



August 2012

**FDA-Required REMS Program for Serious Drug Risks**

**Subject: Announcement of a Risk Evaluation and Mitigation Strategy (REMS) for all extended-release/long-acting opioid analgesic drug products due to their risks of misuse, abuse, addiction, and overdose.**

Dear **Alabama Board of Nursing**:

We encourage you to share the following information with your licensees.

Extended-release and long-acting (ER/LA) opioid analgesics are approved for the management of chronic moderate-to-severe pain in the U.S., and can be safe and effective in appropriately selected patients when used as directed. However, opioid analgesics are also associated with serious risks and are at the center of a major public health crisis of increased misuse, abuse, addiction, overdose, and death.

The U.S. Food and Drug Administration (FDA) has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ER/LA opioid analgesics to ensure that the benefits continue to outweigh the risks of adverse outcomes (addiction, unintentional overdose, and death) resulting from inappropriate prescribing, abuse, and misuse. A REMS is a strategy to manage a known or potential serious risk associated with a drug product. In the interest of public health and to minimize the burden on the healthcare delivery system from having multiple unique REMS programs, pharmaceutical companies subject to this REMS have joined together to implement this REMS for all ER/LA opioid analgesic drug products.

The principal components of this REMS are:

- a) Prescriber training on all ER/LA opioid analgesics,
- b) the *Patient Counseling Document on Extended-Release and Long-Acting Opioid Analgesics* (PCD), and
- c) a unique Medication Guide for each ER/LA opioid analgesic drug product.

The branded and generic drug products subject to this REMS include *all*:

- extended-release, oral-dosage forms containing
  - hydromorphone,
  - morphine,
  - oxycodone,
  - oxymorphone, or
  - tapentadol;
- fentanyl and buprenorphine-containing transdermal delivery systems; *and*
- methadone tablets and solutions that are indicated for use as analgesics.

**Prescriber Action**

Under the REMS, prescribers are **strongly encouraged** to do **all** of the following:

- **Train (Educate Themselves)** — Complete REMS-compliant training offered by an accredited provider of continuing education (CE) for their discipline. This training is being developed and will be offered early next year at no or nominal cost to prescribers. You will be notified when REMS-compliant training will become available. *REMS-compliant training* will: (a) be delivered by accredited CE providers; (b) cover all elements of the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics (“FDA Blueprint”); (c) include a post-course knowledge assessment; and (d) be subject to independent audit of content and compliance with applicable accrediting standards.
- **Counsel Their Patients** — Discuss the safe use, storage, and disposal of ER/LA opioid analgesics with patients and their caregivers every time they prescribe these medicines. The enclosed *Patient Counseling Document (PCD) on Extended-Release/Long-Acting Opioid Analgesics* should be used to facilitate these discussions.

- **Emphasize Understanding the Medication Guide** — Stress to patients and their caregivers the importance of reading the Medication Guide that they will receive from their pharmacist every time an ER/LA opioid analgesic is dispensed to them, as the information in the Medication Guide may have changed.
- **Consider Using Other Tools** — In addition to the PCD, there are other publicly-available tools to improve patient, household, and community safety when using ER/LA opioid analgesics, as well as compliance with conditions of treatment, including Patient-Prescriber Agreements (PPAs) and risk assessment instruments.

### **REMS-compliant Training Programs**

A critical component of the ER/LA Opioid Analgesics REMS program is essential safety education for prescribers. REMS-compliant training for prescribers, as described previously, will include both general and product-specific drug information, as well as information on weighing the benefits and risks of opioid therapy, appropriate patient selection, managing and monitoring patients, and counseling patients on the safe use of these drugs. In addition, the education will include information on how to recognize evidence of, and the potential for, opioid misuse, abuse, addiction, and overdose.

It will be some time before the REMS-compliant training funded by educational grants from the pharmaceutical companies subject to this REMS becomes available. The FDA developed core messages to be communicated to prescribers in the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics ("FDA Blueprint"), which will be used by accredited CE providers to develop REMS-compliant training courses. A follow-up letter notifying you of the availability of REMS-compliant training funded under this REMS will be sent not later than thirty (30) days before such training is offered. However, REMS-compliant education may also be offered by academic institutions or professional societies independent of REMS-related funding. We encourage you to successfully complete REMS-compliant training offered to improve your ability to prescribe these medications more safely.

### **The Patient Counseling Document on Extended-Release/Long-Acting Opioid Analgesics (PCD)**

Enclosed with this letter is the Patient Counseling Document that was developed under the REMS for ER/LA opioid analgesics to assist you in having important conversations with patients for whom you select an ER/LA opioid analgesic. It contains important safety information common to the drug products subject to this REMS, and includes space for you to write additional information to help your patients use their specific ER/LA opioid analgesic safely. The PCD should be provided to the patient or their caregiver at the time of prescribing. Patients and their caregivers should be counseled on:

- the importance of taking these medicines exactly as you prescribe them,
- the need to store ER/LA opioid analgesics safely and securely — out of the reach of children, pets, and household members — to avoid risks from unintended exposure,
- the importance of not sharing these medications, even if someone has the same symptoms as the patient, *and*
- the proper methods of disposal of unneeded ER/LA opioid analgesics.

Prescribers can re-order or print additional copies of the PCD from [www.ER-LA-opioidREMS.com](http://www.ER-LA-opioidREMS.com).

### **Adverse Event Reporting**

To report all suspected adverse reactions associated with the use of the ER/LA opioid analgesics, contact:

- the pharmaceutical company that markets the specific product, or
- the FDA MedWatch program:
  - by phone at 1-800-FDA-1088 (1-800-332-1088) or
  - online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

More information about this REMS can be obtained at: [www.ER-LA-opioidREMS.com](http://www.ER-LA-opioidREMS.com) or by calling the ER/LA Opioid Analgesic REMS Call Center at 1-800-503-0784.

Sincerely,

*The ER/LA Opioid Analgesic REMS Companies*

Patient Counseling Document on  
Extended-Release / Long-Acting Opioid Analgesics

Patient  
Name:

The **DOs** and **DON'Ts** of  
Extended-Release / Long - Acting Opioid Analgesics

**DO:**

- Read the **Medication Guide**
- Take your medicine exactly as prescribed
- Store your medicine away from children and in a safe place
- Flush unused medicine down the toilet
- Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Call 911 or your local emergency service right away if:**

- You take too much medicine
- You have trouble breathing, or shortness of breath
- A child has taken this medicine

**Talk to your healthcare provider:**

- If the dose you are taking does not control your pain
- About any side effects you may be having
- About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements

**DON'T:**

- **Do not** give your medicine to others
- **Do not** take medicine unless it was prescribed for you
- **Do not** stop taking your medicine without talking to your healthcare provider
- **Do not** break, chew, crush, dissolve, or inject your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider
- **Do not** drink alcohol while taking this medicine

For additional information on your medicine go to: **dailymed.nlm.nih.gov**

Patient Counseling Document on  
Extended-Release / Long-Acting Opioid Analgesics

Patient  
Name:

Patient Specific Information

**Take this card with you every time you see your healthcare provider and tell him/her:**

- Your complete medical and family history, including any history of substance abuse or mental illness
- The cause, severity, and nature of your pain
- Your treatment goals
- All the medicines you take, including over-the-counter (non-prescription) medicines, vitamins, and dietary supplements
- Any side effects you may be having

**Take your opioid pain medicine exactly as prescribed by your healthcare provider.**