



**South Dakota
Board of Pharmacy**
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BOARD POLICY STATEMENT COVID-19 TESTING BY PHARMACISTS

The South Dakota Board of Pharmacy acknowledges that the United States Department of Health and Human Services (HHS) published guidance on April 8, 2020 regarding the fact that the Public Readiness and Emergency Preparedness (PREP) Act passed, authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, and that the Food and Drug Administration (FDA) has authorized¹ through its Emergency Use Authorization (EUA.)² Further the HHS Office of General Counsel has issued an advisory opinion that says licensed pharmacists may order and administer COVID-19 tests regardless of state or local restrictions.³

Further, the Coronavirus Aid, Relief, and Economic Security (CARES) Act allows patients who are uninsured to have testing costs billed by pharmacists to HRSA for COVID-19 testing services.⁴ Additionally, the SD Medicaid program will pay pharmacists as well.⁵

It is the Board's policy that during the COVID-19 Federal Emergency, pharmacists may order, perform, and report COVID-19 tests without a separate provider order or collaborative practice agreement if the requirements listed below are met. Currently, most of the tests are Clinical Laboratory Improvement Amendments (CLIA) waived tests per the Centers for Disease Control (CDC) and supported by the Food and Drug Administration (FDA) and therefore will require a CLIA waiver to perform these tests.^{5,6} When the emergency declaration has ended, the pharmacist may only perform these tests by physician order. This policy statement is to further clarify and allow pharmacists to order and perform COVID-19 testing for their patients.

This policy is in effect for the duration of the State of South Dakota declared emergency or the PREP Act, whichever expires soonest

Before a pharmacist may begin testing, the following must be completed:

1. The pharmacy notifies the Board before testing commences and provides the Board with the policy and procedures written for testing which includes the type of FDA approved test, staff training, the location of testing, i.e., parking lot of pharmacy, planned personal protective equipment (PPE) use, documentation, informing the provider of the test, and a confirmatory testing referral plan for presumptive results which do not coincide with symptoms.
2. A pharmacist conducting COVID-19 testing must be dedicated to testing only and may not be working in a dispensing role while performing testing.
3. The pharmacy must obtain a Clinical Laboratories Improvement Act (CLIA) waiver to perform these tests, if they will be using a device to process the tests in house. If sending to a commercial laboratory, the CLIA waiver is not required.
4. The pharmacy must assure that all pharmacists performing these tests have the appropriate PPE to protect themselves and any staff from aerosolization as well as the proper training to perform and handle these tests.

5. The pharmacist may perform testing in a location which is not a licensed location, as long as the pharmacist conducting the testing is licensed.
6. The pharmacist must report all test results to the South Dakota Health Department at **sd.gov/diseasereport** by completing the reporting document, with both positive and negative tests for all individuals tested.
7. The pharmacy must receive a letter from the board allowing the pharmacy to begin testing.

References:

1. US HHS Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act: <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>
2. FDA Emergency Use Authorization for therapeutic and medical devices to diagnose and respond to public health emergencies: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
3. HHS Office of General Counsel Advisory Opinion, found at <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>
4. HRSA Uninsured CARES Act: [COVID-19 Uninsured Program Portal](#)
5. Medicaid Provider Bulletin & FAQ: https://dss.sd.gov/docs/medicaid/providers/ProviderBulletins/2020/COVID19_FAQ_Providers%205.1.20.pdf
6. How to obtain a CLIA waiver: <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>
7. CLIA waiver state contacts: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

Passed by the South Dakota Board of Pharmacy on June 5,2020._____