

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Lemrey “Al” Carter, Executive Director/Secretary
DATE: May 21, 2020
RE: HHS Issues Advisory Opinion on the PREP Act in Response to Inquiries About Licensed Pharmacists Ordering and Administering COVID-19 Diagnostic Tests Under the Act

The United States Department of Health & Human Services (HHS) Office of the Secretary issued “Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act [(PREP Act)] and the Secretary’s Declaration Under the Act” on Tuesday, May 19, 2020, in response to the Office of the General Counsel inquiries about 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.

Secretary Alex M. Azar II (Secretary) has designated licensed pharmacists as “qualified persons” under his [declaration](#) for purposes of administering Food and Drug Administration (FDA)-authorized COVID-19 tests independent of state licensing laws. Under the PREP Act, state and local authorities may not prohibit or effectively prohibit “qualified persons” from ordering and administering covered countermeasures for the following 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.
- 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.
- States and localities cannot challenge in court the Secretary’s designation of persons authorized to order and administer covered countermeasures.

During the effective period of the PREP Act declaration, a state or locality 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 under the PREP Act’s preemption provision.

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.

To view the HHS Advisory Opinion, please visit <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>.

cc: NABP Executive Committee