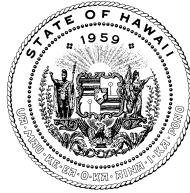


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PREP Act Guidance Document: Pharmacist Administering the COVID-19 Test

Background:

Public Readiness and Emergency Preparedness Act (PREP ACT)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

Health and Human Services' Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States. The United States Department of Health and Human Services (HHS) is the lead agency for the federal government's response to the COVID-19 pandemic.

A key component of that response is rapidly expanding COVID-19 testing across America. Within HHS, the Office of the Assistant Secretary for Health leads federal efforts to support that expansion.

On April 8, 2020, the U.S. Department of Health & Human Services, Office of the Assistant Secretary for Health issued a "Guidance" stating that pharmacists, in partnership with other healthcare providers, are well positioned to aid COVID-19 testing expansion. Pharmacists are trusted healthcare professionals with established relationships with their patients. The vast majority of Americans live close to a retail or in-

dependent community-based pharmacy. That proximity reduces travel to testing locations, which is an important mitigation measure. Pharmacists also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), OASH issues this guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized. See 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.¹ By doing so, such pharmacists will qualify as "covered persons" under the PREP Act. And they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests. 42 U.S.C. § 247d-6d(a)(1).

This guidance does not speak to or change reimbursement policy whether a licensed pharmacist may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test.

HHS' May 19, 2020 Advisory Opinion 20-02 on the PREP ACT

In response from pharmacists and pharmacies asking whether the PREP ACT preempts state licensing laws that restrict the ability of pharmacists to order and administer COVID-19 diagnostic tests where the Department of Health and Human Services (HHS) has expressly authorized pharmacists, under the PREP Act, to order and administer those tests, the Secretary concluded that based on the following reasons, the Secretary's March 10, 2020 declaration, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized.

- Giving pharmacists the authorization to order and administer COVID-19 tests to their patients means easier access to testing for Americans who need it. Pharmacists play a vital role in delivering convenient access to important public health services and information.
- In an effort to expand testing capabilities, we are authorizing licensed pharmacists to order and administer COVID-19 tests to their patients. The accessibility and distribution of retail and independent community-based pharmacies make pharmacists the first point of contact with a healthcare professional for many Americans.

On April 14, 2020, OGC issued an Advisory Opinion on the PREP Act discussing, among other things, the OASH guidance. The opinion explained that licensed pharmacists "are covered as qualified persons (and hence as covered persons) even if they may not be licensed or authorized by the State to prescribe the tests pursuant to § 247d-6d(i)(8)(A), because they fit within the alternative definition of 'qualified persons' pursuant to § 247d-6d(i)(8)(B), as provided by the Secretary in the declaration."

Since then, OGC has been asked whether, under the PREP Act, licensed pharmacists may order and administer COVID-19 tests even in states that prohibit licensed pharmacists from ordering and administering those tests.

October 20, 2020, HHS issued another “Guidance” for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns to administer COVID-19 tests, including serology tests, that the FDA has approved, cleared, or authorized.

This authorization preempts any state and local law that prohibits or effectively prohibits those who satisfy these requirements from administering COVID-19 tests as set forth above. It does not preempt state and local laws that permit additional individuals to administer COVID-19 tests to additional persons.

HHS’ SUMMARY OF CONCLUSIONS

Under the PREP Act, state and local authorities may not prohibit or effectively prohibit “qualified persons” from ordering and administering covered countermeasures for three reasons.

- *First*, through his PREP Act declaration, the Secretary can designate a “qualified person” to use and administer a covered countermeasure even when that person is not authorized to do so under state law. See § 247d-6d(i)(8)(A)–(B). In his declaration, the Secretary designated licensed pharmacists as qualified persons for purposes of administering FDA-authorized COVID-19 tests independent of state licensing laws.
- *Second*, the PREP Act expressly preempts any state or local legal requirement that prohibits or effectively prohibits a qualified person from ordering and administering a covered countermeasure pursuant to the Secretary’s declaration.
- *Third*, states and localities cannot challenge in court the Secretary’s designation of persons authorized to order and administer covered countermeasures. Under the PREP Act, “No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary” pursuant to his declaration under § 247d-6d(b).

By including those broad and robust provisions, Congress made clear that states and localities may not “establish, enforce, or continue in effect” any legal requirement that prohibits or effectively prohibits licensed pharmacists from ordering and administering FDA-authorized COVID-19 tests.

To further effectuate the PREP Act, including § 247d-6d(i)(8)(B), Congress included an express-preemption provision in the PREP Act to preclude state and local governments from establishing or enforcing such prohibitions when they would serve to prohibit “qualified persons” from administering countermeasures recommended by a PREP Act declaration:

During the effective period of [the] declaration ..., or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that ... is different from, or is in conflict with, any requirement applicable under this section; and relates to the ... prescribing, dispensing, or administration by qualified persons of the covered countermeasure.

It is important to note that the PREP Act does not preempt all state and local legal requirements. Not all legal requirements that regulate the pharmacy profession differ from or conflict with the PREP Act or any declaration issued under that Act with respect to COVID-19 tests.

Persons seeking PREP Act immunity are responsible for determining whether their products are covered countermeasures, whether a person or entity is a covered person, whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities.

Conclusion/FAQs:

1. Can a pharmacist administer the COVID-19 test?

Response: Yes

2. Under what authority may a pharmacist administer the COVID-19 test?

Response: Pursuant to the Department of Health and Human Services' PREP Act

3. What does the State require in order for a pharmacist to administer the COVID-19 test?

Response: The State requires that you comply with the HHS guidance that directs pharmacists to review Food and Drug Administration's (FDA's) emergency use authorizations (EUAs) for diagnostic and therapeutic medical devices to diagnose and respond to public health emergencies. The FDA has clearly articulated which point of care tests for COVID-19 are considered CLIA waived according to an emergency use authorization. As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of erroneous result."

The FDA is the agency which determines which tests meet these criteria when it reviews a device manufacturer's application for a waiver.

Pharmacies that intend to perform point of care COVID-19 testing, utilizing a CLIA waived device, must also receive a CLIA Certificate of Waiver, as described in How to Apply for a CLIA Certificate of Waiver-CMS, for each pharmacy location where testing will be performed by applying to their CLIA state survey agency contact. These state CLIA contacts can also provide details on qualifications for an exception that would allow multiple state testing locations under one CLIA Certificate of Waiver.

In addition to these applicable federal statutory and regulatory requirements, pharmacies that intend to perform point of care COVID-19 testing must also comply with any additional state laws and regulations. A number of states have waived or streamlined the process to begin this type of testing according to COVID-19 pandemic executive orders. Compliance with the PREP Act, that includes but is not limited to compliance with CDC and local Department of Health guidelines and recommendations to prevent the spread of an infectious disease and CLIA Waived testing

4. Is a prescription required from a health care provider for a pharmacist to administer the COVID-19 test?

Response: No, the HHS PREP Act allows a pharmacist to “order and administer” COVID-19 test.

5. Can a pharmacy intern administer the COVID-19 test under the supervision of a pharmacist?

Response: ~~No, the HHS PREP Act does not include pharmacy interns, only pharmacists.~~ Yes, new “guidance” issued by HHS on October 20, 2020.

6. What kind of immunity is afforded a pharmacist or pharmacy intern or pharmacy technician who chooses to perform this activity?

Response: Please see the link below:

<https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>

7. What COVID-19 test may I administer?

Response: See response to question #3.

8. Can a pharmacy technician administer the COVID-19 test?

Response: Yes, new “guidance” issued by HHS on October 20, 2020.