



**South Dakota
Board of Pharmacy**

4001 W. Valhalla Blvd., Ste. 106
Sioux Falls, SD 57106
Phone: 605-362-2737 Fax: 605-362-2738
PharmacyBoard@state.sd.us

DATE: June 5, 2020, Revised 9/24/2020, Revised June 25, 2021
WHAT: Board Policy Statement Number 20-06-05
WHY: April 8, 2020 PREP Act Authorizing Pharmacist and Technician Testing for COVID-19

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 be 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 until the PREP Act for countermeasures against COVID-19 concludes.

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 authorized 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 results.
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. Pharmacy interns and technicians may assist in the COVID-19 testing if the actual testing is performed by a patient or a pharmacist.
3. For testing that is completed by the patient, pharmacy staff may provide the patient with supplies and education. Pharmacy technicians and interns may witness the patient performing self-testing and proper placement of the test medium into proper containers, if applicable.

4. The pharmacy must obtain a Clinical Laboratories Improvement Act (CLIA) waiver to perform 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.
5. The pharmacy must assure that all staff performing and assisting with these tests have consented to performing the assigned tasks, have accessible the appropriate PPE to protect themselves and any staff from aerosolization, and have received proper training to perform the assigned tasks involved in the testing process.
6. The pharmacist may perform testing in a location which is not a licensed location, if the pharmacist is conducting the testing is licensed with the Board.
7. The pharmacist or testing vendor must report test results to the South Dakota Health Department at **sd.gov/diseasereport**
8. The pharmacy must receive an approval from the board allowing the pharmacy to begin testing before any type of testing is done in the pharmacy or by pharmacy staff.
9. For PREP Act Immunization Guidance, see Policy Statement 20-12-11

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](https://www.hrsa.gov/covid19/uninsured)
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.

Revised and Passed by the South Dakota Board of Pharmacy on September 24, 2020

Revised and Passed by the South Dakota Board of Pharmacy on June 25, 2021