Pharmacists May Soon Be Allowed to Prescribe Certain Drugs, Competing with Licensed Practitioners

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In 2012, the State and National Board of Pharmacists, and several retail pharmacy chains, have pushed to create a third category ("A New Paradigm") within the Federal Drug Administration's (FDA) Register that redefines certain "prescription drugs" for common illnesses, to "nonprescription drugs", under a pharmacist's discretion.

If the proposal passes, in three years, medical practitioners may see a pharmacist's role expand to become a different type of practitioner who can prescribe certain routine medications to patients who walk through their doors. Doctors will be forced to work with pharmacists to coordinate a level of care to ensure the safety of their patients. National pharmacy chains like Walgreens are already heading in this direction by moving their pharmacists from behind the counter, to front and center where they can educate and consult with their customers. (Link: http://my.chicagotribune.com/#section/-1/article/p2p-81524140/ Accessed 5/7/2015)

The rationale for this new proposal, according to the 2012 FDA Register (Link: http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4597.pdf) ultimately stems from the concern that many people with chronic medical conditions, such as asthma, migraine headaches, high blood pressure, and high cholesterol, are currently being under-treated. These people walk into pharmacies everyday asking their pharmacists for advice. The State Board of Pharmacists feel that pharmacists should be allowed to dispense medications to treat these prevalent conditions, since 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, and other types of practitioners. Under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 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 FDA Register.

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

The current argument by both the pharmacist boards and drug chains is that certain treatments for ailments like high cholesterol, high blood pressure and triglycerides, are routine enough that a pharmacist (who has some medical training) should be able to make an assessment based on blood test results to prescribe the appropriate medication. This decreases the time and effort it takes to get a prescription from a doctor and would benefit all the under-treated patients who do not have the time to visit the doctor 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 Dr. Robert Glatter, Forbes magazine contributor. (Link: http://www.forbes.com/sites/robertglatter/2012/05/11/should-pharmacists-prescribe-prescription-medications)

As a medical doctor, Glatter has similar concerns as his colleagues in the medical field. "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 Affordable Care Act. Now more patients have access to health care and there are not enough general practitioners to treat them all, states the FDA Register. The advantage of allowing a pharmacist to see patients and prescribe drugs for common illnesses, directly contributes to reducing health care costs. If a patient can visit their pharmacist for routine treatment, rather than visit a doctor who bills at a higher rate, then the FDA has contributed to decreasing health care costs.

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." Other patients need to visit their doctor for routine blood tests before a doctor will write a new prescription or authorize more refills. The FDA feels this is unnecessary and utilizing a pharmacist as an intermediary for these situations under a safe environment would eliminate some of these issues.

By allowing pharmacists to handle basic health care needs, this practice would relieve the burden of urgent care providers, emergency doctors, and 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 a letters of opposition to this "New Paradigm". As far as the medical community is concerned, there are significant risks allowing pharmacists to play a bigger role in the medical field. The AMA argued that pharmacists do not have the training to correctly prescribe a medication that is currently listed as a prescription drug under the FDA Register and by redefining certain medications to nonprescription under this third category, could become harmful to the patient.

"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," expressed Glatter.

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*, individuals from both sides spoke in favor or against this potential change in the FDA rules. Beverly Schaefer, RPh**,** who represented the National Community of Pharmacists Association, spoke at the public hearing and claimed, "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."
(Link: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM301937.pdf, FDA public hearing transcripts)

Both the State and National Boards of Pharmacists 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 FDA Register.

A few medical practitioners attended the FDA public hearing on expanding non prescription drugs and voice their concern and opposition to the addition of a third category proposed in the FDA Register. One such practitioner, Dr. Sandra Adamson Fryhofer, an internist, voiced her opinion, "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 a clap in the audience). So, I'm very concerned about doses of medication and that's a big source of confusion, especially for my elderly patients."

Dr. Fryhofer, continued by explaining that what seems to be a small dosage change can be a 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 medial professionals felt 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.

"Only licensed doctors of medicine, osteopathy, dentistry, and podiatry have the statutory authority to prescribe drugs," says Goertz. "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," explained AAFP Board Chair Roland Goertz, M.D., M.B.A., of Waco, Texas in AAFP letter to the FDA opposing the proposal.

Even though the AMA and the AAFP wrote letters of opposition, there were very few individuals from the medical community who were present at the public hearing. There were a significant number of individuals representing the pharmacists and drug chains that supported the proposal under discussion at the FDA public hearing in 2012.

The good news is that the FDA has discussed seeking input into evidence that would deem certain prescription drugs to be redefined as nonprescription and administered under safe use. "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," stated the FDA in their Federal Registry.

So what will the future look like in the health care system if pharmacists are aloud to administer certain medications that used to be categorized as a prescription drug? How will medical providers and pharmacists coordinate together in this new system? At this time there is no answer. Nobody has come up with any good solutions.

In less than three years, pharmacists may join the rankings of licensed practitioners in a limited capacity to not only test patients before prescribing them, but to use their best judgment on what types of medications, previously deemed prescription drugs, to prescribe to treat common illnesses. General practitioners and urgent care doctors will need to find a way to coordinate with pharmacists in their area to minimize the health risks to their patients. One possible solution is to require pharmacists to consult with a patient's doctor before prescribing a certain medication, especially if there is any question or concern.