

NEVADA STATE BOARD OF PHARMACY

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Partial Waiver of Off-Site Pharmacy Practice to Permit Pharmacy Personnel to Perform COVID-19 Testing

May 6, 2020

In order to reduce opportunities for the transmission of COVID-19 and safeguard the health of Nevadans and practitioners, the Nevada State Board of Pharmacy has partially waived existing regulations of off-site pharmacy practice to permit registered pharmacy personnel (pharmacists, intern pharmacists, and pharmaceutical technicians) to perform COVID-19 testing off-site, in conformance with federal authorization. *See* NAC 639.401-.418.

This partial waiver is being issued in accordance with NAC 639.170.

Pharmacists are permitted to oversee, perform, and/or handle testing for COVID-19, and intern pharmacists or pharmaceutical technicians are permitted to perform and/or handle testing for COVID-19, subject to the following requirements:

- 1. The COVID-19 test must be either **FDA-approved** or subject to an **FDA Emergency** Use Authorization (EUA); AND
- 2. The COVID-19 test must be **CLIA-waived** For a list of CLIA-waived tests see: https://www.fda.gov/medical-devices/emergency-use-authorizations#covid19ivd

In addition, the pharmacy may be subject to licensing and regulation as a **medical laboratory** by the State of Nevada Bureau of Health Care Quality and Compliance pursuant to NRS Chapter 652. (See http://dpbh.nv.gov/Reg/MedicalLabs/Medical_Laboratories_-_Home/ for more information.)

The Bureau has advised that the testing is subject to the following parameters: the medical laboratory must provide an authorized person to order the test, the test must require the patient to collect his or her own specimen for the test, the specimen must be sent to the medical laboratory for analysis, the test report must contain information on the testing laboratory on the final report, the information must be provided to the provider and/or the patient, and positive test reports must be reported to the State of Nevada.

The relevant federal authorization upon which this waiver is based includes, without limitation:

• U.S. Department of Health and Human Advisory Opinion 20-02 on the authority of licensed pharmacists to order and administer FDA-approved COVID-19 diagnostic tests, issued May 19, 2020 – available at:

https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf

• U.S. Department of Health and Human Services guidance under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer FDA-approved COVID-19 diagnostic tests, issued April 8, 2020 – available at:

 $\underline{https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf}$

NOTE: The Board will not be approving policies, procedures, or technology solutions, but the pharmacy engaged in off-site testing should be able to justify how the policies, procedures, or technology meets the requirements of this guidance.

This guidance is in effect until October 15, 2020.

For questions regarding this partial waiver, please e-mail the Board office at pharmacy@pharmacy.nv.gov

J. David Wuest, R.Ph. Executive Secretary Nevada State Board of Pharmacy