



A Dose of Free Market Medicine

Expanding Access to Healthcare Through Pharmacists



Key Takeaways:

- ▶ During the COVID-19 pandemic, many states temporarily waived regulations on pharmacists because they were seen as accessible healthcare providers and could relieve stress on the healthcare system.
- ▶ Since then, several states have followed Idaho's lead in permanently reforming pharmacists' scope of practice, granting them greater authority to administer vaccines, perform low-risk tests, and recommend treatment for certain conditions such as the flu or strep throat.
- ▶ While Tennessee is ahead of most states in terms of allowing pharmacists to administer vaccines, Tennessee should grant more independent authority to pharmacists to test and treat conditions diagnosed with well known rapid diagnostic tests.
- ▶ Additionally, Tennessee should seek to remove any other regulatory barriers that make it more difficult to administer CLIA-waived tests and encourage more pharmacies to obtain a CLIA waiver, and allow pharmacists to determine the number of pharmacy technicians they wish to supervise.



Introduction

The cost of and access to healthcare consistently ranks as one of Americans' top concerns. And these concerns are well founded. Historically, many counties in Tennessee are considered underserved areas, have underserved populations, or have a shortage of primary care providers.¹

In order to improve access to healthcare, Americans for decades have debated expanding the role of advanced practice providers (APPs) like nurse practitioners and physician assistants.² However, during the pandemic, deregulation and a flurry of reforms centered around a different healthcare provider: pharmacists.³ For example, Florida passed a law that allows pharmacists to test for and treat the flu and strep throat.⁴ Tennessee's neighbor, Arkansas, in 2021 gave pharmacists the ability to vaccinate and prescribe medications to prevent adverse reactions to patients as young as three years old.⁵ These reforms occurred because pharmacists were seen as accessible front-

line providers that could relieve pressure on the healthcare system, since nearly 90 percent of Americans live within five miles of a pharmacist.⁶ This means pharmacies can provide better access to patients—particularly in rural areas. Nearly 80 percent of community pharmacies serve areas with populations of less than 50,000; only 11 percent of physicians serve rural areas.⁷ Tennesseans also overwhelmingly support greater flexibility for pharmacists: 57 percent of voters—including a large majority of Democrats, Republicans, and Independents—believe that licensed pharmacists should be able to diagnose and treat common illnesses such as strep throat or the flu, while only 26 percent oppose it.⁸

Although most states have looked at pharmacist regulations in light of the pandemic, one state has been leading the charge for increased access to healthcare by reforming pharmacist laws for much longer: Idaho.



The Idaho Prescription

Since 2011, when the Idaho Legislature gave pharmacists the authority to prescribe fluoride supplements, the Gem State moved from the commonly used “precautionary approach” in which pharmacists’ ability to prescribe is generally prohibited unless a specific exemption exists to a “permissionless” one.⁹ In 2015, legislators gave pharmacists the ability to prescribe Narcan and other opioid antagonists to help combat the opioid epidemic.¹⁰ The following year, pharmacists received the ability to prescribe some immunizations to children as young as six, and also to prescribe epinephrine auto-injectors (commonly known as EpiPens).¹¹

Change dramatically accelerated in 2017 when lawmakers switched from a piecemeal approach, approving one drug at a time, to broader regulatory reform by empowering the Idaho Board of Pharmacy to establish criteria determining if a pharmacist could prescribe a particular device or medication, especially for conditions that:

- ▶ do not require a new diagnosis (such as vaccines and other preventive care);
- ▶ are minor and self-limiting (such as conditions that will likely eventually resolve themselves, like the flu);
- ▶ have a low-risk identification test that is waived under the federal Clinical Laboratory Improvement Act (CLIA); or
- ▶ pose an immediate danger to the patient.¹²

Idaho's reforms were not solely limited to pharmacists' ability and ways to serve patients, but also how they can operate. In 2018, the Idaho Telehealth Access Act made it easier for the state to approve and allow pharmacists licensed in other states to serve Idahoans.¹³ As a result, pharmacies can now fill prescriptions without a pharmacist on site, allowing pharmacy technicians to run the daily operations with a licensed pharmacist on call.¹⁴

The highest measure of regulatory reform is when the burden of proof for the necessity of a regulation is shifted from the regulated to the regulators.¹⁵ And that is exactly what Idaho did. In 2019, Idaho lawmakers unanimously allowed pharmacists to prescribe any medication that fit established guidelines, unless the Board of Pharmacy expressly prohibited them from doing so.¹⁶

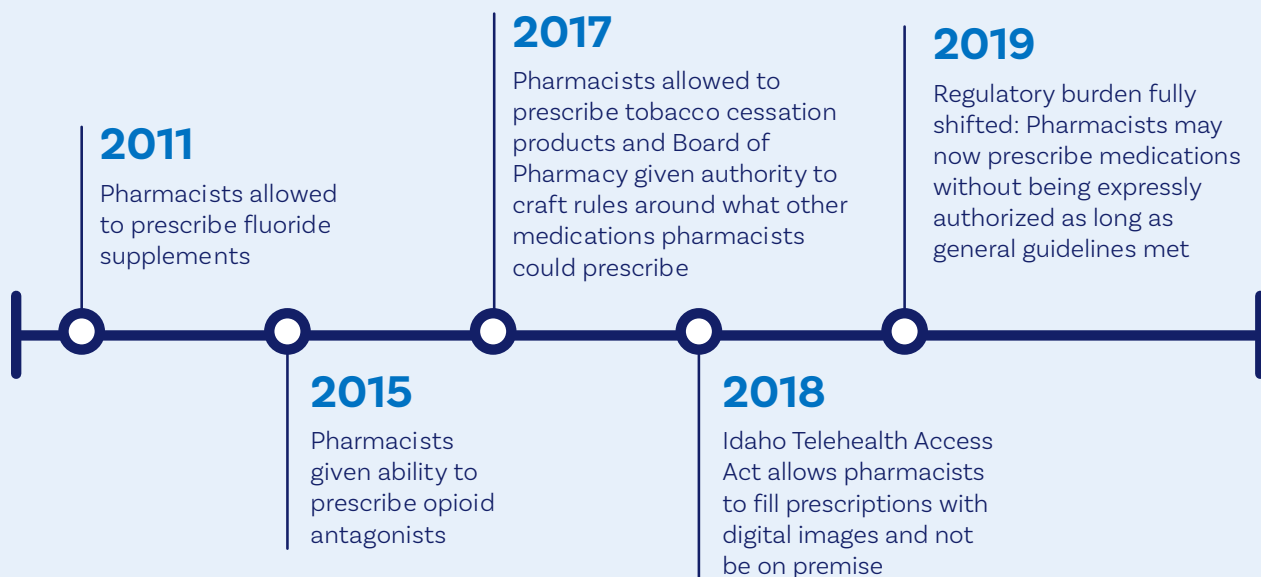


Figure 1. Reforming the practice of pharmacy was Idaho's emphasis for nearly a decade.

The results of these reforms have been profound. First, they have led to new providers entering the marketplace—from new community pharmacies opening in towns that previously did not have one to national giant CVS Healthcare opening a facility for mail orders in Boise.¹⁷ Second, concerns around pharmacists prescribing medications for which they lacked specialized training or the potential for decreased communication between healthcare providers has not occurred, as many pharmacies that do prescribe voluntarily undergo additional training before doing so, while some pharmacists have stated that coordination with other providers has never been higher.¹⁸ Tennessee should look to Idaho as a leader to fully leverage community pharmacists to increase access to quality healthcare.

The Five Active Ingredients to Pharmacist Reform

When analyzing the recent reforms different states have made around the practice of pharmacy, issues fall into five main categories:

1. Pharmacists' Ability to Administer Immunizations
2. Patients' Need for Prescriptions for Immunizations
3. Prescriptive Practice Authority
4. Testing
5. Pharmacy Technician Ratio Requirements



Vaccination Age Restrictions

Some states do not allow pharmacists to administer vaccines to minors, requiring families and children to make appointments with pediatricians. Meanwhile, more states make delineations between pharmacists administering recommended vaccines to minors from birth to six years old versus those recommended from seven to 18 years old. While Tennessee requires parental consent for pharmacists or any healthcare professional to administer vaccines to children, it is one of 27 states that does allow pharmacists to administer vaccines to people of any age.¹⁹

Diagnosis: Clean Bill of Health

Prescription Requirements for Vaccinations

A related issue is that some states require a patient-specific prescription before a pharmacist can administer a vaccine, especially if the patient is a minor.²⁰ Meanwhile, in Tennessee, pharmacists do not need a patient-specific prescription to administer a vaccine.²¹

However, Tennessee pharmacists do need to be part of a collaborative pharmacy practice agreement with a physician or other healthcare professional that covers vaccines in order to administer vaccines at all, and the scope of each agreement is negotiated between the pharmacist and other provider.²² Granting pharmacists the ability to administer vaccines without a collaborative practice agreement could lower the burden on providers and increase pharmacists' ability to respond and adapt to future needs. For example, in Idaho, the regulatory language was broadened to allow pharmacists to administer vaccines and prescribe medications so long as they were not explicitly prohibited by the board. Another way would be to revise regulatory requirements to adhere to industry guidelines. In Oregon, regulation allows pharmacists to administer all vaccines recommended by the Advisory Committee on Immunization Practices, creating a flexible and adaptive regulatory environment as industry guidelines change.²³

Diagnosis: Symptoms Showing

Treatment Recommendation: Eliminate the necessity for Collaborative Practice Agreements for pharmacists to administer regularly recommended vaccines.

Pharmacists' Prescriptive Authority: "Testing and Treating"

In addition to administering vaccinations, an increasing number of states are realizing the value of giving pharmacists the authority to prescribe medications, generally after administering simple diagnostic tests. However, this authority often exists on a continuum:

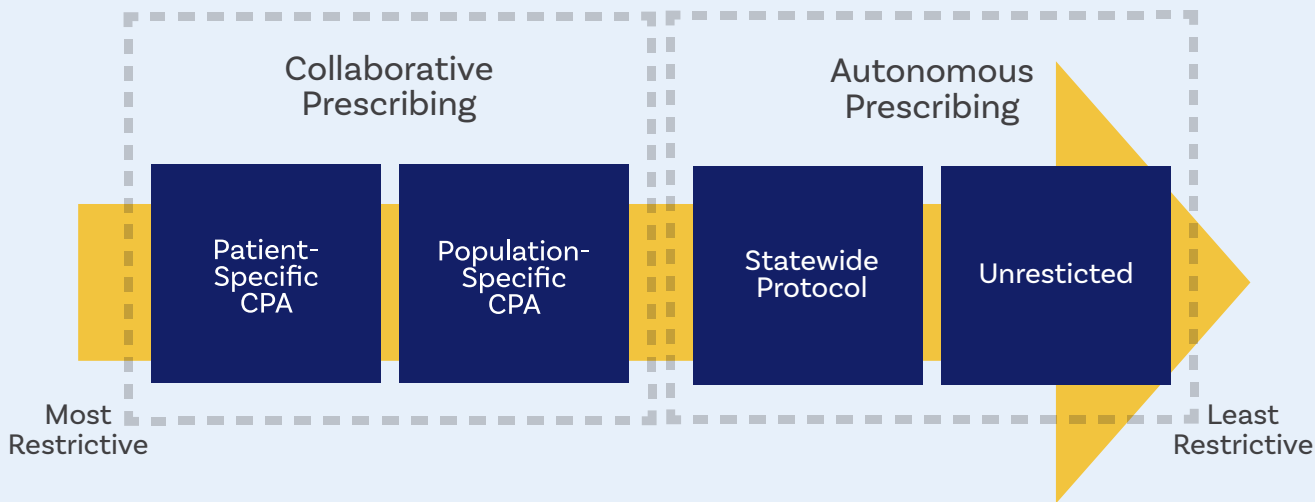


Figure 2: While many states allow pharmacists to prescribe medications, the rules surrounding prescribing vastly differ from state to state. This authority to prescribe either depends on a collective prescribing agreement (CPA) or is given directly by the state.²⁴

While most states generally prohibit a pharmacist's ability to prescribe outside of a few circumstances, six states recently gave pharmacists the authority to prescribe independently of any supervising physician:

Pharmacist's Ability to Prescribe is a Growing Trend

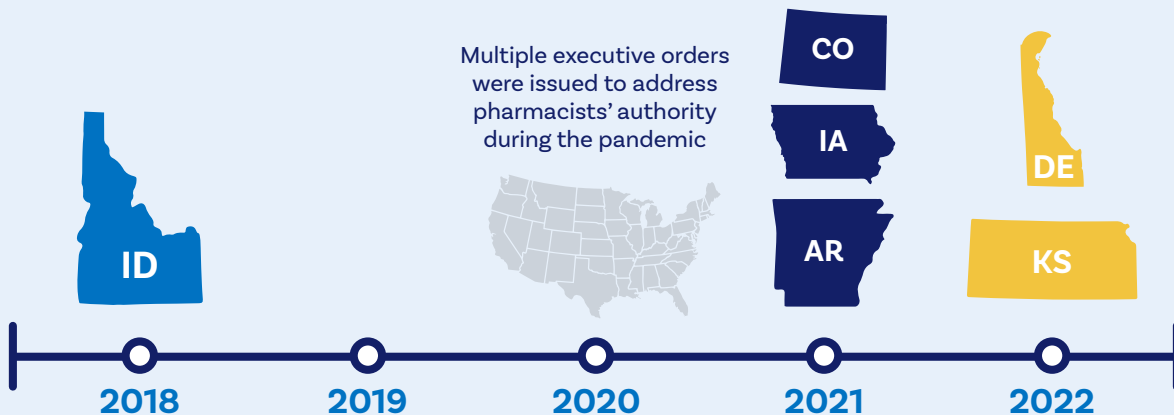


Figure 3: A growing number of states have expanded pharmacists' ability to prescribe since the pandemic.²⁵

Typically, pharmacists in these states are limited to prescribing drugs to treat conditions that can be identified by a CLIA-waived test or for specific conditions like flu, strep throat, or COVID-19. The federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 provides oversight of clinical laboratories and testing to diagnose, prevent, and treat diseases.²⁶ However, facilities can obtain a certification to administer tests that are deemed “low risk” as part of the CLIA waiver program. These tests include those for conditions such as influenza, strep throat, and HIV, among others.²⁷ Meanwhile, as discussed earlier, pharmacists in Idaho have much broader authority, with the ability to prescribe medications if they fit within the guardrails set by the regulatory board.

Why are these states granting so much more authority to pharmacists? In addition to increased access, another reason could be shorter wait times and lower costs for patients. Sometimes, patients must wait days for an appointment with a primary care physician, whereas pharmacists often do not require appointments, have longer operating hours, and are more likely to be open on weekends. Additionally, because the prices for medications have increased more slowly than medical services, patients can often save money on treatment for these lower-level conditions by avoiding a traditional medical office.²⁸ In fact, research has shown that as states have expanded pharmacists’ prescriptive authority, lower prices and higher health outcomes have resulted.²⁹

Where does Tennessee fall on this continuum? As mentioned earlier, Tennessee’s collaborative pharmacy practice statute is broad enough to cover pharmacists prescribing medications after a CLIA-waived diagnostic test, like the six states mentioned above. However, that ability is limited to what each pharmacist and licensed physician agree to.³⁰ Additionally, all treatment must be patient-specific except for vaccinations, screening and testing (but not treating), as well as the dispensing of opioid antagonists.³¹

The only other exception is birth control pills. In 2016, Tennessee passed a statewide protocol for pharmacists to prescribe hormonal contraceptives to females 18 years of age or older or emancipated minors.³² A statewide protocol is a framework that outlines the conditions under which pharmacists are authorized to prescribe a certain medication or category of medications.³³ For example, 18 states have protocols that allow pharmacists to prescribe tobacco-cessation products without a collaborative practice agreement with a physician or other healthcare provider.³⁴

Diagnosis: Symptoms Showing

Treatment Recommendation: Grant pharmacists the ability to independently test and treat conditions as the result of a rapid diagnostic test (such as CLIA-waived tests) and expand statewide protocols to include tobacco-cessation products and epinephrine auto-injectors.

CLIA-Waived Testing

If Tennessee pharmacists are given the ability to test and treat conditions based on a rapid diagnostic test, they also need the ability to administer such tests. Since 1988, the number of facilities that have undergone the CLIA waiver process, including pharmacies, has steadily increased.³⁵ In Tennessee, the number of CLIA-waived pharmacies rose from 21 percent in 2015

to 34 percent in 2020.³⁶ As of September 30, 2023, that number has jumped to 39 percent.³⁷ Having more pharmacists obtain that certification increases patients' access to simple diagnostic tests.

CLIA Waived Pharmacies in Tennessee

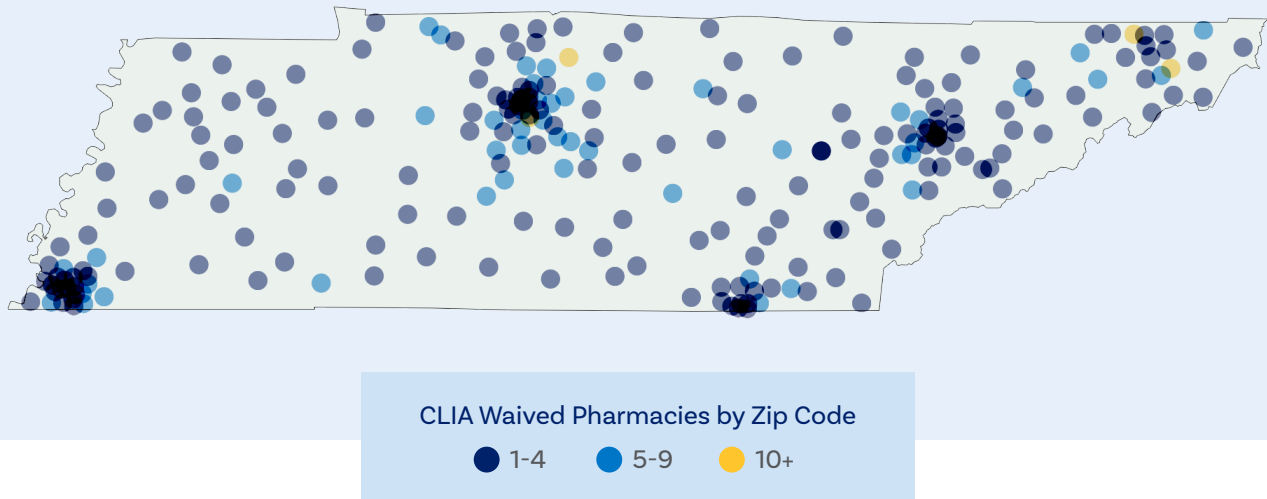


Figure 4: Pharmacies that have obtained a CLIA waiver exist in hundreds of zip codes and nearly every county and in Tennessee.

However, many pharmacies nationwide are not currently taking advantage of this process as statewide averages range from zero to 60 percent of pharmacies that have obtained a CLIA waiver.³⁸ Some argue that the reason for the disparity is due to state-level barriers such as testing procedures, licensure requirements for lab workers like phlebotomists, and waste disposal requirements.³⁹

During the pandemic, Tennessee Governor Bill Lee waived certain regulatory requirements, such as prior approval from the Medical Laboratory Board, in order to allow for the creation of alternative COVID-19 testing sites.⁴⁰ The General Assembly made this deregulation permanent when it exempted pharmacists that have obtained a CLIA waiver from the Tennessee Medical Laboratory Act.⁴¹ This deregulatory effort may be why we have seen the percentage of CLIA-certified pharmacies jump from 34 to 39 percent in three years. While the state does not license phlebotomists, state lawmakers should look for other ways to lessen the burden of providers looking to serve patients under a CLIA waiver, such as regulations around medical waste disposal and encourage more pharmacies to obtain a CLIA waiver.

Diagnosis: Strong Vitals but Improvements Remain

Preventative Care Recommendations: The state should look at other regulations that lessen the incentive to obtain a CLIA waiver or interfere with pharmacies providing services under one.

Pharmacy Technician Ratios

Pharmacy technicians are trained employees who assist pharmacists in their duties and work under their supervision. Pharmacy technicians often help fill prescriptions, obtain medical history information from patients, manage inventory, and file insurance claims and other billing information, among other duties.⁴² While six states (Colorado, Delaware, Hawaii, New York, Pennsylvania, and Wisconsin) do not regulate pharmacy technicians in any way, the vast majority require some combination of training, education, or simple registration.⁴³ Tennessee does not require pharmacy technicians to obtain mandatory training or education, but does require them to register with the Board of Pharmacy.⁴⁴

An even more burdensome regulation is the max ratio of technicians to pharmacists. This is especially egregious when one considers that similar medical professionals, like nurses and doctors, do not face similar ratio restrictions on their working relationships. As of 2020, 22 states regulated the ratio of technicians to licensed pharmacists, including Tennessee.⁴⁵ State-imposed ratios typically range from two to four technicians per pharmacist; Florida has the highest ratio, at 1:8 in certain situations.⁴⁶ Interestingly, Tennessee is the only state that has made its ratio stricter in recent years, moving from three technicians per pharmacist in 2016 to two technicians per pharmacist today.⁴⁷ However, a pharmacist may request a waiver from the Board of Pharmacy to increase the ratio to four technicians per pharmacist.⁴⁸ Luckily, a proposed regulation reform currently being considered would move Tennessee's pharmacist to technician ratio cap from 1:2 to 1:6 and provides ways to seek a waiver to go beyond this.⁴⁹

Diagnosis:

On Life Support

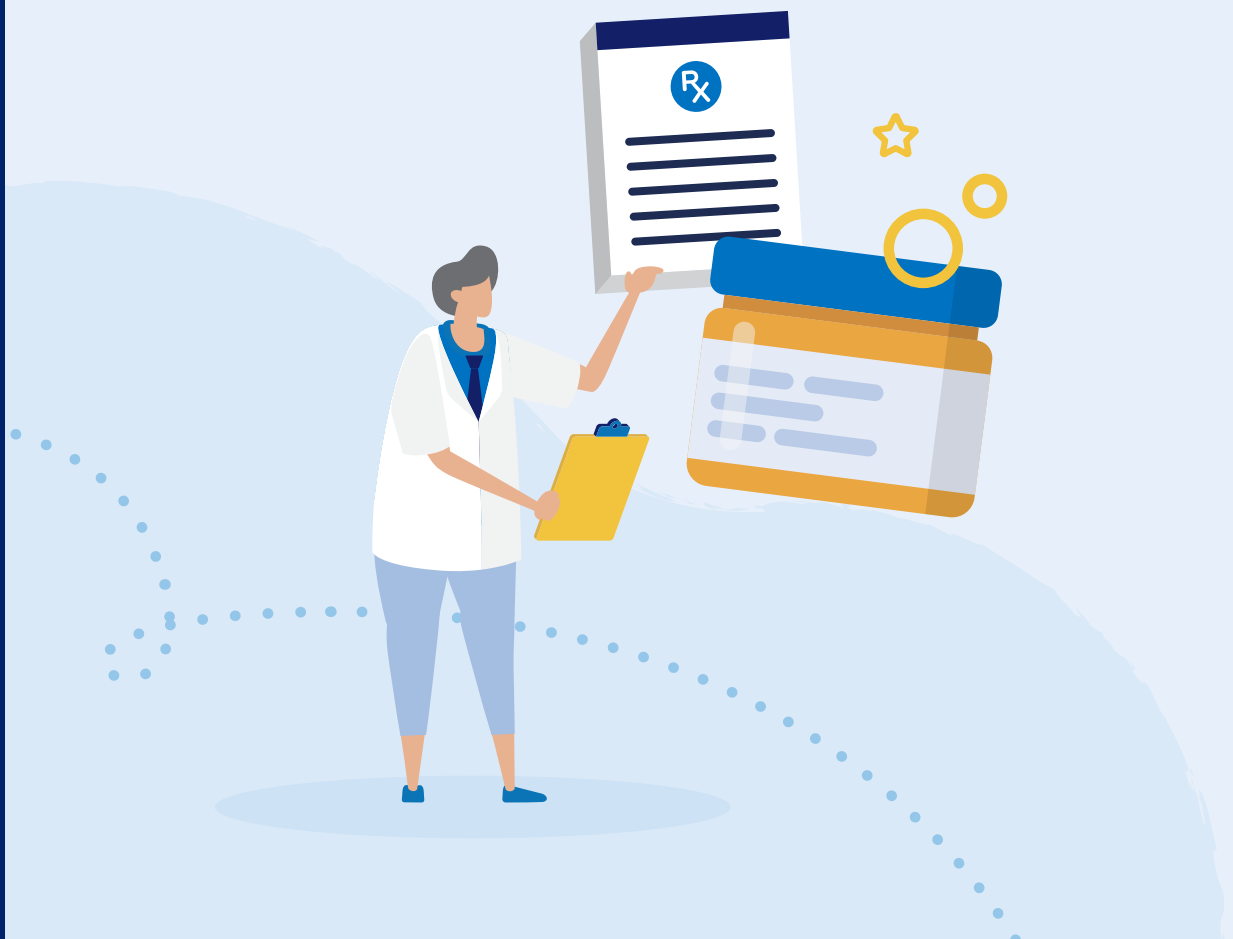
Treatment Plan:

Tennessee policymakers should eliminate the ratio on pharmacy technicians and allow licensed pharmacists to determine their workforce.



Conclusion

While no one would ever say the COVID-19 pandemic was a good thing in any situation, one silver lining is that it led to a wave of healthcare deregulation. Waiving restrictions such as medical testing licenses and certificate of need requirements allowed our healthcare system to better respond and adapt to the massive demand during the pandemic. If a healthcare regulation was waived to help fight a public health crisis, one is led to wonder what purpose it really serves to begin with. Since the pandemic, many states have made some of these deregulations permanent and are seeking to further increase access to quality care and capacity in the healthcare system by reforming the regulations on pharmacists' scope of practice. Pharmacists are often the most accessible healthcare professionals in many communities, especially rural ones. A growing number of states, most notably Idaho, have given pharmacists more authority to administer vaccines, permit them to test and treat minor conditions, have reduced the regulatory burden on their prescriptive authority, and now allow them to employ more technicians to assist them in their work. While Tennessee has done some things well and passed some decent deregulatory efforts, many opportunities exist to expand pharmacists' ability to serve Tennesseans while remaining within their technical knowledge. Doing so would increase access to healthcare and health outcomes of Tennesseans statewide. It's time for a dose of free market medicine in healthcare.



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