DEA Proposal on Hydrocodone Combination Products Divides Pharmacists

The Impacts on Pharmacy Workload and Prescription Drug Abuse Are at Issue

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Very few federal regulatory issues cause a split among pharmacists, but the potential change of hydrocodone combination products from a Schedule III to a Schedule II controlled substance is a current cleaver. It not only divides individual pharmacists—various pharmacy associations disagree as well. Those divisions may become more acute as the Drug Enforcement Administration (DEA) works to finalize a late-February proposal to list hydrocodone combination products (HCPs) such as AbbVie’s Vicodin on Schedule II. The Food and Drug Administration (FDA) recommended that the DEA make the change last December based on a vote by an FDA advisory committee. The DEA, which makes final controlled-substance designations, published a proposed rule on February 27.

The rescheduling would ostensibly help diminish prescription drug abuse involving HCPs, since Schedule II controlled substance prescriptions cannot be refilled. Legitimate patients would have to go back to the physician. There would be some additional recordkeeping and inventory requirements for pharmacies, but nothing they’re not already doing for other Schedule II drugs, such as oxycodone (OxyContin, Purdue Pharma).

Pharmacists’ comments to the DEA have been impassioned on both sides (pro and con). Michael Sinks, PharmD, says his pharmacy often receives prescriptions for outlandish quantities of HCPs (i.e., Vicodin and Watson Laboratories’ Norco). Quantities can be as high as 240 tablets, sometimes 540 tablets for a single prescription. “I have called physicians countless times about the maximum amount of acetaminophen that a patient can take in a single day (which is often overlooked because of the perception that acetaminophen is harmless),” he writes. “I am in total agreement with this proposal and there is no doubt in my mind that it would lead to lives being saved.”

But Doug Wells, a community pharmacist for 35 years, thinks physicians will start prescribing acetaminophen with codeine phosphate instead of HCPs. “However, researchers tell us that approximately 30% of the population are unable to efficiently convert the inactive drug codeine into its active metabolite, hydrocodone, in the body,” he writes. “Although this proposal may seem warranted to stem the tide of hydrocodone abuse, it is far too drastic. Such a draconian measure would be akin to restricting tire sales in order to decrease automobile traffic deaths. It makes no sense.”

Pharmacy associations are split, too. The American Society of Health-System Pharmacists (ASHP) supports the rescheduling. The National Association of Chain Drug Stores and the National Community Pharmacists Association (NCPA) oppose it.

The NCPA says rescheduling will likely pose significant hardships and delay relief for many patients, especially those in nursing home and long-term care settings, as well as rural areas. Moreover, there are alternative solutions to combat abuse without harming patients. “Bottom line is that we believe there are other options available to reduce prescription drug abuse without harming patients with legitimate needs as rescheduling would do,” says Kevin Schweers, NCPA spokesman.

But Kasey Thompson, PharmD, MS, Vice President of Policy, Planning, and Communications for the ASHP, supported rescheduling in a November 2013 letter to Kathleen Sebelius, then U.S. Health and Human Services Secretary. He wrote: “ASHP believes that hydrocodone combination products are similar to other controlled substances found in Schedule II and should therefore be assigned to Schedule II.” He downplayed the impact on patients and providers from the elimination of automatic refills. He added that by their very nature, prescriptions for acute pain treatment would have limited or no refills.

Dr. Thompson did admit that the “full impact of this change on patients, physicians, pharmacists, and other health care providers is difficult to predict.” But Carlos Aquino, Compliance Consultant for the Pharma Compliance Group, who inspects pharmacies for drug distributors and is conversant with DEA requirements for pharmacies, thinks any additional administrative impositions on pharmacies will be minimal.

Aquino says that one difference between Schedules III and II is that a pharmacy must provide an exact count of the number of dosage units of Schedule II drugs in a biannual inventory report. If the pill count in any container is under 1,000, the pharmacy can estimate the exact number. If it is over 1,000, the pharmacy must actually count the number. “It is the dumbest regulation I have ever heard of,” he says. But he also notes that hydrocodone combination products typically come in bottles of 100 and 500.

A DEA official downplays any pharmacy burden from Schedule II requirements, such as keeping records segregated from Schedule III, IV, and V records or ordering using the DEA 222 form. Kim Burns, RPh, JD, Associate Professor in the Department of Pharmaceutical Sciences at Lake Erie College of Osteopathic Medicine, says dealing with customers with HCP prescriptions may in some instances be time-consuming. If customers show up at the pharmacy wanting a refill, pharmacists may have some extra work explaining why they cannot provide one, and the pharmacist may have to get on the phone to the physician while the unhappy customer paces at the counter.