Class-wide REMS for extended-release and long-acting opioids: Potential impact on pharmacies

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Abstract

Objectives: To provide an update on the recently approved class-wide risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioids and to discuss the potential impact on pharmacy practice.

Data sources: In mid-2011, the Food and Drug Administration notified drug manufacturers that a single, class-wide REMS would be required for ER and LA opioids. This regulation was the result of a multiyear process that incorporated input from government, drug manufacturers, medical associations, and other stakeholders.

Summary: The goal of the class-wide REMS for ER/LA opioids is to reduce addiction, unintentional overdose, and death resulting from inappropriate prescribing, misuse, and abuse. To accomplish these goals, this REMS focuses on physician education on safe and appropriate prescribing and patient counseling on the risks of opioids. Although voluntary, a movement to require physician education to obtain or renew Drug Enforcement Administration licensing is occurring. Pharmacists are not included in the class-wide REMS per se. Pharmacists play an important role in overall risk reduction and are critical to the success of the class-wide REMS.

Conclusion: Although the changing requirements for prescribing ER/LA opioids will not have a direct effect on pharmacist workflow, the pharmacist–patient interaction remains critical for overall risk reduction with this class of medication.

Keywords: Risk evaluation and mitigation strategies, opioid analgesics, extended release, long acting, substance abuse, addiction, overdose.

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Chronic pain is a major public health problem in the United States.[1] Studies that characterize chronic pain as enduring for 3 months or more show prevalence between 15% and 64% in U.S. adults.[2–5] For patients with chronic pain that is moderate or severe and adversely affects functioning, a trial of an opioid analgesic may be considered if the predicted benefits outweigh the risks.[6,7] Use of this approach to therapy has increased markedly during the previous 2 decades, particularly for patients with chronic noncancer pain conditions.[8–11] From 2000 to 2009, the number of prescription opioids dispensed from outpatient community pharmacies increased from 174 to 257 million, the majority of which were written for noncancer pain conditions.[8]

The increased use of prescription opioids, though improving quality of life for many patients with intractable pain, has contributed to a dramatic increase in prescription opioid misuse, abuse, and overdose.[6,12,13] In 2009, 5 million people reported abusing a prescription opioid, and the number of first-time abusers of prescription opioids was comparable with the number of first-time abusers of marijuana.[14] A rise in deaths from prescription opioid overdose also has been observed and is now reported to cause more than five times the number of deaths as heroin overdose.[12] Further, approximately 430 million prescription opioid doses, or 1 in 25 doses, are ingested for nonmedical purposes each year.[13]

At a Glance

Synopsis: The recently approved class-wide risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioids seeks to reduce addiction, unintentional overdose, and death resulting from inappropriate prescribing, misuse, and abuse. The REMS focuses on physician education on safe and appropriate prescribing and patient counseling on the risks of opioids. Although pharmacists are not included in the class-wide REMS per se, they play an important role in overall risk reduction and are critical to the success of the REMS.

Analysis: *Pharmacists arguably are the most accessible health professionals for patients, and given their long-standing relationships with patients and ability to provide patient education, pharmacists will be critical to the success of the class-wide REMS for ER/LA opioids. Although no requirement exists for pharmacists to provide different counseling to patients receiving ER/LA opioids compared with patients receiving nonregulated medications, patient counseling is integral to the success of the class-wide REMS. The medication therapy management model may help incorporate patient counseling into existing infrastructure, as it was in part designed to facilitate pharmacist and patient interaction.*

Despite a long history of attempts to curb the abuse of controlled substances, legislation to enable the Food and Drug Administration (FDA) to initiate enforceable postmarketing risk management strategies was not in place until the Food and Drug Administration Amendments Act (FDAAA) of 2007.[15] Manufacturers of prescription opioids and other medications with known or potential serious risks were required to implement risk evaluation and mitigation strategies (REMSs) to ensure the therapeutic benefits outweigh the risks.[16] In response to the growing number of postmarketing reports of misuse, abuse, addiction, and overdose deaths associated with extended-release (ER) and long-acting (LA) opioid analgesics, FDA announced the need for a class-wide REMS for this medication class in April 2011.[17,18] The REMS program was approved by FDA on July 9, 2012.[19] Of the ER/LA opioids listed in Table 1, methadone is the only agent that is considered an LA formulation.

The core emphasis of this class-wide REMS is prescriber and patient education on the safe use of prescription opioids.[17] Pharmacists arguably are the most accessible health professionals for patients, and given their long-standing relationships with patients and ability to provide patient education, pharmacists will be critical to the success of the class-wide REMS for ER/LA opioids.[8,20,21] This article briefly discusses this change in opioid regulation and prescribing, and the potential impact of this program on pharmacists in various health care settings.

REMSs: Potential components

Since the FDAAA 2007 legislation, a total of 199 products were required to have a REMS.[22] These programs are individualized to address a product's unique risks and include up to five components: (1) medication

Table 1. Extended-release and long-acting opioids included in the class-wide REMS

Brand name[a]	Generic name
Avinza	Morphine sulfate ER capsules (CII)
Butrans	Buprenorphine transdermal system (CIII)
Dolophine[b]	Methadone HCl tablets (CII)
Duragesic	Fentanyl transdermal system (CII)
Exalgo	Hydromorphone HCl ER tablets (CII)
Kadian	Morphine sulfate ER capsules (CII)
MS Contin	Morphine sulfate CR tablets (CII)
Nucynta ER	Tapentadol ER tablets (CII)
Opana ER	Oxymorphone HCl ER tablets (CII)
Oramorph SR	Morphine sulfate SR tablets (CII)
OxyContin CR	Oxycodone (HCl) CR tablets (CII)

Abbreviations used: CII, Schedule II opioid agonist; CIII, Schedule III opioid agonist; CR, controlled release; ER, extended release; HCl, hydrochloride; SR, sustained release.
[a]Generic formulations also require a REMS.
[b]Long-acting opioid refers only to methadone.