



MedGuides Confuse Consumers And Waste Time for Pharmacists

FDA Considers Ways to Improve Pharmacy Operations

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Pharmacy groups are pressing the U.S. Food and Drug Administration (FDA) to make major changes in the agency's program of requirements for medication guides (MedGuides). The program is also under fire from consumer groups but for different reasons.

The pressure comes at a time when Congress is about to pass sweeping new drug safety amendments, including the requirement that the FDA develop a "Risk Evaluation and Mitigation Strategy" (REMS) for many drugs. A MedGuide is one of the congressionally approved means of communicating the REMS to consumers.

Because of language that Congress slipped in a bill a decade ago, the FDA already requires MedGuides to be included for a subset of new drugs—namely, those associated with potentially serious adverse reactions. Mandated for such drugs, the MedGuides are ostensibly easy-to-understand printed information sheets that pharmacists give to consumers to reinforce what their physicians presumably have already mentioned—that the particular prescribed drug might carry some serious side effects. Initially, the FDA expected that MedGuides would be necessary for only a few drugs each year.

The FDA did use the authority gingerly at first. Over the past few years, however, with the addition of two major classes—the nonsteroidal anti-inflammatory drugs (NSAIDs) and the antidepressants—the number of medication guides that have to be distributed has increased substantially. The FDA's Web site lists 65 drug names that must be accompa-

nied by MedGuides. In raw numbers, these guides are required for more than 1,600 individual National Drug Code (NDC) numbers, or 8% to 10% of all prescriptions.

Typically, a MedGuide, which drug manufacturers print and then distribute to pharmacies, is about three pages long, although some guides can be as many as 30 pages long. Pharmacists are responsible not only for handing the MedGuide to customers but also for ensuring that they receive a second handout, Consumer Medication Information (CMI). This multipage compendium contains additional information about the drug beyond its potential adverse effects.

Drug manufacturers developed CMIs in response to a congressional mandate that required them to voluntarily put together an action plan. The plan's goal was to ensure that 95% of prescriptions dispensed to patients in the U.S. would be accompanied by useful medication information. In 2006, the FDA was supposed to have determined whether the 95% mark has been reached. No one inside or outside the FDA thinks the answer to that question is "yes" or that the figure is anywhere near 95%. That is why the agency is apparently moving forward to create a plan on how to make the MedGuide more useful. The agency held a two-day workshop on that topic in June.

There are numerous problems with the MedGuides themselves. In 2005, the FDA indicated that they were not being distributed by pharmacies to the consumers; sometimes the manufacturers weren't delivering the guides to the pharmacies. Even when the pharmacy had a stack of MedGuides in a back room, the pharmacists typically had difficulty keeping track of which drugs required them. In a 2004 FDA study of 5,000 randomly selected pharmacists that examined their knowledge of risk-minimization tools, 29% of pharmacists were not familiar with these medication guides.

In reality, many pharmacists simply don't have the time to become familiar with the guides. Marcie Bough, PharmD, Director of Federal Regulatory Affairs of the American Pharmacists Association (APhA), explains:

Many pharmacists reported significant administrative burden and logistical problems trying to comply with the MedGuide regulation. Pharmacists are experiencing disruptions in pharmacy workflow that sometimes [affect] the overall quality of care patients receive.

Consumer groups would be just as happy if pharmacists were taken out of the equation and if the MedGuides were distributed by physicians instead. Lisa Van Syckel, a representative of a group called Drug Awareness, says:

If the sales representatives are carrying these type of documents around, they are fully capable of bringing medication guides to the physicians' office. It's not that difficult. There the doctor could provide the medication guide to the parent, to the child, prior to prescribing the medication.

However, it is unlikely the FDA will shift the responsibility of distribution from pharmacists to physicians. Instead, the agency might allow the MedGuide and CMI to be combined and printed out by the pharmacist with other prescription information at the time a prescription is filled.

John Coster, Vice President of Policy and Programs with the National Association of Chain Drug Stores, says that his group and other organizations have been asking the FDA to be allowed to print the guides as part of the single-pass document that comes with the prescription.

"I know no pharmacist [who] wants to store pads of paper or paper documents in their pharmacies," he says. "That's not the world we're living in anymore." ■