Pharmacists With Prescribing Privileges: A New Class of Medical Practitioner

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Urgent message: *State boards of pharmacy, the National Association of Boards of Pharmacy, and large national drugstore chains are pushing for regulatory changes that would enable pharmacists to diagnose medical conditions and prescribe a range of medications, creating a new class of health-care provider for some patients who are treated in urgent care centers today.*

"Within five years I expect pharmacists to have prescribing privileges," said Patrick Carroll, MD, chief medical officer for Walgreens Healthcare Clinics, to the Urgent Care Association of America at its 2015 spring conference.[1]

State pharmacy boards, the National Association of Boards of Pharmacy, and several retail pharmacy chains have pushed to create a third category under U.S. Federal Drug Administration (FDA) regulations, redefining certain prescription drugs for common illnesses as "nonprescription drugs," which would give pharmacists the right to routinely dispense them without prescription by physicians. If this proposal passes, urgent care providers may see pharmacists become a new type of health-care provider for walk-in patients. Physicians will be forced to work with pharmacists to coordinate a level of care to ensure the safety of their patients.

National pharmacy chains have been moving to redefine the role of the pharmacist for some time, engaging automation and pharmacy technicians in the dispensing process and focusing pharmacists on educating and consulting with patients. Walgreens, for instance, is moving its pharmacists from behind the dispensing counter to a front-and-center desk where they can interact one-on-one with customers.[2] The retail drugstore chains, which have also launched in-store 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 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.

The rationale for this new proposal, according to the February 12, 2012 issue of the *Federal Register*,[3] ultimately stems from the concern that many people with chronic medical conditions, such as asthma, migraines, high blood pressure, and high cholesterol levels, are currently being undertreated.

These patients walk into pharmacies every day to ask their pharmacists for advice. State pharmacy boards say that pharmacists should be allowed to dispense medications to treat these prevalent conditions because many people place a significant level of trust in their pharmacist, especially patients with limited access to medical care.

Currently, all prescription medication must be prescribed by a licensed practitioner, which is defined as a medical doctor, nurse practitioner, physician's assistant, or other type of practitioner, such as podiatrists and chiropractors, under limited circumstances. Under section 503(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S. Code 353(b)(1)(A)), a drug must be dispensed by prescription if, ''because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such a drug," according to the *Federal Register*.[3]

At this time, pharmacists are able to dispense medications lawfully prescribed by others, evaluate whether there are any dangerous or fatal drug interactions, identify any incorrect dosages written on the prescription, and provide consultation on how to take a particular medication. They also have the ability to give advice on which over-the-counter medication to take for a particular ailment. That pharmacists are already advising patients is one of the arguments that pharmacists and drugstore chains have given the FDA in supporting their mission to change the law.

The current argument by both the pharmacy boards and drugstore chains is that certain treatments for ailments like high cholesterol levels, high blood pressure, and high triglyceride levels are routine enough that a pharmacist (who has some medical training) should be able to make an assessment on the basis of blood test results to prescribe the appropriate medication. This decreases the time and effort it takes a patient to get a prescription from a physician and would benefit all the undertreated patients who do not have the time to visit a physician for something as minor as obtaining a prescription. For example, "a pharmacist could make a recommendation regarding an appropriate drug therapy, based on results of testing for cholesterol or triglycerides," explained Robert Glatter, MD, *Forbes* magazine contributor.[4] Glatter has concerns similar to those of his medical colleagues:

I can certainly appreciate a pharmacist prescribing an inhaler to an asthma patient who is in acute distress in a pharmacy, or an [EpiPen auto-injector] to a person with an acute [life-threatening] allergic reaction standing in line at a pharmacy counter. However, I agree that the practice of allowing pharmacists to routinely prescribe certain classes of drugs has the potential to create an unsafe practice in certain subgroups of patients with multiple medical problems.

The FDA, however, views this proposal as an opportunity to provide a larger population of patients better access to basic health care, especially with the enactment of the Patient Protection and Affordable Care Act. The *Federal Register*acknowledges that a greater number of insured Americans, combined with an insufficient number of general practitioners, creates barriers to access.[3] The advantage of allowing a

pharmacist to see patients and prescribe drugs for common illnesses directly contributes to reducing health-care costs. The vision is that a patient can visit a pharmacist for routine treatment, rather than visit a physician who bills at a higher rate.

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, especially if "limited" prescribing privileges focus on creating a lower cost venue for these routine, minor conditions. 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 FDA has also found that "some patients who obtain an initial prescription do not continue on necessary medication because they would need to make additional visits to a health care practitioner for a prescription refill."[3] Other patients need to visit their physician for routine blood tests before the physician will write a new prescription or authorize more refills. The FDA feels that this is unnecessary and that allowing a pharmacist to act as an intermediary in these situations, in a safe environment, would eliminate some of these issues.

By allowing pharmacists to handle basic health-care needs, this practice would relieve a burden for urgent care providers, emergency physicians, and other medical practitioners, allowing them to focus on more serious cases, the FDA believes. The medical field, however, disagrees.

Both the American Medical Association (AMA) and the American Academy of Family Physicians (AAFP) wrote letters of opposition about this new paradigm, pointing to significant risks in allowing pharmacists to play a bigger role in the medical field. The AMA has argued that pharmacists do not have the training to correctly prescribe a medication that is currently listed as a prescription drug by the FDA and that redefining certain medications as nonprescription could cause patients harm.

Glatter wrote[4]:

The proposed practice of allowing pharmacists to prescribe [so-called] "routine medications" under this proposal has the net effect of blurring the lines in the traditional relationship between patients, medical providers, and pharmacists.

During the FDA's March 22, 2012 public hearing, Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription, representatives from both sides expressed their perspectives on this potential change to the FDA rules.[5] Beverly Schaefer, RPh, who represented the National Community Pharmacists Association, said at the hearing:

Pharmacists have demonstrated over the years their ability to provide increased access to health care with implementing mass vaccination campaigns throughout the nation.

During the 2009/2010 H1N1 influenza season, nearly one third of all immunizations were administered in [a] pharmacy.

State pharmacy boards, the National Association of Boards of Pharmacy, and all pharmacist associations agreed: Pharmacists who are allowed to prescribe certain routine medications will be able to streamline the system and provide medication to a greater population of those in need of health care. The FDA is also considering certain routine medications to be defined as both prescription and nonprescription. "Dual availability could help ensure greater access to needed medications by making obtaining them more flexible," explained the *Federal Register*.

A few medical practitioners attended the FDA public hearing on expanding nonprescription drugs and voiced their concern and opposition to the addition of a third category proposed in the *Federal Register*. One such practitioner, internist Sandra Adamson Fryhofer, MD, MACP, FRCP, said[5]:

Well, one of the concerns I have, and you mentioned doses of medications, as an internist, I take care of adults of all ages, [from] adolescents [to the elderly]. My oldest patient is 94 and I hope she lives to be 104, and if I have anything to do with it, she will. [There was clapping from the audience.] So, I'm very concerned about doses of medication and that's a big source of confusion, especially for my elderly patients.

Fryhofer continued, explaining that what might seem to be a small dosage change can be detrimental to a patient's health. "The difference between some of my patients taking 10 milligrams of a blood pressure medicine and five milligrams of a blood pressure medicine can be the difference between them being able to walk to the restroom or falling right out of bed and having a hip fracture." Several medical professionals expressed the belief that if a pharmacist is going to take on some of the responsibilities of a medical practitioner, then maybe they should be going to medical school.

In the AAFP's letter to the FDA opposing the proposal, AAFP Board Chair Roland Goertz, MD, MBA, explained[6]:

Only licensed doctors of medicine, osteopathy, dentistry, and podiatry have the statutory authority to prescribe drugs. Allowing the pharmacist authority to dispense medication without consulting with the patient's physician first could seriously compromise the physician's ability to coordinate the care of multiple problems of many patients.

Even though the AMA and the AAFP wrote letters of opposition, very few individuals from the medical community were present at the 2012 public hearing. However, a significant number of individuals were present who represented the pharmacists and drugstore chains supporting the proposal.

The good news is that the FDA has discussed seeking evidence that certain prescription drugs can safely be redefined as nonprescription and administered by pharmacists[3]:

We anticipate that, depending upon the situation, applications for approval of nonprescription products with conditions of safe use may need to include patient studies (e.g., self-selection studies, label comprehension studies, and actual use studies) to demonstrate that the drug would be safe and effective under the specified conditions.

What will the future of our health-care system look like if pharmacists are allowed to administer certain medications that have always been categorized as prescription drugs? How will urgent care practitioners, general practitioners, and pharmacists work together in this new system to minimize health risks to patients? No one knows yet. But it is vital that we address this issue.

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