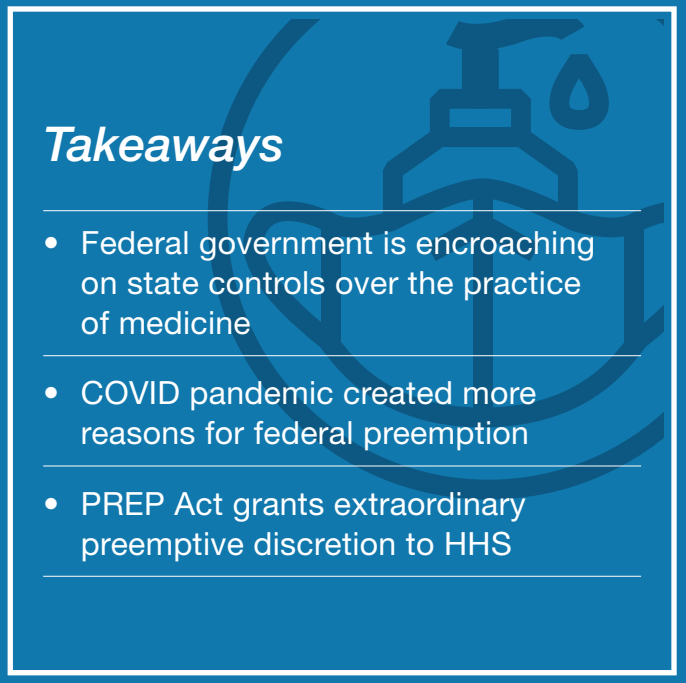
COVID-19 fuels federal preemption of state practice-of-medicine laws



Takeaways

- Federal government is encroaching on state controls over the practice of medicine
- COVID pandemic created more reasons for federal preemption
- PREP Act grants extraordinary preemptive discretion to HHS

On February 26, 2020, as fears of a potential pandemic caused by COVID-19 spread across the globe, we argued that federal public health powers are ostensibly quite limited, as illustrated by the scope of quarantine powers granted to the U.S. Centers for Disease Control and Prevention. The article flagged the foreseeable risk that conflicts may arise between the federal government and the states over the application of quarantine and other public health powers.

A year later and many of these tensions have been pushed aside for the greater purpose of responding to the pandemic. In doing so, many long-standing principles of state regulation of the practice of medicine and other healing arts have been preempted. This article reflects on some lessons learned and the possible changes ahead, focusing on the federal government's COVID-19 testing proposal and the use of federal laws to respond to public health emergencies.

On January 21, 2020, COVID-19 first came to U.S. shores in Seattle; by mid-February 2020, a local nursing home had the first outbreak, which indicated that community spread was occurring. Other than short-lived controversy over whether to let a cruise ship dock in San Francisco, and some half-hearted air travel bans and screening, it was clear that quarantines were not going to be an effective tool to prevent the further spread of SARS-CoV-2. By March 11, 2020, the World Health Organization had declared a pandemic, and on March 13, 2020, President Donald Trump declared a national emergency, and health authorities switched strategies to detection and mitigation.

One of the first strategies implemented by the federal government was a widespread testing regime. On March 13, President Trump held an event in the Rose Garden where he announced a drive-through testing strategy involving the large retail pharmacy chains (plus one "big box" store). In this effort, the federal government declared that it would arrange for and manage all of the testing and would provide security, personal protective equipment (PPE), and collection kits. The pharmacies would host the sites, and their employees would collect specimens. The collected samples would be sent to third-party clinical laboratories, and the federal government would arrange for notifications of results to patients, all of this to be powered by a scheduling and management database that would be built by Google, which had "1,700 engineers working on the problem."

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Most of this did not come to pass (at least not as proposed) in spite of best efforts by retailers – because the government could not source test kits or PPE, or provide any testing capabilities, and Google was never engaged to create a scheduling/management database. Nevertheless, the drive-through testing proposal raised a number of interesting questions. The use of retail pharmacy partners to quickly scale testing sites made sense given their geographic footprints, health care supply chain experience, and licensed pharmacists. But state law often restricts the ability of pharmacists to order and administer COVID-19 tests as these are activities characterized – by certain state laws – as beyond a pharmacist's scope of practice. These scope-of-practice limitations are generally absolute and cannot be circumvented by training, credentialing, or certification.

The practice of medicine – and other clinical practice – is regulated by the states. This concept was deemed so important (at one time) that it is enshrined as the very first paragraph of the Medicare Act, 42 U.S.C. section 1395, which prohibits any federal interference with the "supervision or control over the practice of medicine or the manner in which medical services are provided…" Even if we push aside this statement as a predicate assuagement for passage of a new government social welfare system, it is undisputed that state law sets the requirements for the practice of medicine and other healing arts. States supervise and license physicians, therapists, nurses, optometrists, hospitals, nursing homes, and other providers and clinicians. States decide (usually through professional boards) the scope of practice of each of these professions within the state. Indeed, and specific to the COVID-19 testing proposal, physicians and osteopaths have long opposed expansion of practice by pharmacists, qualified nurse practitioners, and other clinicians, with the American Medical Association even using the social media hashtag #stopthescopecreep. The numerous news articles covering these past debates or "battles" tend to use adjectives like "bitter" and "fierce" in describing scope-of-practice disputes.

Because the scope of practice is a state law issue, governors were urged to use their emergency powers to temporarily allow for an expansion of practice that would increase COVID-19 testing. A number of states issued orders to expand testing, usually to include pharmacists and pharmacy technicians. In spite of these efforts, however, many states did not act, which led the U.S. Department of Health and Human Services (HHS) to issue a series of directives under the PREP Act, 42 U.S.C. section 247d-6d, a post-9/11 law that was triggered by a March 17 declaration by the HHS secretary that a public health emergency existed under the PREP Act.

The PREP declaration confers broad immunity on covered persons from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure. The only exception is "willful misconduct." In its April 8, 2020, guidance, HHS took the position that the countermeasure is the COVID-19 testing and that ordering pharmacists are the covered persons, and they may receive immunity under the Act. In spite of this view of immunity, pharmacists were reluctant to risk their professional licenses on the basis of a guidance document, which led HHS to issue a formal advisory opinion on May 19, 2020.

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In this opinion, HHS explicitly took the position that state laws prohibiting pharmacists from ordering tests were preempted, writing that:

> *Because of that [PREP] 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. section 247d-6d(b)(8)(A).*
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> *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.*

In a little-noticed footnote to this opinion, HHS argues that PREP grants extraordinary preemptive discretion to HHS:

> *When Congress intends to exempt state-licensing laws from its preemption provisions, Congress explicitly says so. See, e.g., 42 U.S.C. section 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. section 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."*** (emphasis added).

Perhaps emboldened by the circumstances of the pandemic and the lack of pushback from state governments, HHS pushed ahead with numerous additional amendments and advisory opinions on related subjects, including telehealth, vaccination administration, and even decisions not to provide covered countermeasures.

For example, on the issue of telehealth and state law limitations on remote practitioners, **HHS wrote:**

> *To help maximize the utility of telehealth, the Secretary declares that the term "qualified person" under 42 U.S.C. 247d-6d(i)(8)(B) includes healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice. When ordering and administering Covered Countermeasures through telehealth to patients in a state where the healthcare personnel are not already permitted to do so, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients through telehealth* ***in the state where the healthcare personnel are licensed or otherwise permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures through telehealth is preempted****. Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.* (emphasis added).

"Telehealth is a good 'tip of a spear' to effect change on a nationwide basis, but so are testing issues as the need for point-of-care testing will likely continue into the near future."

While all of these preemptions are limited to covered countermeasures during the pandemic, we would note that one could take a very broad view of a covered countermeasure. It is also worth noting that this type of preemption does not act as a direct preemption of a specific scope of practice (which attracts more political attention), but instead allows for one state to drive the scope of practice in any state without regard to specialty. So a qualified nurse practitioner in a state with a broad scope of practice would be able to perform a service that might otherwise be reserved for physicians in the state where the patient is located.

In closing, as this article was written, vaccine manufacturers were testing COVID-19 vaccine booster shots with a likely deployment in the fall or winter of 2021. Assuming that these vaccine boosters will be purchased and distributed by the United States, then it would be likely that HHS will continue to renew the public health emergency declaration for purposes of PREP coverage. This potentially means another year of the preemption described above and also likely renewed executive orders and expansions under state law. Telehealth is a good "tip of a spear" to effect change on a nationwide basis, but so are testing issues as the need for point-of-care testing will likely continue into the near future. It will, of course, be interesting to see whether these scope-of-practice expansions are made permanent via federal or state legislation. Now that the precedent has been set, Congress may consider the benefit of some preemptive laws relating to scope-of-practice restrictions, at least for purposes of federal health care programs.

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