HEALTH CARE LEGISLATION EDUCATION PRESENTATION

CARES ACT SECTION 18115PDF ICON

COVID-19
RAPID ANTIBODY TEST
REPORTING

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AGENDA

- COVID-19 chronological summary of events
- COVID-19 Testing and Tracking Legislation
- COVID-19 Reporting protocols
- COVID-19 Reporting requirements what, who and how
- COVID-19 Legislation execution challenges
- Summary

COVID-19 PANDEMIC ISSUES

December 2019	January 2020	February 2020	April 2020	June 2020
Global COVID-19 Pandemic is identified In China. CARES Act initiative launched.	United States officials Are alerted of the potential For the COVID-19 pandemic To enter the United States	Rapid spread in hot spots of The United States, create a Dire shortage of PPE and analytical resources	Options for sourcing, new Testing methods and additional resources are identified. Several versions of COVID-19 antibody testing are deployed.	June 6, 2020 CDC, NIH and FDA require strict reporting of ALL COVID-19 antibody testing to include serological, blood, nasal, pharynx and others.

CARES Act Section 18115pdf icon

TESTING & TRACKING LEGISLATION

- How to identify the magnitude
- Identify system overload and deficiencies
- Estimate impact to patient and public health & safety
- What system and where within the system is the most efficient process for tracking data
- Missing protocols for national disease reporting
- Lack of physical resources to execute a full test protocol
- Lack of appropriate human resource staffing to execute tracking
- Lack of LAB readiness and TEST cartridge production
- Limited communication with international sources and resources
- Limited communication with national interstate cross-boarder tracking

WHAT IS THE REPORTING PROTOCOL

OVERVIEW

- MISSION: The public health response to COVID-19 depends on comprehensive laboratory testing data.
- EXECUTION: Timely and accurate data will contribute to understanding COVID-19's impact and testing coverage and can contribute to the identification of supply chain issues for reagents and other materials.
- DELIVERABLES: The information below outlines reporting requirements for laboratories. Additional technical guidance on implementing the COVID-19 laboratory reporting requirement to comply with the CARES Act Section 18115pdf icon.

WHO MUST REPORT

- **All** laboratories with a Clinical Laboratory Improvement Amendments (CLIA)external icon certificate must report the results of the COVID-19 tests that they conduct to the appropriate state or local public health department.
- Laboratories are defined as:
  - Laboratories that perform clinical diagnostic testing under CLIA,
  - non-laboratory COVID-19 testing locations, and
  - other facilities or locations offering point-of-care testing or in-home testing related to COVID-19.
  - Laboratories must report data for all testing completed, which includes viral and antibody testing, for each individual tested. This data must be reported within 24 hours of test completion, on a daily basis, to the appropriate state or local public health department, based on the individual's residence.

HOW IT MUST BE REPORTED

- Laboratory data elements may be reported in the following ways:
  - Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with ordering provider or patient, as applicable.
  - Submit laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platformexternal icon), where the data will then be routed to the appropriate state and local authorities and routed to CDC after removal of personally identifiable information according to applicable rules and regulations.
  - Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state.
  - Public health departments will submit de-identified data to CDC on a daily basis, using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.

WHAT TO REPORT AND THE ISSUES RELATED

- There are forty (40) patient required demographic and data point information requirements for each test. To protect patient privacy, data that state and jurisdictional health departments send to CDC will be deidentified and will not include some patient-level information. The deidentified data shared with CDC will contribute to understanding COVID-19's impact, positivity trends, testing coverage, and will help identify supply chain issues for reagents and other materials.
- Lab test orders add on an additional seven (7) outlined reporting requirements. Anyone who orders a COVID-19 test, collects a specimen, or performs a laboratory test must make every reasonable effort to collect complete demographic information and must include these data when ordering a laboratory test to enable the entities that perform the test to report these data to state and jurisdictional health departments. When information is not available, ordering health care providers (or their designees), laboratories performing COVID-19 tests, and health departments should consider leveraging other information sources to obtain these data.
- A platform for standardization was first launched on March 6, 2020 and has been adjusted 111 times. CDC has posted a LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping Guide for COVID-19 test results for tests with emergency use authorization from the U.S. Food and Drug Administration (FDA) that can be used by clinical laboratories and instrument manufacturers. This specification supports the use of standardized LOINC and SNOMED Clinical Terms (CT) codes to improve the accuracy of reporting tests for the SARS-CoV-2 virus. Using these harmonized LOINC and SNOMED-CT codes helps ensure that the same type of test is represented uniformly across the United States.

EXECUTION PITFALLS & CHALLENGES

New guidance from HHSpdf iconexternal icon specifies what data must be reported to comply with the COVID-19 laboratory reporting requirement in CARES Act Section 18115. The new guidance requires facilities and ordering providers to gather more complete patient demographic information to send to state and local public health departments. State and local health departments will then forward the deidentified data to CDC.

Most asked QUESTIONS:

- Do ALL test results, positive and negative, require reporting?
- Will facilitators be required to ask AOE questions?
- What protocol is to be used in reporting AOE information?
- How will CDC extract from clinical reporting and CLER data?
- What security protocols have been implemented in the collection of AOE data?
- Have LOINC codes been assigned to these test and the testing protocols?
- How will the data reported to state and jurisdictional entities be used and monitored?

SUMMARY

- The current Health Care systems are not suitable for the integration of high-volume response measures.
- The existence of multiple platforms such as long hand, CPOE and various EMR programs create communication barriers.
- Electronic options are in the process of standardization. Electronic reporting options are available to reduce the burden on providers reporting test results. Laboratories that are not currently reporting electronically to their state or local health department and want assistance in establishing electronic reporting can contact CDC's Emergency Operations Center, Laboratory Reporting Working Group at eocevent405@cdc.gov.

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