

COVID-19 Vaccine Administration and Pharmacist Scope of Practice Reform

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September 2020

As major pharmaceutical companies begin phase III trials for COVID-19 vaccines, some experts are optimistic that the United States will have an approved vaccine by early 2021.¹ This is good news, given the regulatory hurdles to vaccine innovation and development, and the concern that these hurdles would cause the pandemic to persist even longer.²

Even if a vaccine is developed relatively swiftly, it needs to be widely administered in order for the pandemic to be countered effectively. Low participation rates might well result in pandemic persistence. Vaccinations for many illnesses, such as influenza, fall consistently short of their recommended population reach.³ This is due, in part, to complex state restrictions on how vaccines may be administered and by whom.⁴ Pharmacists, in particular, could provide better access to vaccine administration, if states would let them.

The ongoing pandemic has already brought to light unnecessary regulations affecting pharmacist-administered vaccines. In August, the Department of Health and Human Services cited low uptake of existing vaccines for children, due to fewer routine medical visits during the pandemic, and issued an emergency directive allowing pharmacists to administer vaccines without prescriptions to patients over three years old during the declared state of emergency.⁵ This directive overrides current restrictions in nearly half of the states, which either restrict or forbid pharmacists from independently providing vaccinations for children.⁶ The differences at the state level in pharmacists' ability to administer vaccines (when there is no state of emergency in effect) are worth examining to find permanent solutions that enable better vaccine administration.

In response to the COVID-19 pandemic, the Mercatus Center has commissioned this series of working papers and policy briefs to promote effective ideas among key decision makers. These publications have been internally reviewed but not peer reviewed.

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This brief will identify the state-based scope-of-practice restrictions on pharmacists that will inhibit uptake of a COVID-19 vaccine. Policy solutions that would give pharmacists broader scope to administer vaccines would remove this roadblock to vaccination, particularly for Americans who have difficulty accessing a physician. Idaho, which has recently expanded the scope of practice for pharmacists in an innovative way, now has a regulatory model that offers several important lessons to state regulators.

VACCINE UPTAKE IN THE UNITED STATES

The Centers for Disease Control and Prevention cites “extremely low” US vaccination rates and has consistently looked for ways to increase participation. For example, for the 2017/18 and 2018/19 flu seasons, an estimated 37.1 percent and 45.3 percent of US adults received a flu vaccination respectively.⁷ The US Office of Disease Prevention and Health Promotion’s Healthy People 2020 initiative targeted a flu vaccination rate of 70 percent.⁸ The Centers for Disease Control and Prevention maintains that some of the leading causes of death in the United States are from “vaccine preventable” diseases such as the flu.

To the extent that the existing disparity between vaccination rates and vaccination rate goals might be indicative of future COVID-19 vaccination participation, this is a matter of concern.⁹ Vaccines are a cost-effective measure to save lives, preserve medical capacity, and reduce overall public spending on health crises.¹⁰ State regulations all too often make it more difficult for consumers to find a vaccination provider, and, on the margin, they lower vaccination rates.

PHARMACISTS AND VACCINES

In the United States, pharmacists began undergoing formal training for vaccine administration in 1996.¹¹ Since then, pharmacists’ role in providing vaccinations in communities has gradually expanded: pharmacists can now vaccinate more age groups, as well as work without physician oversight in some jurisdictions. Pharmacists are particularly suited for rapidly increasing vaccination coverage, given the prevalence of community pharmacies and the fact that pharmacies tend to be open for longer hours than a typical doctor’s office. States where pharmacists are permitted to administer flu vaccines to patients 65 or older have higher vaccination rates.¹²

Pharmacists can be the key healthcare providers for vaccinations when it comes to arresting the current pandemic, but regulations could limit their effectiveness.¹³ The regulation of pharmacist vaccination authority remains complex and varies widely among states.¹⁴ Pharmacists that can administer vaccines help bridge a gap in vaccination rates, but state regulatory barriers often still prevent optimal scope of practice—and, thus, optimal vaccination rates.¹⁵

PHARMACIST SCOPE-OF-PRACTICE RESTRICTIONS FOR VACCINATION ADMINISTRATION

State restrictions on pharmacist-administered vaccines fall into three main categories: patient age restrictions, prescription requirements, and practice authority models. State requirements vary widely in all three categories.

Patient age restrictions and prescription requirements are often related; prescriptions are more commonly required for younger patients. Currently, 28 states allow pharmacists to administer vaccines to patients of any age, though the details of this authority differ depending on the state.¹⁶ For example, consider two sets of neighboring states: Georgia pharmacists can technically administer vaccines to patients of any age, but individual prescriptions are required for patients under age thirteen; Tennessee does not require prescriptions for a pharmacist to administer vaccines to patients of any age.¹⁷ In Oregon, pharmacists can give vaccinations to patients of any age but require prescriptions for patients under seven years old, while California allows pharmacists operating independently (and not under a prescriber protocol, which requires physician permission for pharmacist-prescribed vaccines) to administer vaccines to patients over three years old.¹⁸ Age-based restrictions on pharmacist-administered vaccines are often at odds with recommendations from the Advisory Committee on Immunization Practices (ACIP) for vaccination best practices. (ACIP recommendations guide many states on vaccine administration rules.)¹⁹

Prescription requirements by vaccine type vary just as much as age restrictions do. In Texas, pharmacists can administer vaccines to anyone with a prescription, whereas in Arkansas a patient with a prescription must be at least seven years old to receive a pharmacist-administered vaccine. In Illinois, pharmacists can administer a measles, mumps, and rubella vaccine to a patient of any age without a prescription, but in Missouri, patients must have a prescription.²⁰

Finally, state regulatory models differ in the autonomy given to pharmacists administering vaccines. Individual prescription requirements are the most restrictive model, followed by prescriber-issued protocols, and, finally, by independent practice or prescriptive authority. Prescriber-issued protocols, or standing orders, are issued by physicians and give express permission to a pharmacist or group of pharmacists to administer vaccines per the physician's authority.²¹ Protocols and standing orders that are issued statewide give pharmacists blanket authority to administer vaccines.

State policymakers considered broadening vaccination protocols in Kansas, where adolescent vaccination rates ranked 44th in the United States in 2016. A bill would have expanded pharmacists' authority, allowing them to administer all vaccines to those over six years old.²² Though the bill ultimately failed, similar legislation passed the following year, allowing pharmacists to administer flu vaccines to patients age six or older and every vaccine to patients age twelve or older, subject to protocol and certain training requirements.²³ Public health experts are optimistic that data will show increases in vaccination rates for Kansans.²⁴ Data have already shown,

for example, that the HPV vaccination rate for teenagers increased from 51.8 percent in 2016 to 65.9 percent in 2019.²⁵

The majority of states require prescriptions or prescriber-issued protocols for pharmacist-administered vaccines. Even in the minority of states that do allow independent pharmacists to administer vaccines, that authority doesn't apply to every available vaccine.²⁶

THE IDAHO MODEL

Over the past decade, Idaho legislators have passed incremental reforms to expand pharmacist prescribing authority to cover certain individual drugs like statins and opioid antagonists. These reforms culminated in two bills, passed in 2017 and 2019, that represented a landmark shift in the regulatory framework for pharmacist prescribing authority.²⁷ The 2017 legislation shifted the regulatory framework away from granting pharmacists authority to prescribe individually named drugs through discrete legislation; instead, it introduced four criteria for pharmacist-prescribed drugs that the Idaho Board of Pharmacy would oversee. Under this new model, pharmacists could prescribe FDA-approved drugs to patients under the following circumstances: the patient's illness does not require a new diagnosis, it is minor or self-limiting, it can be identified with low-risk tests, and it puts the patient in need of an immediate prescription.²⁸ The Idaho Board of Pharmacy was authorized to write and issue rules identifying which illnesses and treatments met these criteria.

This broadened framework greatly expanded pharmacist prescribing and treatment authority, and this authority was expanded again in 2019. In that year, the Idaho legislature passed a bill further strengthening pharmacists' ability to prescribe any medication that fits within the four criteria delineated by the 2017 legislation, unless the Board of Pharmacy expressly prohibits pharmacists from prescribing it. Now the Board of Pharmacy is no longer required to list approved drugs for pharmacist prescriptions; it has to list only any prohibited drugs. Authors of a recent study from the Mercatus Center at George Mason University explain, "the burden of proof was reversed, and a framework of permissionless innovation was established."²⁹

The Idaho model has important implications for pharmacist-administered vaccine reform. First, consider how state regulations vary regarding patient age restrictions, prescription requirements, and vaccine types allowed to be administered by pharmacists: there are no known adverse health outcomes in states that allow pharmacists greater authority to vaccinate. This suggests that pharmacist-administered vaccines are subject to arbitrary and unnecessarily complex state regulations. Second, the Idaho model shows the level of autonomy that pharmacists can successfully handle. Instead of requiring drugs to be individually approved for pharmacist-issued prescriptions, Idaho substitutes a broader regulatory framework that allows pharmacist discretion, providing a model that is more adaptable to changing public health needs. This framework lends itself well to vaccine uptake.

SOLUTIONS

There are several solutions to these overly restrictive vaccination regulations. Finding the solution that works best for a particular state depends on its current regulatory framework for pharmacist-administered vaccines, and on how much the state wants to expand pharmacist autonomy. These solutions are presented on a spectrum from least restrictive to most.

Issue Statewide Standing Orders for Pharmacists to Administer COVID-19 Vaccines

Because existing vaccine uptake is low for many vaccines and among many age groups in the United States, the Centers for Disease Control and Prevention recommends using standing orders or protocols to ensure that pharmacists are authorized to administer vaccines without requiring a physician-written prescription for each patient.³⁰ Standing orders and protocols on the organizational level are commonly used in pharmacies and physician offices, but, given the urgency of administering a COVID-19 vaccine once it's available, statewide standing orders should be issued granting pharmacists the authority to administer a COVID-19 vaccine.

A statewide standing order, issued by a state medical board or department, permits more efficient vaccine uptake because it allows pharmacists throughout the state to administer the vaccine without seeking permission from a physician on an organizational or individual level. Statewide standing orders are already used for time-sensitive medical crises. For example, statewide orders for pharmacist-dispensed naloxone are a common tool to combat the ongoing opioid crisis by increasing opioid antagonist access for people at risk of overdose.³¹ Issuing statewide standing orders for a COVID-19 vaccine would increase the number of available providers for patients.

Broaden Regulatory Language on Pharmacist-Administered Vaccines

Revising regulatory language on pharmacist-administered vaccines can increase pharmacists' adaptability to provide vaccinations during future health crises. There are two main ways to do this: First, states can further broaden regulatory language, as was done in Idaho. There, pharmacists are given the autonomy to prescribe medications, so long as these medications are not explicitly prohibited from pharmacist prescribing by the Board of Pharmacy. This approach, which lists what isn't allowed instead of what is, is an innovative way to regulate pharmacist-administered vaccines, and it promotes pharmacist autonomy to the highest level.³²

Second, regulatory language can be revised to follow industry guidelines. In Oregon, for example, regulation allows pharmacists to administer "all ACIP recommended vaccines,"³³ which gives them permission to adapt to any updated ACIP recommendations (which are likely to include a COVID-19 vaccine once it is available).³⁴ This framework prevents lag in vaccine administration due to boards or legislatures having to approve individually named vaccines for pharmacist administration. Letting the industry, instead of the legislature, set the recommendations creates this increased adaptability.

Relax Age Restrictions on Pharmacist-Administered Vaccines

The lack of consistency in age restrictions for various vaccinations and in prescription requirements suggests that state regulations applying higher age restrictions are overly burdensome. States that impose age restrictions on pharmacist-administered vaccines should revise these downward to include larger age groups where appropriate. California provides a good model, similar to the directive of the Department of Health and Human Services during COVID-19: patients over three years old can receive vaccinations from pharmacists practicing independently, so long as the pharmacist documents the vaccination in the California Immunization Registry.³⁵

CONCLUSION

A COVID-19 vaccine will require swift uptake if it is to be an effective tool in pushing back the pandemic. To achieve this, states must reform existing regulatory barriers to pharmacist-administered vaccines, which are overly complex and burdensome in many states and affect individuals' ability to be vaccinated. Greater access to pharmacist-administered vaccines will lead to better and faster uptake of a COVID-19 vaccine.

ABOUT THE AUTHOR

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