

HHS Advisory Opinion Regarding Pharmacists' Abilities to Order and Administer COVID-19 Tests

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This blog was originally written as a client alert on May 24, 2020.

To provide guidance to pharmacists seeking to understand whether they may order and administer COVID-19 diagnostic tests under the PREP Act, even in states restricting them from doing so, the Department of Health and Human Services (HHS) issued an Advisory Opinion on May 19, 2020. The HHS concluded that the PREP Act preempts state and local requirements prohibiting a pharmacist from ordering and administering authorized COVID-19 tests.

BACKGROUND OF THE PREP ACT DECLARATION

On March 17, 2020, HHS published an administrative Declaration under the Public Readiness and Emergency Preparedness Act (the PREP Act), which provides broad-based legal immunity for manufacturers, suppliers, and administrators of certain products used to combat COVID-19 (as discussed in our article [here](#)). The Declaration serves to encourage the development, manufacture, and distribution of both new and existing drugs, devices, and other measures to help combat the pandemic.

Pursuant to the PREP Act Declaration, on April 8, 2020, the Office of the Assistant Secretary for Health issued “Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act” (found [here](#)). This guidance explained that immunity from liability under the PREP Act extends to licensed pharmacists who order and administer FDA-authorized COVID-19 tests. The stated purpose of this guidance was to provide “easier access to testing for Americans who need it”—particularly for healthcare workers and first responders.

On April 14, 2020, in response to inquiries about immunity under the PREP Act, the General Counsel of HHS issued its first Advisory Opinion related to COVID-19 (as discussed in our article [here](#)), clarifying the scope of immunity under the PREP Act Declaration.

Most recently, on May 19, 2020, HHS issued a second Advisory Opinion (found [here](#)) in response to inquiries from “pharmacists, pharmacies, and one trade association” regarding whether the PREP Act permits licensed pharmacists to order and administer COVID-19 tests—even in states where they are prohibited from doing so.

SUMMARY AND IMPLICATIONS OF MAY 19, 2020 ADVISORY OPINION

The May 19, 2020 Advisory Opinion concluded that under the PREP Act, state and local authorities may not prohibit licensed pharmacists (as qualified persons) from ordering and administering COVID-19 tests that are authorized by the FDA. The Advisory Opinion reached this conclusion for three reasons. First, the PREP Act Declaration “designated licensed pharmacists as qualified persons for administering FDA-authorized COVID-19 tests independent of state licensing laws.” Second, the PREP Act explicitly preempts any state or local laws that prohibit a qualified person from ordering and administering a covered countermeasure (in this case, a COVID-19 test). Finally, state and local authorities cannot file a lawsuit challenging the designation of persons authorized to order and administer covered countermeasures. The Advisory Opinion concluded that, for these reasons, during the effective period of the PREP Act Declaration, “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.”

The Advisory Opinion is not a final action or final order, nor does it have the force or effect of law. While it provides useful guidance for lawmakers and pharmacists, relevant state and local laws should still be considered in determining whether to order or administer COVID-19 tests. For any questions about the effect of this Advisory Opinion, please contact Sandra Edwards, Sarah Krajewski, or your Winston relationship attorney.

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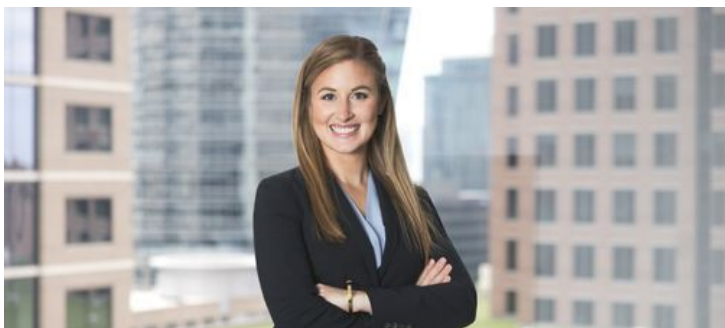
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