



**ADVISORY OPINION 20-02 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT
AND THE SECRETARY'S DECLARATION UNDER THE ACT
MAY 19, 2020**

We have received requests from pharmacists, pharmacies, and one trade association asking the Office of the General Counsel (OGC) whether the Public Readiness and Emergency Preparedness (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. For the reasons and subject to the limitations set forth below, we conclude that the PREP Act, in conjunction with 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.

BACKGROUND

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 the Food and Drug Administration (FDA) has authorized."¹ OASH did so as an Authority Having Jurisdiction pursuant to the Secretary's March 10, 2020 declaration under the PREP Act. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); 85 Fed. Reg. 21,012 (April 15, 2020) (amending the March 10, 2020 declaration); *see also* Pub. L. No. 109-148, Public Health Service Act §§ 319F-3, 319F-4, 42 U.S.C. §§ 247d-6d, 247d-6e.

Secretary Alex M. Azar II explained the need for the authorization, as follows:

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. The Trump Administration is pleased to give pharmacists the chance to play a bigger role in the COVID-19 response, alongside all of America's heroic healthcare workers.²

Assistant Secretary for Health Brett P. Giroir, M.D. further stressed the need for the authorization:

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. This will further expand testing for Americans, particularly our healthcare workers and

¹ <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

² <https://www.hhs.gov/about/news/2020/04/08/hhs-statements-on-authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.html>

first responders who are working around the clock to provide care, compassion and safety to others.³

Consistent with that authorization, numerous states have made clear that licensed pharmacists may order and administer FDA-authorized COVID-19 tests.⁴ Some of those states—including Alaska, New Mexico, and Virginia—relied on the HHS guidance when authorizing their licensed pharmacists to order and administer FDA-authorized COVID-19 tests.⁵

On April 14, 2020, OGC issued an Advisory Opinion on the PREP Act discussing, among other things, the OASH guidance.⁶ The opinion explained (at 6-7) 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.

This Advisory Opinion addresses that question and sets forth the current views of OGC.⁷ 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.

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.

³ *Id.*

⁴ See <https://naspa.us/resource/covid-19-testing/>; see also, e.g., <https://www.nacds.org/news/california-urged-to-remove-remaining-covid-19-testing-barriers-on-pharmacists-to-advance-testing-ramp-up-and-re-opening-of-state/> (noting on April 23, 2020, that “[n]ineteen other states have put into place policies consistent with the HHS guidance ... that authorizes pharmacists to order and conduct testing for COVID-19 that the [FDA] has authorized”).

⁵ See, e.g., <https://alaskapharmacy.org/wp-content/uploads/2020/03/4-16-20-AK-BOP-COVID-19-Tests-Ordering-Administering.pdf>; <https://www.dhp.virginia.gov/Pharmacy/news/COVIDTestingGuidance.pdf>; http://www.rld.state.nm.us/uploads/FileLinks/ad6770c244f74bdaaeaa53842023b4c7/Pharmacist_Ordering_and_Administering_COVID_19_Testing.pdf.

⁶ <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf>.

⁷ See *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”).

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.

LEGAL FRAMEWORK

The PREP Act lists five categories of “covered person[s]” who are eligible for PREP Act immunity when administering or using a “covered countermeasure”—(1) a manufacturer of the countermeasure; (2) a distributor of the countermeasure; (3) a program planner of such countermeasure; (4) a qualified person who prescribed, administered, or dispensed the countermeasure; and (5) an official, agent, or employee of a person or entity described in the four categories above. *See* 42 U.S.C. § 247d-6d(i)(2).

There are two categories of “qualified person.” *See* 42 U.S.C. § 247d-6d(i)(8).⁸

The first category includes those who are authorized under state law to take the relevant actions with respect to a covered countermeasure—namely, someone who is “a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed.” 42 U.S.C. § 247d-6d(i)(8)(A).

The second category includes “a person within a category of persons so identified in a declaration by the Secretary under subsection (b).” 42 U.S.C. § 247d-6d(i)(8)(B).

By including that second category, the PREP act makes clear that the Secretary may designate someone as a “qualified person” even if that person is *not* authorized to prescribe, administer, or dispense such countermeasures under state law *when that person prescribes, administers, or dispenses the coun-*

⁸ There is only one provision of the PREP Act that discusses those authorized under state law to prescribe, administer, or dispense a covered countermeasure. And that is the definition of “qualified person” under § 247d-6d(i)(8).

termes in that State. Because the definition of “covered person” makes someone’s status as a “qualified person” relevant only to the extent that the person performs one of those three acts, it necessarily applies to those who act without state authorization.

If the definition of “qualified person” were limited to persons already authorized under state law to prescribe, administer, or dispense a covered countermeasure, then § 247d-6d(i)(8)(B) would be superfluous in light of § 247d-6d(i)(8)(A), which automatically includes those who are authorized under state law to do those very things. The Secretary would never have occasion to immunize someone under § 247d-6d(i)(8)(B) if states and localities could prohibit those persons from prescribing, administering, or dispensing the covered countermeasures in the first place. *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (“It is ‘a cardinal principle of statutory construction’ that ‘a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.’” (Citations omitted)).

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.

42 U.S.C. § 247d-6d(b)(8).

OGC has not located published federal case law discussing the breadth of the “different from, or is in conflict with” preemption language. *But see, e.g., Casabiana v. Mount Sinai Med. Ctr.*, 2014 WL 10413521, *2 (N.Y. Sup. Ct. Dec. 2, 2014); *Parker v. St. Lawrence Cty. Pub. Health Dep’t*, 102 A.D.3d 140, 143-44 (N.Y. Sup. Ct. App. Div. 2012). But courts have broadly interpreted similar preemption clauses, including those that preempt state or local laws that are “different from, or in addition to” federal legal requirements. *See, e.g., Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008)). According to the Supreme Court, that preemption language “sweeps widely” and preempts any language that “deviates from [requirements] imposed by federal law.” *Nat’l Meat Ass’n. v. Harris*, 565 U.S. 452, 459, 461 (2012). A state or local legal requirement is “different from, or in addition to” federal requirements if it is not “genuinely equivalent” to the federal requirements. *Wolicki-Gables*, 634 F.3d at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

The PREP Act is distinct from the provision above in that it preempts any state or local legal requirement that is “different from, or *is in conflict with*”—instead of “in addition to”—PREP Act requirements. (Emphasis added). But that difference is immaterial here. The plain meaning of “different” is “not the same” or “having at least one property not possessed by another.” WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 630 (1961). Those definitions of “different” encompass

“not genuinely equivalent” and “deviat[ions] from.” So the PREP Act’s preemption clause has a sufficiently broad sweep to encompass state requirements that would prohibit or effectively prohibit pharmacists from administering FDA-approved COVID-19 tests.

And at a minimum, that sweep is broad enough to preempt a state or local legal requirement that prohibits or effectively prohibits activity by qualified persons whom the Secretary has authorized to perform those activities through his declaration, which is a requirement under the PREP Act. Such prohibitions are plainly “not genuinely equivalent” to PREP Act requirements. If anything, they are directly “in conflict with” those requirements.

LICENSED PHARMACISTS AND COVID-19 TESTING

As explained in the April 14, 2020 Advisory Opinion (at 6-7), the Secretary has designated licensed pharmacists as “qualified persons” under his declaration. And by designating licensed pharmacists as “qualified persons,” the Secretary has also authorized licensed pharmacists to order and administer FDA-authorized COVID-19 tests in states where the licensed pharmacists are not authorized to do so.

Because of that authorization, “no State or political subdivision of a State may establish, enforce, or continue in effect with respect to [FDA-authorized COVID-19 tests] any provision of law or legal requirement that is different from, or is in conflict with, any requirement applicable under this section” and that “relates to . . . the prescribing, dispensing, or administration by qualified persons of the covered countermeasure.” 42 U.S.C. § 247d-6d(b)(8)(A).⁹

As explained above, 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. So during the effective period of the PREP Act declaration, a state or locality cannot establish, enforce, or continue any such legal requirements under the PREP Act’s preemption provision.¹⁰

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.

⁹ The Secretary’s declaration under § 247d-6d(b) is a requirement for PREP Act immunity under §§ 247d-6d(a)(1), (i)(8)(B). The declaration’s designations of covered countermeasures and qualified persons are also requirements to establish PREP Act immunity under §§ 247d-6d(a)(1), (i)(8)(B).

¹⁰ When Congress intends to exempt state-licensing laws from its preemption provisions, Congress explicitly says so. *See, e.g.*, 42 U.S.C. § 1395w-26(b)(3) (“The standards established under this part shall supersede any State law or regulation (*other than State licensing laws* or State laws relating to plan solvency)” (emphasis added)); 8 U.S.C. § 1324a(h)(2) (“The provisions of this section preempt any State or local law imposing civil or criminal sanctions (*other than through licensing* and similar laws)” (emphasis added)). Congress did not do so in the PREP Act. Instead, Congress gave the Secretary virtually unreviewable authority to immunize and designate a “qualified person” to use a “covered countered measure.”

LIMITATIONS

This Advisory Opinion may be supplemented or changed. It is intended to minimize the need for individual advisory opinions.

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.

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