

HEALTH LAW AND COMPLIANCE

Prescribing Pharmacists: Cheaper and More Accessible Than Urgent Care?

Urgent message: As states move forward with legislation enabling pharmacists to prescribe, not just dispense, the urgent care industry must consider the implications on competition, collaboration, and public health.

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n February 11, 2020, the Virginia legislature passed bills HB 1506 and SB 1026, respectively, enabling pharmacists to prescribe medications, not just dispense them (see **Table 1** for full text). The Virginia Senate bill, which is more comprehensive than the House bill, extends pharmacist prescribing to all vaccinations; TB testing; drugs used to treat influenza, *H pylori*, strep, and urinary tract infections; and PrEP/PEP for HIV. Diagnosis would occur by point-of-care testing in the store. The Senate bill also includes "Drugs for which the patient's health insurance provider requires a prescription for coverage" which, taken literally, extends a pharmacist's prescribing power to... all drugs.

As of the writing of this article, the bills are in the Education & Health Committee for reconciliation. Protocols and standards will then have to be defined by the Boards of Medicine and Pharmacy before pharmacists can begin prescribing.

Not only does this type of legislation create an entirely new class of medical provider, but it also raises concerns for public health and safety, while also proposing a radical change in how minor medical conditions are diagnosed and treated.

Supporters of pharmacist prescribing typically offer it as a solution to high healthcare costs, a shortage of medical



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providers in primary care specialties, and historic access barriers to basic care. "Accountable care" entails aligning a patient's needs with the most cost-effective solution for a medical condition. Undergoing instant testing and picking up a prescription in a retail drugstore should be less expensive than an urgent care visit that entails a standalone facility, marketing costs, capabilities to diagnose and treat a range of conditions, technology to maintain records and bill insurance, and a skilled clinical crew to deliver basic services.

Rx pundits would emphasize that pharmacists have a heavy education load—a PharmD can take 5 to 8 years to obtain—and that pharmacists take more pharmacology and pharmacotherapeutic classes than any other healthcare professional. But while pharmacists are undoubtedly *the experts* in body chemistry, they have not been trained in diagnosis, including conducting a history and physical and recognizing other complicating factors apart from a positive lab test.

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Table 1. Sections of Legislation Passed in the Commonwealth of Virginia in February 2020, Detailing the Substances a Pharmacist May Prescribe

HOUSE BILL NO. 1506

- § **54.1-3303.1**. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.
- A. Notwithstanding the provisions of § **54.1-3303**, a pharmacist may initiate treatment with, dispense or administer the following drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:
- 1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;
- 2. Epinephrine;
- 3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment as recommended by the American College of Obstetrics and Gynecology;
- 4. Prenatal vitamins for which a prescription is required; and 5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services.

SENATE BILL NO. 1026

- § **54.1-3303.1**. Prescribing, dispensing, and administering of controlled substances by pharmacists.
- A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may prescribe, dispense, and administer the following drugs and devices in accordance with a statewide protocol developed by the Board in consultation with the Board of Medicine and set forth in regulations of the Board:
- 1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention;
- 2. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;
- 3. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § **54.1-3466**, as may be necessary to administer such naloxone or other opioid antagonist; 4. Epinephrine;
- 5. Drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement
- 6. Tuberculin purified protein derivative for tuberculosis testing; 7. Injectable or self-administered hormonal contraceptives;
- 8. Drugs or devices for the treatment of diseases or conditions caused by infection with influenza virus, Helicobacter pylori bacteria, or group A Streptococcus bacteria or a urinary tract infection if such infection is confirmed by a positive result on an approved test administered by the pharmacist. If an approved test administered by the pharmacist is negative, the pharmacist shall not prescribe, dispense, or administer such drugs or devices and shall refer the patient to a healthcare provider for diagnosis and treatment;
- 9. Drugs for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; 10. Prenatal vitamins for which a prescription is required if a pregnancy test confirms the pregnancy of the person to whom the vitamins are dispensed; and
- 11. Drugs for which the patient's health insurance provider requires a prescription for coverage.

Prescribing medication is only one small piece of what an urgent care provider does. So, influenza can be detected by a test—and a prescription written. But what happens when the patient also has pneumonia? Pulse ox is low, respiratory rate is high and labored, and no air movement in the bases? How is this patient, diagnosed by an instant test, going to be "treated" by a pharmacist in a drugstore?

Most states allow some form of pharmacist prescribing, but it's almost always pertaining to health concerns that do not require a diagnosis. For example, 48 states and Washington, DC allow pharmacists to dispense naloxone without a physician's prescription. Patients in 10 states, including Oregon and California, can walk up to a pharmacy counter, fill out a health questionnaire, get their blood pressure checked, and, if every-

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thing's okay, obtain contraception from the pharmacist. While in other states, pharmacists can extend, adjust and/or substitute physician prescriptions, particularly for chronic conditions.

Separately, state boards of pharmacy have been lobbying for "provider status" which would include pharmacists in health insurance reimbursement for services beyond Rx dispensing. A provider in the scope of the Social Security Act is a medical professional who is able to bill (ie, be reimbursed by) the Medicare program, usually under Part B, for services rendered. While pharmacists have been able to get reimbursed for the meds they dispense, in the past they've not had a mechanism to charge for the "professional services" they offer. Getting recognized as providers from a billing perspective is another necessary step toward pharmacists becoming full-fledged medical practitioners.

States like Montana, New Mexico, North Carolina, North Dakota, and California give pharmacists midlevel practitioner status, allowing them to enter into a collaborative practice agreement with any physician in order to initiate and modify any type of drug therapy, including controlled substances. Collaborative practice agreements (CPAs) are legal documents that establish a relationship between pharmacists and collaborating physicians. With this midlevel practitioner status, patients can now walk into a pharmacy for immediate attention concerning drug-managed conditions like chronic pain.

For urgent care operators, for whom the majority of patients they see are wanting treatment for low-acuity conditions such as upper respiratory infections, urinary tract infections, and minor skin conditions, a pharmacist with dispensing privileges would constitute a new class of competition. Consumers who could approach a pharmacy counter for a diagnosis and prescription for a minor condition could save significant time and money by not visiting an urgent care center.

The move towards pharmacist prescribing does seem to be driven more by corporate interests (ie, revenue) than the desires of pharmacists themselves. For the past several years, major pharmacy chains have been remodeling stores to move pharmacists from behind the counter to a "front-and-center desk" where they can interact more directly with the public, for both counseling and also to administer services. 1 It's only logical these investments have been in anticipation of legislation that would expand the pharmacist's capability. Pharmacists are seen by retailers as an expensive, well-trained, but underutilized resource who serve the following functions:

- Dispenser
- Gatekeeper
- Drug information expert

How would giving pharmacists the authority to prescribe change the dynamic between pharmacist and

Supporters of pharmacist prescribing claim it benefits patients by:

- Improved patient outcomes
- Improved patient education and adherence
- Decreased adverse drug events (increased patient safety)
- Increased patient access to medicines

The chain pharmacy lobby also claims prescribing will advance the pharmacy profession through:

- · Better use of pharmacists' skills and training
- Professional autonomy
- Increased reimbursement opportunities
- Better integration into interdisciplinary healthcare teams

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- Patient advocate
- Clinician
- Prescriber
- Diagnostician
- Fducator

The retail drugstore chains, which have also launched instore clinics staffed by nurse practitioners and have acquired other ancillary services such as home intravenous infusion and durable medical equipment, claim that pharmacists are trusted by patients because the pharmacists have training in human physiology and chemistry that emphasizes drug efficacy and interactions, and that pharmacists have a "complete view" of a patient's health by seeing the patient's prescriptions from multiple providers. They have also expressed the belief that dispensing, which does entail some verification of dosing and interactions, is not an appropriate use of pharmacists' education and skill set. Rather, dispensing can be automated or supervised remotely using digital technology.

But a recent New York Times piece profiled how drugstore pharmacists are already overworked, due to increasing mandates of retail chain owners. Specifically, "They struggle to fill prescriptions, give flu shots, tend the drive-through, answer

Walgreens' \$140 Million Theranos Gamble: The Technology Was Fraudulent; the Business Strategy Was Not

In October 2018, Walgreens announced it would be opening at least 600 blood-draw locations in conjunction with pathology giant LabCorp. This type of diagnostic testing onsite is a prerequisite to pharmacist prescribing, but not the first time Walgreens has pursued a business strategy of instore diagnostic testing.

In 2010, Walgreens teamed up with Silicon Valley startup Theranos to open 40 in-store diagnostic centers while also investing over \$140 million in Theranos' small sample point-of-care testing technology, with the idea a patient could receive a diagnosis (and, subsequently, treatment) instantly in the store. Walgreens has an incredible footprint of approximately 10,000 retail locations, making it easily accessible to the vast majority of Americans. Well, in 2015, after a Wall Street Journal article cast doubt on the efficacy of Theranos technology, that company shut down for good and in 2017, Walgreens received a \$30 million settlement on its initial \$140 million investment.

While the Theranos technology was clearly one of the biggest frauds in U.S. history, the business strategy was nothing of the sort. What would the impact be to urgent care if a patient could enter a drugstore, get an instant flu test with immediate results, and then purchase Tamiflu OTC? The barrier to fully realizing the value of in-store testing is no medical provider in the store—and limitations with the retail clinic model—so point-of-care testing is necessarily paired with the pharmacist prescribing treatment based on the lab test.

Source: Sweeney B. Walgreens partners with a new blood-testing firm. Modern Healthcare. Available at: https://www.modernhealthcare.com/article/20181011/ NEWS/181019973/walgreens-partners-with-a-new-blood-testing-firm. Accessed March 2, 2020.

phones, work the register, counsel patients and call doctors and insurance companies—all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less."2

And we're hearing all sorts of double-talk from the Rx lobby, including a third-party complaint in a criminal action involving excessive dispensing of opioids in Florida:3 "Pharmacists do not write prescriptions and do not decide for doctors which medications are appropriate to treat their patients," the complaint says. "While pharmacists are highly trained and licensed professionals, they did not attend medical school and are not trained as physicians. They do not examine or diagnose patients. They do not write prescriptions."

So long as a pharmacist dispenses the right medication to the right patient, following the provider's instruction, and exercises some diligence to identify any interactions with other drugs the provider may not have known about, professional liability for malpractice generally falls on the medical provider. Pharmacists who prescribe would be subject to a whole new legal dynamic, as they would now have to be accountable for both following a clinical process and the outcomes of that process. Additionally, prescribing privileges for pharmacists would eliminate historic controls separating prescribing from dispensing, while introducing conflicts-of-interest that could trigger Stark Law (antireferral) implications.

"Expansion of the pharmacist's services from dispensing to prescribing could take certain low-acuity visits, such as flu and urinary tract infections, away from urgent care. However, greater concerns center around pharmacists' lack of experience and training in diagnosis, as well as conflict-of-interest issues in removing the separation between prescribing and dispensing."

Conclusion

Retail pharmacies have made significant investments in store design, diagnostic and lab alliances, clinic operations and partnerships, and acquisition of adjacent service lines like IV infusion and home health which all align with an overall plan of changing the pharmacist's role from dispensing to prescribing.

The two largest U.S. pharmacy chains have over 20,000 stores, most of which are at high-visibility, easily accessible intersection locations. An expansion of the pharmacist's services from dispensing to prescribing could take a chunk of lowacuity visits like flu and urinary tract infections away from urgent care. But there are greater concerns regarding pharmacist's lack of experience and training in diagnosis as well as conflict-of-interest issues in removing the current controls between prescribing and dispensing.

References

- 1. Kamin B. Walgreens' designs prove an upgrade for shoppers. Chicago Tribune. September 28. 2014.
- 2. Gabler E. How chaos at chain pharmacies is putting patients at risk. The New York Times. January 31, 2020.
- 3. Finnegan J. Who is to blame for the opioid crisis? In Florida, Walgreens and CVS point finger at physicians. FierceHealthcare. February 13, 2020.