

PREP ACT IMMUNITY FOR PHARMACISTS ORDERING COVID-19 TESTS: NEW HHS OGC ADVISORY OPINION ADDRESSES CONFLICTING STATE LAWS

On May 19, 2020 the Department of Health and Human Services (“HHS”) Office of the General Counsel (“OGC”) issued an advisory opinion (the “Opinion”) that concludes that the Public Readiness and Emergency Preparedness (“PREP”) Act, “...preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the [FDA] has authorized.” While this Opinion may inform decisions by state boards of pharmacy, pharmacies, and pharmacists when assessing whether pharmacists may order and administer COVID-19 tests, a state-specific analysis should still be conducted to determine compliance with state licensure requirements and assess potential civil and criminal liability.

BACKGROUND

OGC specified that it issued the Opinion in response to inquiries “...from pharmacists, pharmacies, and one trade association...” regarding whether the PREP Act “...preempts state licensing laws that restrict the ability of pharmacists to order and administer COVID-19 diagnostic tests where [HHS] has expressly authorized pharmacists, under the PREP Act, to order and administer those tests.” While this is certainly a significant development, OGC cautioned that “[t]his Advisory Opinion [. . .] sets forth the current views of OGC. It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.” This leaves open questions regarding PREP Act coverage for certain state administrative actions.

In its analysis, OGC emphasized that on April 8, 2020, the Office of the Assistant Secretary for Health (OASH) effectively authorized “...licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized”, pursuant to the Secretary’s March 10, 2020 declaration under the PREP Act.^[1] Subsequently, on April 14, OGC issued another Advisory Opinion, which explained OGC’s perspective 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... because they fit within the alternative definition of ‘qualified persons’....”^[2] Accordingly, OGC outlined three reasons that state and local authorities may not prohibit, explicitly or otherwise, “qualified persons” from ordering and administering covered countermeasures^[3] under the PREP Act:

1. The PREP Act declaration allows the Secretary to designate a “qualified person” to use and administer a covered countermeasure even when that person is not authorized to do so under state law, and the Secretary specified that licensed pharmacists are “qualified persons” for purposes of administering FDA-authorized COVID-19 tests independent of state licensing laws.
2. “Qualified persons” may order and administer covered countermeasures pursuant to the Secretary’s declaration because the PREP Act expressly preempts any state or local legal requirement that would prohibit or effectively prohibit such action.
3. Under the PREP Act, states and localities cannot challenge the Secretary’s designation of persons authorized to order and administer covered countermeasures.

Using this line of reasoning, OGC concluded that “any state or local law or legal requirement that prohibits or effectively prohibits licensed pharmacists from ordering and administering FDA-authorized COVID-19 tests are different from or in conflict with the declaration—and therefore, a legal requirement under the PREP Act.” Therefore, while the PREP Act declaration remains in effect, a state or local regulators “cannot establish, enforce, or continue any such legal requirements under the PREP Act’s preemption provision.”

PRACTICAL TAKEAWAYS

Although this Opinion may assist state and local regulators in determining how to apply their state licensure laws and assess potential liability concerns regarding the ability of pharmacists to order and administer COVID-19 tests, this guidance should be thoughtfully weighed against all applicable state and local requirements. More specifically, the PREP Act addresses potential civil liability related to the provision of covered countermeasures and not potential criminal penalties that may result from state licensure violations. OGC even cautioned that “[i]t is important to note that the PREP Act does not preempt all state and local legal requirements. [. . .] 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.”

Thus, state boards of pharmacy, pharmacies, and pharmacists should carefully assess the full scope of their proposed activities related to ordering and administering COVID-19 tests to determine the potential application of this Opinion.

Hall Render is actively tracking all HHS guidance related to the COVID-19 pandemic. If you have any questions on the issues discussed in or related to this article, please contact:

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Hall Render’s attorneys and professionals continue to maintain the most up-to-date information and resources at our [COVID-19 Resource page](#), through our 24/7 COVID-19 Hotline at (317) 429-3900 or by contacting your regular Hall Render attorney.

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[references]

[1] *Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act*, available at: <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>.

[2] Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the march 10, 2020 Declaration under the Act, April 17, 2020, as modified on May 19, 2020, available at: <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf>.

[3] “Covered Countermeasures” include “any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures [. . .] except for claims involving ‘willful misconduct’ as defined in the PREP Act”, see U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 and PREP Act FAQs, question 4, available at: <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx> and <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q4>.

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