guidance related to all laboratories performing SARS-CoV-2 testing. The methods for submission, required data elements, and additional information can be found in that guidance and accompanying FAQs.[2] Laboratories performing SARS-CoV-2 test will be required to follow this guidance or any updates to this guidance.

Assuring a rapid and thorough public health response to the COVID-19 pandemic relies on having complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the public health 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.

New and/or Modified CLIA Regulations for SARS-CoV-2 Test Results

These new or modified CLIA regulations apply to all CLIA-certified laboratories performing SARS-CoV-2 testing. New or updated language is in italics.

New/Modified Requirements

- **§ 493.2 Definitions.** (*Modified*):
  Condition level requirements means any of the requirements identified as "conditions" in *§ 493.41 and* subparts G through Q of this part.
- **§ 493.41 Condition: Reporting of SARS-CoV-2 test results.** (*New*):
  During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.
- **§ 493.555(c) Federal review of laboratory requirements.** (*New*):

[1] https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf
[2] https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf

(c) The organization's or State's agreement with CMS that requires it to do the following: *(6) Notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a).*

- **§ 493.1100 Condition: Facility administration.** (*New)*
  (a) Reporting of SARS-CoV-2 test results. During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.
- **§ 493.1804 General considerations.** (*Modified*)
  (c) Imposition of alternative sanctions.
  (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (*Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.*)
- **§ 493.1834 Civil money penalty.** (*New*)
  (d)(2)(iii) *For a condition level deficiency under §§ 493.41 or 493.1100(a), a CMP of $1,000 for the first day of noncompliance and $500 for each additional day of noncompliance.*

Reporting Requirement for SARS-CoV-2 Test Results

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. Molecular (RT-PCR) tests detect the virus's genetic material and antigen tests detect specific proteins on the surface of the virus. Both types of tests are used to detect active or acute infection with SARS-CoV-2. Serology (antibody) testing, is used to look for the presence of antibodies which are proteins produced by the body in response to infections.

Please note that health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings will be required to report test results under this regulation.

CLIA Survey Guidance

CMS is continuing to assess automated methods to gather data for determining compliance with the laboratory reporting mandate. The use of available data will be augmented by the following:

Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PPM)

Generally, laboratories that have a CoW or PPM certificate are not routinely surveyed. For the duration of the PHE, on-site surveys of 5% of CLIA CoW and PPM laboratories will be conducted for the purpose of determining compliance with:

- Implementing the new CLIA Condition-level regulation (493.41) pertaining to COVID-19 reporting requirements;
- Confirming that laboratories hold the appropriate type of CLIA certificate (i.e., not testing outside certificate); and
- In addition, PPM laboratories will be surveyed to assess for compliance with the applicable CLIA requirements for PPM procedures.

Complaints received in CoW or PPM laboratories should be investigated according to State Operations Manual (SOM) Chapter 5 procedures after consultation with CMS operations branch locations. Complaints related to SARS-CoV-2 testing or reporting will be prioritized. Complaint surveys will count as part of the 5% of surveys. The 5% of these laboratories will be spread over the three years of the PHE, rather than 5% annually.

It is recommended that new and updated CLIA applications that indicate testing for SARS-CoV-2, as well as communication from laboratories indicating the addition of this testing received since February 1, 2020, be used to prioritize surveys.

Certificate of Compliance (CoC) and Certificate of Registration (CoR)

CoC and CoR laboratories will be assessed for compliance with the reporting requirement at 493.1100(a) at the time of an initial, recertification, or complaint survey. Review of a laboratory's reporting documentation should be incorporated into the routine survey process.

CLIA Citation Guidance

Failure of a CLIA-certified laboratory to report SARS-CoV-2 test results as required by the new requirements at §§ 493.41 and 493.1100(a) will result in a **mandatory citation**. This applies to all CLIA certificate types. A laboratory must have documentation that they have reported all SARS-CoV-2 test results.

- D1002 (*new D-Tag*) must be used for noncompliance with reporting SARS-CoV-2 waived testing results; and
- D3000 must be used for noncompliance with reporting SARS-CoV-2 nonwaived testing results

Laboratories operating under a Certificate of Waiver will be cited at **D1002**; all other certificate types, including PPMs, will be cited at **D3000**.

Imposition of Civil Money Penalties (CMPs)

The regulatory amendments at §§ 493.41 and 493.1100(a) require all CLIA-certified laboratories, including those holding a CoW and 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 SARS-CoV-2 test results, CMS will impose a CMP as required under §§ 493.1804 and 493.1834. Such CMPs will be $1000 for the first day of noncompliance with the new reporting requirements, and $500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results.

The Exempt States (ESs) 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.

New Long-Term Care Enforcement Regulations

Imposition of CMP for Failure to Report COVID-19 data to CDC NHSN

On May 8, 2020, CMS published an interim final rule with comment period (May 8th IFC), titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program".[3] The May 8th IFC contained a new reporting requirement at §483.80(g)(1) and (2) for nursing homes to report confirmed or suspected COVID-19 cases, and other related data. This requirement was intended to support and strengthen COVID-19 surveillance locally and nationally, as well as increase transparency for residents, their representatives, and families.

To coincide with the new reporting requirement, CMS released policy memo QSO 20-29-NH, which detailed how CMS will enforce the new reporting requirement identified at new tag F884.The August 26th IFC adds a new regulation at § 488.447 that codifies this process for enforcingthe reporting requirement using a CMP for each week a facility fails to report in the CDC NHSN system. This new regulation specifies the CMP amount starting at $1000 for the first occurrence of noncompliance with the reporting requirements at 483.80(g)(1)-(2) (i.e., the failure to report), and increasing by $500 for each subsequent time the nursing home fails to report COVID-related data. The maximum allowable amount is $6,500 per citation. The regulation also notes that compliance with these reporting requirements are assessed weekly, that a plan of correction is not required to be submitted, and that these CMP amounts are subject to annual adjustments for inflation under 45 CFR §102.3. Finally, the IFC notes that this regulation will continue to be in effect for up to one year beyond the end of the PHE.

LTC Facility Testing Requirements for Staff and Residents

Testing staff and residents is a critical component to other infection prevention and control (IPC) actions aimed at preventing SARS-CoV-2 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents. Therefore, the new interim final rule, CMS-3401-IFC, also includes new requirements at 42 CFR § 483.80(h), that the facility test all staff and offer tests for all residents for COVID-19 as specified by the Secretary. CMS will issue guidance related to these new requirements, including a revised COVID-19 Focused Survey for Nursing Homes to reflect the new requirement that will be cited at tag F886 in an upcoming policy memorandum which will be released on the CMS website.

Contact: Questions related to CLIA may be submitted to: LabExcellence@cms.hhs.gov. Question related to LTC Enforcement may be submitted to: DNH_Enforcement@cms.hhs.gov. Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

[3] https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State Agency/CMS Branch Location training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: CLIA Branch Managers
CLIA Location Staff