

## **ACCME Participates in FDA REMS Meetings; Compiles REMS Fact Sheet**

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FDA REMS Meetings, Fact Sheet for CME Providers

The ACCME has participated in two meetings with the Food and Drug Administration (FDA) about Risk Evaluation and Mitigation Strategies (REMS). We have also produced a fact sheet for accredited CME providers about the FDA Extended-Release and Long-Acting Opioid Analgesics REMS.

### **ACCME Presentation at FDA REMS Public Meeting**

Murray Kopelow, MD, ACCME President and CEO, made a [presentation](#) at the FDA Standardizing and Evaluating REMS Public Meeting, held July 25–26, 2013. He explained that the ACCME has a long-standing commitment to supporting public health priorities and described how accredited CME for prescribers supports the goals of FDA REMS. He explained the scope of the ACCME accreditation system, which includes 2,000 accredited providers that offered more than 130,000 activities in 2012, educating more than 24 million health care professional participants.

Accredited CME supports public health priorities by addressing health care professionals' practice gaps, providing education that is designed to facilitate change, and evaluating the education for its effectiveness. With [the Extended-Release and Long-Acting Opioid Analgesics REMS](#), the FDA provided a [blueprint](#) which contains the core educational messages for accredited CE providers to follow when developing REMS CE. Moving forward, Dr. Kopelow suggested that the FDA consider continuing to standardize the REMS process, but allowing more flexibility in content. The strength of CME lies in its expertise in producing educational activities targeted to physicians based on their professional practice gaps, individualized needs, and stages of learning and change. With more flexibility, accredited prescriber education related to REMS could go further in addressing individual prescribers' educational and practice needs.

He said that the effectiveness of REMS could also be measured in terms of how successfully it promotes access to education, mobilizes the education community to an issue, and draws the medical professions' attention to a problem.

He emphasized that accredited prescriber education related to REMS will be independent of commercial influence and will meet the requirements of the ACCME Standards for Commercial Support.

"I was honored to have the opportunity to present at the FDA REMS meeting," said Dr. Kopelow. "We appreciate that the FDA recognizes the value of accredited education. The ACCME has a long-standing commitment to supporting the role of accredited CME as a strategic partner in public health and safety initiatives. Certainly, accredited CME should be considered as a strategic asset to all those trying to improve drug safety."

Download Dr. Kopelow's [presentation](#).

### **ACCME Participates in the Conjoint Committee on CME Meeting with FDA about ER/LA Opioid Analgesics REMS**

The Council of Medical Specialty Societies (CMSS) Conjoint Committee on CME (CCCME) and other representatives of the CE community met with the FDA on July 23 discuss the [Extended-Release and Long-Acting \(ER/LA\) Opioid Analgesics Risk Evaluation and Mitigation Strategy \(REMS\)](#). The

centerpiece of the ER/LA Opioid Analgesic REMS is a prescriber education program about the risks of opioid medications as well as safe prescribing and safe use practices. The CCCME explained its goal to exceed the FDA's targets for educating 25% of the 320,000 physician prescribers of ER/LA opioids in the first year and 60% of prescribers by the fourth year. CE providers described their education initiatives related to the ER/LA Opioid Analgesics REMS. Kate Regnier, MA, MBA, Deputy Chief Executive and COO, ACCME, participated in the meeting; the ACCME is a member of the CCCME.

### **Fact Sheet for Accredited Providers about the ER/LA Opioid Analgesics REMS**

The ACCME has compiled "[Accredited Continuing Medical Education and the FDA's Risk Evaluation and Mitigation Strategies: A Fact Sheet for Accredited CME Providers.](#)" The fact sheet for accredited providers within the ACCME system answers questions about the ER/LA Opioid Analgesics REMS and explains the role of accredited continuing education, the ACCME, and accredited providers in addressing prescription drug safety and fulfilling the goals of the REMS. It describes how the ACCME is participating in the REMS data collection and auditing process as a service to the CME community and to the FDA.

[Download the fact sheet.](#)

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