Risk Evaluation and Mitigation Strategy (REMS) for Opioid Analgesics

Extended-release, long-acting (ER/LA), and immediate-release (IR) opioid analgesics are powerful pain-reducing medications that have both benefits as well as potentially serious risks. The **ER/LA Opioid Analgesic REMS**

(https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17), approved on July 9, 2012, is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics.

The FDA has determined that a REMS is necessary for IR opioid analgesics to ensure that the benefits of these drugs continue to outweigh the risks, and the IR opioid analgesics that are intended to be used in the outpatient setting will be subject to the same REMS requirements as the ER/LA opioid analgesics.

To start this process, the FDA sent the relevant **letters (/Drugs/DrugSafety/InformationbyDrugClass/ucm305245.htm)**, detailing the new requirements, to IR opioid analgesic manufacturers. The ER/LA opioid analgesic manufacturers also received letters detailing additional modifications to the approved REMS.

The modified REMS will include revisions to the Blueprint for health care professional training to require additional educational content in pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). Additional information will also be included about the safe use of opioids as well as some basic information about addiction medicine and opioid use disorders.

Training will also be made available to other health care professionals involved in the management of patients with pain such as nurses and pharmacists, not only prescribers. Training will be aimed at making sure providers who write prescriptions for any opioids are doing so for properly indicated patients and under appropriate clinical circumstances.

FDA believes that all health care providers involved in the management of pain should be educated about the safe use of opioids. The FDA's Opioid Policy Steering Committee is currently considering if there are circumstances under which the FDA should require some form of mandatory education for health care professionals to make certain that prescribing doctors are properly informed about appropriate prescribing recommendations, understand how to identify the risk of abuse in individual patients, and know how to get addicted patients into treatment.

This is all part of a broader effort to make sure providers are properly informed about suitable prescribing and the risks and benefits associated with all opioid analgesics.

Additional Resources

- **FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (Revised FDA Blueprint) (https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf)** (PDF - 141 KB)
- **Opioid Medications (/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm)**
- **Accredited Opioid REMS CE: Free or Nominal Charge (http://www.er-la-opioidrems.com) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics (FDA Blueprint) (/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM515636.pdf)** (PDF - 580KB)

Meetings with Industry and Stakeholders

- **Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics: Exploring the Path Forward - May 9-10, 2017 (/Drugs/NewsEvents/ucm538047.htm)**
- **Industry Meeting on Modifying ER/LA Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) – January 25, 2017 (/Drugs/DrugSafety/InformationbyDrugClass/ucm536125.htm)**
- **May 3-4, 2016 Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (/AdvisoryCommittees/Calendar/ucm490628.htm)**

Background and Historical Information

- **Safety Measures for Extended-release and Long-acting Opioids (/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm)**
- **Safety Measures for Immediate-Release Opioids (/Drugs/DrugSafety/InformationbyDrugClass/ucm491437.htm)**
- **Historical Information on Opioid Analgesic REMS (/Drugs/DrugSafety/InformationbyDrugClass/ucm305245.htm)**

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More in Information by Drug Class
(/Drugs/DrugSafety/InformationbyDrugClass/default.htm)