

Pharmacists Welcome FDA's Opioids REMS

How Directly Will They Be Affected?

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On July 9, the FDA finally approved its first class-wide Risk Evaluation and Mitigation Strategy (REMS) for extended-release (ER) and long-acting (LA) opioid analgesics in an effort to address prescription drug abuse and misuse. Pharmacy groups generally supported the opioids REMS, especially because they had been critical of the FDA's approach to issuing REMS, first authorized by the 2007 FDA reform bill. Pharmacy groups argued that all of the REMS published during the previous 5 years concerned single drugs, including those in the same class. These multiple in-class REMS, written by the individual manufacturers, often had different requirements, were confusing, and imposed unnecessary administrative burdens on pharmacies.

The class-wide REMS, which covers opioids made by 20 companies, was a welcome "blueprint" for future REMS, even though it does not specifically require pharmacists to do anything. However, pharmacists will have to be conversant with the elements of the blueprint and will most likely be handing out the blueprint's new patient medication guides. The final blueprint also includes a 3-hour training course on proper prescribing and pain management with ER/LA opioids. Although the course is generally meant for physicians, nurses, and physician assistants, it might also be relevant for pharmacists and other health care professionals.

As a result, subtle pressures might be put on the pharmacy profession, and perhaps on state boards of pharmacy, to start offering continuing education (CE) courses on opioids in addition to the options currently available. Edith Rosato, RPh, IOM and Chief Executive Officer of the Academy of Managed Care

Pharmacy, says that she does not know of any opioids CE credits being offered to pharmacists, but she was happy to see reference made to pharmacists in the blueprint and thinks that the profession would be well served by the voluntary creation of such courses.

The REMS requires the 20 drug companies that make ER and LA opioids to pay for the development of training modules via independent grants to accredited CE course providers. The programs will be based on the learning objectives established by the FDA blueprint. Manufacturers will maintain a Web site that includes REMS information, and they will send letters to physicians registered with the Drug Enforcement Administration within 60 days of the FDA-approved training.

Most of the responsibility for implementing the REMS falls on the pharmaceutical companies, who will pay for the training materials and will attempt to entice physicians (in some way, as yet unknown) to take the training to satisfy the FDA's new "success thresholds." Of the 320,000 active prescribers currently registered with the DEA, 60% must take the course within 4 years after the first REMS becomes available in March 2013.

Companies will be required to audit the success of the training programs (e.g., by stating how many physicians took the CE credit course). However, in deference to the physician lobby, physicians are not actually required to set foot in a classroom. Moreover, the FDA does not have the legal authority to make opioid training mandatory. Although a provision did address that topic in the Senate version of the FDA's user fee bill that was passed by Congress in June, the bill was kicked out in the final version because the House of Representatives opposed that provision.

The drug manufacturers probably deserve some credit here. They did not go to Congress crying about overregulation in an effort to defang the opioids REMS. Mallinckrodt, the pharmaceuticals business division of Covidien, is one of the world's largest manufacturers of opioid

products. Lynn Phillips, Manager of Media Relations, says, "Mallinckrodt has been involved in the development of, and supports the announced class-wide, Risk Evaluation and Mitigation Strategy for extended-release opioids."

The only affected branded Mallinckrodt product is Exalgo (hydromorphone HCl ER tablets). The company's generic products that fall under the REMS include the fentanyl transdermal system (patch), ER methadone HCl tablets, and morphine sulfate ER capsules.

The FDA's development of a class-wide REMS for opioids stems from the Obama administration's concern about overdoses, which increased in the previous decade. The administration put out several initiatives in this area, of which the FDA class REMS was one.

"Misprescribing, misuse, and abuse of extended-release and long-acting opioids are a critical and growing public health challenge," says FDA Commissioner Margaret A. Hamburg, MD.

Based on the 2010 National Survey on Drug Use and Health, public health experts estimate more than 35 million Americans 12 years of age and older have used an opioid for a nonmedical use at some point—an increase from about 30 million in 2002. In 2009, there were nearly 343,000 emergency visits involving the nonmedical use of opioid analgesics. According to the Centers for Disease Control and Prevention, 14,800 Americans died from overdoses involving opioids in 2008. In 2009, these medications were involved in 15,597 deaths—nearly four times as many deaths as in 1999.

The new REMS might not make much of a dent in decreasing the total number of opioid-related deaths, particularly those of addicts compelled to use the drugs for purposes not specified by the label. Certainly, a significant percentage of deaths might be reduced if pharmacists had more time to talk to patients or, in mail-order cases, if they could look over a patient's records or talk with the patient's physician before the prescription was filled. ■

