

NCPA Member Summary of HHS Rules Regarding Pharmacists Authority to Provide COVID-19 Testing in Relation to State Law

On May 19, 2020 HHS' Office of General Counsel (OGC) released an [advisory opinion](#) clarifying that **pharmacists are authorized to order and administer Food and Drug Administration (FDA)-authorized COVID-19 tests, which effectively overrides state and local rules preventing pharmacists from doing so.** Although this advisory opinion is not legally binding, it is a valuable tool that empowers pharmacists to order and administer testing during the COVID-19 public health emergency (PHE). NCPA is still working on provider status with Congress and communicating with CMS to clarify payment for pharmacists' services associated with providing these tests.

Under the Public Readiness and Emergency Preparedness Act (PREP Act), state and local authorities may not prohibit or effectively prohibit "qualified persons" from ordering and administering covered countermeasures for three reasons:

- 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.¹ **As explained in the April 14, 2020 [Advisory Opinion](#) (at 6-7), the Secretary has designated licensed pharmacists as "qualified persons" under his declaration.**
- The PREP Act expressly **preempts any state or local legal requirement that prohibits a qualified person from ordering and administering** a covered countermeasure² pursuant to the Secretary's declaration.
- States and localities cannot challenge in court the Secretary's designation of persons authorized to order and administer covered countermeasures.³

Therefore, by designating licensed pharmacists as "qualified persons," the Secretary has authorized licensed pharmacists to order and administer FDA-authorized COVID-19 tests in states where the licensed pharmacists are not authorized to do so.

- On April 8, 2020, the Office of the Assistant Secretary for Health (OASH) issued [guidance](#) **"authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that [FDA] has authorized."** OASH did so as an Authority Having Jurisdiction pursuant to the Secretary's March 10, 2020 declaration under the PREP Act.
- On April 14, 2020, OGC issued an [advisory opinion](#) stating that **licensed pharmacists are covered as qualified 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."⁴

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¹ See § 247d-6d(i)(8)(A)-(B).

² Under the March 10, 2020 declaration, covered countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

³ See § 247d-6d(b)(7).

⁴ Pursuant to § 247d-6d(i)(8)(B).