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COVID-19 Testing – Additional Considerations

At the start of the COVID-19 pandemic, each state and the federal government announced various states of public health emergencies which enabled them to suspend or modify various laws, rules, and regulations to accommodate and focus on efforts to respond to the pandemic.

In the laboratory sector, this meant that several states relaxed or suspended state licensure rules and other regulations to accommodate and respond to testing during the pandemic. Additionally, several states adopted requirements specifically related to approval for COVID-19 testing. While some requirements are still in place, many of those public health emergency declarations have ceased and the laws, rules and regulations that laboratories relied on during the pandemic are no longer applicable.

Laboratories that responded to the unprecedented demand for testing specimens may have agreed to test specimens from states that they normally did not receive specimens from or entered into various arrangements with employers or potential third parties to collect specimens. The regulatory landscape has shifted since the beginning of the pandemic and as such laboratories must now review and maintain compliance with federal and state laws. However, to illustrate some notable changes, a few states and their particular requirements during this pandemic are highlighted here.

Notably, to test specimens from patients residing in the state of New York, a laboratory must be licensed by the Clinical Laboratory Evaluation Program. At the beginning of the pandemic, then-Governor Andrew Cuomo issued various executive orders relaxing the regulations and requirements, including those pertaining to clinical laboratories. Four of these orders were discontinued as of June 25, 2021, including: (1) the order permitting clinical laboratories holding a CLIA (Clinical Laboratory Improvement Amendments) certificate to perform testing on specimens from New York in the absence of a state-issued clinical laboratory permit; (2) the executive order permitting remote supervision; (3) allowing laboratories operating temporary collections stations or patient service centers to collect specimens from individuals suspected of or suffering from a COVID-19 infection; and (4) the suspension of the regulations requiring specimens to be examined only at the request of a licensed physician or other specifically-authorized individual. Clinical laboratories - whether out-of-state and which were granted a waiver, or those generally creating collection stations and allowing individuals to order their own tests - should reevaluate their practices given the discontinuance of these major executive orders.

Many states relaxed the rules regarding out-of-state personnel coming into the state to assist, respond to or mitigate the effects of COVID-19 and those personnel were permitted temporary licensure. Additionally, many states relaxed various regulations and enabled flexibilities to encourage telehealth. Many of the orders allowing for such accommodations have now ended.

Yet other states require a laboratory to get specific approval to provide COVID-19 testing, even if the laboratory's certificate includes virology. For example, any clinical laboratory in New Jersey that intends to perform COVID-19 testing must obtain state approval to add COVID-19 as a test prior to performing patient testing.

And in June 2021, Massachusetts issued a Commissioner of Public Health Order requiring clinical laboratories not already exempt under Massachusetts law and wishing to perform CLIA-waived COVID-19 testing, to apply for a temporary laboratory license. Additionally, such entities wishing to have extension sites must receive approval from the Department of Public Health.

As laboratories continue to respond to the COVID-19 pandemic, it is important that they continue to review the state and federal rules and regulations to ensure they remain in compliance.

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