COVID-19: #NEVERNEEDED REGULATIONS

Policymakers should

- remove regulations that impede the rapid and efficient supplying of tests, vaccines, and therapeutics to patients;
- remove regulations that impede the flow of health care practitioners to areas where they are most needed;
- remove regulations that block patients from the benefits of telehealth technology;
- remove regulations that block experienced health care professionals from other countries from providing health care to patients in America; and
- remove regulations that prevent health care professionals from serving patients to the full extent of their training.

During the early days of the COVID-19 pandemic, policymakers implemented emergency measures that removed regulatory barriers to a rapid and efficient response to the crisis. Unfortunately, most of the emergency measures have expired and the old barriers have returned. Yet by issuing the emergency actions, policymakers tacitly recognized that the regulations unjustifiably block people's access to health care.

Getting Patients Access to Tests, Vaccines, and Therapeutics

The Food and Drug Administration's test approval process resulted in an avoidable and costly delay in getting test kits for COVID-19 infection out to the public, which impeded an effective response to the pandemic by more than a month.

Eventually, the FDA permitted states to independently approve tests for use within their borders even if the tests had not yet received FDA approval. This temporary emergency action allowed several states that were hard-hit by the pandemic to rapidly ramp up testing. In some instances, states imported tests

of proven quality that had been used in other countries. The devolution of authority to the states—50 "laboratories of democracy"—should remain in effect. The pre-pandemic federal monopoly on approving tests was never needed.

Congress should consider granting states the authority to approve drugs and other devices that may be marketed within their borders, independent of FDA approval, even when no public health emergency exists.

The Pfizer/BioNTech, Moderna, and Johnson & Johnson COVID-19 vaccines were developed and granted emergency approval in record time. The first messenger RNA vaccines became available less than a year after the pandemic reached North America. According to a report from the World Economic Forum, a vaccine takes an average of 10 years and $500 million to be developed and approved.

The FDA fast-tracked approval of COVID-19 vaccines as well as therapeutics under the Coronavirus Treatment Acceleration Program (CTAP). Under CTAP, the FDA grants emergency use authorization, if the benefits outweigh the risks, to vaccines that have already completed Phase 1 trials that demonstrate safety and Phase 2 trials that demonstrate safety and efficacy, but have not yet completed Phase 3 (long-term protection) trials. Therapeutics such as remdesivir, Paxlovid, and molnupiravir have similarly been fast-tracked.

Policymakers should learn from this. Fast-tracking drug and vaccine approvals should become the rule, not the exception. Better yet, patients should be able to choose between drugs and vaccines that are FDA-approved and those approved by other "trusted" countries' regulatory agencies. Patients should even be allowed access to therapeutics approved by independent third-party certifiers if the label clearly states how and from whom the drug received certification. And as coronavirus cases mounted, the FDA should have sought to ameliorate the shortage of test kits by authorizing the use of tests already being used in similar countries.

Congress should pass legislation granting patients access to drugs and medical devices (including tests) already approved in similar countries. This already exists among the European Union states plus Iceland, Liechtenstein, and Norway. In July 2019, Sen. Ted Cruz (R-TX) introduced S. 2161, the Reciprocity Ensures Streamlined Use of Lifesaving Treatment (RESULT) Act, which would allow the marketing of drugs approved in certain countries but not yet approved by the FDA, if "there is an unmet need." It granted the FDA authority to block such drugs if the agency determined they were not safe and efficacious. Unfortunately, that provision, along with the "unmet need" requirement, undermined the goals of the proposed legislation. The bill failed to advance out of the Senate Committee on Health, Education, Labor and Pensions.

Health Care Practice across State Lines

The pandemic acutely demonstrated how state licensing laws impede the free flow of health care practitioners to where patients need them. In several of the states hardest hit by the pandemic, governors suspended state licensing laws to allow practitioners licensed in any state to come to the aid of other states' residents. These emergency actions tacitly recognize a pressing problem: state clinician licensing laws block access to care.

Some states have already enacted laws recognizing the out-of-state occupational and professional licenses of health care providers who establish permanent locations within their jurisdictions. In early 2019, Arizona became the first state to do so, and several other states have since followed suit. The remaining states and the District of Columbia should do the same.

Such reform would make it much easier for health care practitioners to provide services to patients in various parts of the country. However, requiring practitioners to establish permanent locations within respective states renders the reform less effective. For greater impact, state lawmakers in all 50 states and the District of Columbia should remove this requirement. States would still retain the power, under our federal system, to grant licenses and regulate occupations and professions within their borders.

The social distancing measures required to address the COVID-19 pandemic led to a newfound appreciation for telemedicine, a technological advance that has been available for several decades. State licensing laws for health care practitioners have impeded the widespread use of telehealth. Most states allow health care practitioners to provide telemedicine to patients only in the state in which those providers are licensed, a barrier to the free flow of health care services across state lines.

Incongruously, patients can travel to another state to receive medical treatment and even surgery from a doctor licensed in that state, but those doctors cannot travel to the patients' states to provide the same services unless they are licensed in those states.

Though many states, early in the pandemic, temporarily removed barriers to the movement of health care practitioners or the delivery of telehealth across state lines, some of those measures have since lapsed and the barriers returned. But policymakers in Arizona learned from the experience that these regulatory barriers were never needed. In May 2021, Arizona became first state to allow its patients to receive telehealth services from health care practitioners licensed in any of the other states and the District of Columbia. Out-of-state telehealth providers are subject to the laws governing the health care professions of the state of Arizona, as well as review and disciplinary action by the relevant professional licensing boards of the state of Arizona. They are required to

show proof of malpractice insurance coverage. Liability cases will be heard in Arizona courts subject to Arizona liability law.

Policymakers in the other states and territories should follow Arizona's example. But federal policymakers can also act. To the extent consistent with its authority to tear down barriers to interstate commerce under Article 1, Section 8, of the Constitution, Congress should define the "locus of care" as the state in which the practitioner is located as opposed to the state in which the consumer of the service resides. Although states have constitutional authority to regulate the practice of medicine for residents within their borders, crossing state lines to provide telehealth or short-term in-person care can reasonably be classified as interstate commerce.

Removing the obstacles to health care delivery across state lines will increase access to care and allow patients to use expertise that may exist in areas of the country otherwise beyond their reach. It would also remove the protection from out-of-state competitors that health care providers otherwise enjoy. The increased competition would redound to the benefit of patients by lowering prices and improving quality of care.

Congress should also apply this definition of the locus of care to practitioners licensed in one state who provide short-term in-person care in a state where they do not have a permanent location. Examples of providers to whom such an act would apply include those who usually work through agencies to provide care during short temporary stints in medically underserved areas; those located very close to the border of a neighboring state; and out-of-state experts in rare and specialized medical conditions brought in to consult and help manage a fragile patient unstable for transfer. These examples are analogous to telemedicine practice.

Defining the locus of practice as the state in which a health care practitioner is licensed would make it easier for locum tenens ("fill in") providers and out-of-state specialists to provide itinerant temporary health services to remote and underserved communities, while avoiding the licensing applications and fees in the several states where these communities reside. If a practitioner establishes an office within a state, the practitioner will then become subject to applicable state-based practitioner licensing laws.

Meeting Health Care Workforce Needs

The Canadian provinces, Australia, and most European Union countries have a provisional licensing system whereby experienced foreign doctors are allowed to practice under the supervision of a licensed domestic physician for a designated period. When the supervisory period is complete, and contingent

on passing the same exams required of domestic physicians, they are granted an unconditional license. In many cases, they are required to practice for a certain period in an underserved area. America's patients would benefit if policymakers would create provisional licensing programs for licensed and experienced physicians who were trained and practice in other countries. Gov. Phil Murphy of New Jersey patterned a public health emergency measure on the provisional license model. However, despite any reforms that state lawmakers might enact, federal immigration laws remain an obstacle to their smooth implementation.

Although Congress has no constitutional authority to intervene in state licensing matters, Congress can facilitate state lawmakers who seek to reform state licensing requirements for foreign physicians as well as international medical graduates (IMGs) who do their postgraduate training in the United States by removing immigration law barriers that impede the effectiveness of state licensing reform.

IMGs must obtain exchange visitor (J-1) visas to enroll in U.S. postgraduate training programs. One way to remove immigration law barriers that prevent states from increasing the health care workforce would be to remove the requirement that J-1 visa holders must return to their country of origin for at least two years after they complete their postgraduate training. They should be allowed to apply directly for a green card that would take effect once the J-1 visa expires. At a minimum, Congress should adopt this reform for any physician who works for three years in a medically underserved area without involving state governments.

Congress can—and should—also eliminate the cap on H-1B visas or create an extra allotment of H-1B visas designated for foreign health care professionals who must now compete for H-1B visas with other applicants in highly skilled fields. Likewise, the cap on green cards should be eliminated or an extra allotment created for foreign health care professionals. Congress should also guarantee green cards to the family members of any health care worker if the worker dies while still in a temporary status—a tragedy that is not an infrequent occurrence in the United States.

Scope-of-Practice Laws

To address the demand for health care professionals, a growing number of states have opted out of the federal guideline that requires that certified registered nurse anesthetists (CRNAs) practice under the supervision of physicians. CRNAs are now permitted to practice independently, providing more patients—particularly those in rural areas—access to anesthesia services.

In our federal system, states have power over occupational licensing and determining the scope of work in which a licensee may engage. For licensed health care professions, this is referred to as "scope of practice." For decades, state legislators have witnessed turf battles among the various health care professions. Nurse practitioners (NPs) and physician assistants (PAs), for example, seek to practice independently of physicians and to expand their scope of practice to meet their level of training. This goal is usually met with resistance from medical doctors, who argue that NPs and PAs lack the necessary training to safely provide care beyond a narrowly defined scope. States vary in how they define the scopes of practice of NPs and PAs. Broadening their scope helped address the COVID-19 public health crisis. With the crisis behind us, maintaining the broadened scope will give people more health care options and access, particularly in underserved rural areas.

Pharmacists are another health care profession seeing its scope gradually expand. All 50 states currently allow pharmacists to vaccinate patients, with states differing on age limitations and types of vaccinations allowed. Oregon and Rhode Island allow pharmacy technicians to vaccinate. Several states now allow pharmacists to prescribe hormonal contraceptives, and California and Colorado allow pharmacists to prescribe PrEP (pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) for HIV. Pharmacists' scope of practice can be expanded to include a host of services, including administering and interpreting tuberculosis skin tests; testing and administering prescription meds for patients with influenza and other viral illnesses or common bacterial infections like strep throat; providing nonsedating or low-sedating antihistamines, corticosteroids, and decongestants; and extending routine noncontrolled chronic medication prescriptions for an additional 30–60 days.

Optometrists who have the training should not be blocked from offering simple eye surgical procedures to patients. Policymakers should permit appropriately trained doctorate-level psychologists to prescribe psychotherapeutics. Policymakers should allow dental therapists (analogous to physician assistants) and dental hygienists to practice independently, and to the full extent of their training.

Conclusion

Policymakers suspended regulations they recognized were blocking efforts to save lives during a historic public health emergency. They should learn from this action. They should not reinstate the regulations. Instead, policymakers should permanently remove regulations they tacitly acknowledged are bad for public health.

Suggested Readings

Competitive Enterprise Institute. "How Repeal of #NeverNeeded Regulations Can Help Responses to the COVID-19 Crisis." April 6, 2020.

Dayaratna, Kevin, Paul J. Larkin, and John O'Shea. "Reforming American Medical Licensure." *Harvard Journal of Law and Public Policy* 42, no. 1 (2019): 253–78.

Singer, Jeffrey A. "Solve Imminent Physician Shortage by Licensing Foreign Doctors." *Detroit News*, July 15, 2020.

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Svorny, Shirley. "Liberating Telemedicine: Options to Eliminate State-Licensing Roadblock." Cato Institute Policy Analysis no. 826, November 15, 2017.

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