



State of Nevada Board of Health

September 2, 2022

Update on Medical Laboratory Compliance Agreements After the State of Nevada Public Health Emergency Ended.

Beginning with the June 5, 2020, Nevada Board of Health (BOH) meeting through the June 3, 2022, BOH meeting, the Medical Laboratory agency of the Division of Public and Behavioral Health (DPBH) submitted to the board for approval, 67 compliance agreements for the regulations contained within the Nevada Administrative Code (NAC) 652. Of the 67 compliance agreements that were submitted for approval, there were 40 that would have been affected by the lifting of the Governor's Emergency Declaration which ended on May 20, 2022.

On April 19, 2022, an email was distributed to all laboratories that had submitted compliance agreements to the BOH for approval, to prepare for the lifting of the Governor's Directive which would terminate the terms of the agreements. Individuals that had wanted to work for laboratories that were performing COVID-19 specimen collection and/or testing without applying for and obtaining a State of Nevada laboratory personnel certification, were notified in the same way that they would need to adhere to the regulations in NAC 652 and obtain the laboratory personnel certification according to the laboratory functions that they would be performing.

Laboratory directors that were allowed to be on the premises of the laboratory in which they are directing at least once a quarter during the pandemic, were also notified that they would need to adhere to NAC 652.370(2) which requires them to be on the site of the laboratory at least once a month. All notifications were distributed by email. The notifications that were sent by email which were returned undeliverable, were contacted by phone if a contact phone number was available.

On Friday May 6, 2022, the Governor announced that the Emergency Directive would be lifted effective May 20, 2022. On Tuesday May 10, 2022, a final email was sent out from the Division which informed the laboratories and laboratory directors with compliance agreements and laboratory personnel working under the Governor's Emergency Directive, that on May 20, 2022, the terms of the compliance agreements would be terminated and that all personnel would be required to come into compliance with the Nevada laboratory regulations stated in NAC 652.

The breakdown of the compliance agreements that were affected by the lifting of the Governor's Emergency Directive, are:

- **Compliance Agreements for NAC 652.195:** There were 20 agreements that were submitted to the BOH to allow for laboratories with State of Nevada Exempt laboratory licensure to provide human specimen collection and/or Waived laboratory testing at locations other than the address where the laboratory is located. With some exceptions, most laboratories that are licensed as Exempt laboratories, perform specimen collection and/or Waived laboratory testing only at the address of the laboratory. Operation at multiple locations is primarily only available to laboratories that are licensed as Licensed laboratories.

As of August 5, 2022, these laboratories were found to be operating as follows:

1. There were nine laboratories that are performing COVID testing only at the location of their laboratory.
2. There were six laboratories that closed their operation.
3. There were three laboratories that converted to mobile specimen collection and testing laboratories performing COVID testing.
4. There were two laboratories that I have not received a response from but continue to try and communicate with them.

- **Compliance Agreements for NAC 652.370(2)**: There were five (5) agreements that were submitted to the BOH to allow for laboratory directors of State of Nevada Licensed laboratories to be on site of the laboratory that they direct at least once quarterly and to meet virtually at least once a month. The regulation NAC 652.370(2) requires the laboratory director of a Licensed laboratory to be on the premises of the laboratory at least once a month. There were some laboratory directors of laboratories which required them to travel by airplane to the location of their laboratory. This agreement allowed them to not be in close contact with others to travel to distant parts of Nevada to meet the regulatory requirement.

Our Medical Laboratory Service agency will confirm compliance when there are State inspections performed to ensure that the laboratory directors are on site of their laboratories at least once a month.

- **Compliance Agreements for NAC 652.4855**: There were six (6) agreements that were submitted to the BOH to allow for laboratory specimen collection and/or testing personnel to work under the direction of a laboratory license by the State of Nevada but not require the personnel to have apply for and obtain a laboratory personnel license. The personnel were required to have documentation of training and competency prior to collection and/or testing which was determined by the laboratory and approved by the laboratory director to ensure the safety of the patients and the specimens that were collected and to ensure the quality and reliability of the patient test results that were reported.

Our Medical Laboratory Service agency will confirm compliance when there are State inspections performed to ensure that all specimen collection personnel and laboratory testing personnel have documentation of training and competency as well as meeting the required educational and experience requirements for the laboratory testing that they are performing.

- **Compliance Agreements for NAC 652.397(1)**: There were nine (9) agreements that were submitted to the BOH to allow Registered Nurses (RN's) that are licensed by their board in the State of Nevada, to be laboratory directors of laboratories that perform Waived COVID testing. The regulation NAC 652.397(2) only allows RN's to be laboratory directors of laboratories that are performing Waived glucose tests. This agreement was designed to allow schools to offer COVID testing to the students and staff of the school where RNs were the medical personnel of the school that could best ensure that quality COVID testing was performed.

As of August 5, 2022, these laboratories were found to be operating as follows:

1. One school found a qualified laboratory director to be the laboratory director of their school COVID testing laboratory. This school also converted to a mobile testing laboratory to offer COVID testing to other areas within their school district.
2. There were seven school laboratories that requested to be closed. One of the school laboratories that requested to be closed stated that it was due to an RN was not qualified to be a laboratory director and the other six that had decided to close their lab license stated that they had decided to not continue to provide COVID testing in their school district.
3. There was one school laboratory that I have not received a response, but I am still in communication with them.

It should be noted that beginning on April 25, 2020, through August 5, 2022, the Nevada Medical Laboratory Services has inspected and approved 623 laboratory applications that were submitted to the State for providing various methodologies of COVID testing. In addition, our agency has received and processed an additional 126 federal CLIA certificate applications that were submitted by pharmacies in Nevada to provide COVID testing under the federal Public Readiness and Emergency Preparedness (PREP) Act.

This concludes my report regarding the update on compliance agreements which ended after the State of Nevada Public Health Emergency Declaration ended.

I will be happy to respond to any questions that the Board may have regarding the update.

Respectively submitted by: Bradley Waples, Acting Manager-Medical Laboratory Services

