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Special Bulletin

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CMS Releases Guidance for COVID-19 Reporting Requirements for Laboratories and Long-term Care Facilities

The Centers for Medicare & Medicaid Services (CMS) recently issued new surveyor guidance for COVID-19 laboratory test result reporting for Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories. The new guidance complements a Sept. 2 interim final rule. Laboratories are expected to be in compliance with the new requirements no later than Sept. 23. After that date, laboratories not in compliance will be subject to civil monetary penalties (CMPs). CMS also released new enforcement regulations for long-term care (LTC) facility reporting requirements. Details are discussed below:

Laboratory Reporting Requirements
All laboratories that perform or analyze any COVID-19 test (molecular, antigen, antibody, etc.) **must** report data, regardless of the type of CLIA certificate the laboratory has. In addition, all negative and positive test results, irrespective of method, **must** be reported. *Any facility using point-of-are COVID-19 testing devices under a CLIA waiver also is* ***required to report.***

- Laboratories operating under a certificate of waiver (CoW) and certificate for provider-performed microcopy (PPM) are generally not routinely surveyed; however, for the duration of the public health emergency, 5% of CLIA CoW and PPM laboratories will be surveyed for compliance with COVID-19 reporting requirements, assuring the appropriate CLIA certificate is held, and compliance for CLIA requirements for PPM procedures.
- Laboratories operating under a certificate of compliance (CoC) and certificate of registration (CoR) will be assessed for compliance at the time of an initial, recertification or complaint survey.

Failure to comply with the reporting requirements will result in a **mandatory citation**. All laboratories **must** have documentation demonstrating compliance. After Sept. 23, a laboratory's failure to report COVID-19 test results **will result in a condition-level violation** of the CLIA regulations. For laboratories not in compliance after Sept. 23, CMS will impose a $1,000 CMP for the first day of noncompliance and a $500 CMP for each subsequent day of noncompliance.

In those instances where exempt states (ESs) conduct their own oversight of programs, the agency expects those ESs to report laboratories that fail to report and impose CMPs based on their own updated CMS-approved standards.

Long-term Care Enforcement Regulations
In May, CMS released a separate interim final rule requiring nursing homes to report confirmed or suspected COVID-19 cases, and other related data. Following the release of the interim final rule, CMS issued a policy memo detailing how the agency will enforce the new reporting requirements. Subsequently, the Sept. 2 interim final rule added an enforcement mechanism to the LTC reporting requirements by codifying the use of CMPs for each week a facility fails to report.

Moving forward, LTCs that fail to comply with reporting requirements **will be subject to CMPs**. The amount of the CMP begins at $1,000 for the first occurrence of noncompliance and increases by $500 for each subsequent time the facility fails to report COVID-19-related data. The maximum allowable CMP amount is $6,500 per citation. The compliance reporting requirements will be assessed weekly and the regulation will continue to be in effect for up to one year beyond the end of the public health emergency.

Further Questions
If you have questions, please contact the AHA at 800-424-4301.