

Initial REMS Approval: 07/2012
Most Recent Modification:

**EXTENDED-RELEASE (ER) AND LONG-ACTING (LA) OPIOID
ANALGESICS RISK EVALUATION AND MITIGATION
STRATEGY (REMS)**

GOAL

The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.

I. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each ER/LA opioid analgesic prescription in accordance with 21 CFR § 208.24.

The Medication Guides for ER/LA opioids are part of the ER/LA Opioid Analgesic REMS program and will be available through the ER/LA Opioid Analgesic REMS website (www.ER-LA-opioidREMS.com).

B. Elements to Assure Safe Use

1. Training will be made available to healthcare providers who prescribe ER/LA opioid analgesics.
 - a. Training will be considered “REMS-compliant training” under this REMS if: 1) it, for training provided by CE providers, is offered by an accredited provider to licensed prescribers, 2) it includes all elements of the [FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics \(“FDA Blueprint”\)](#), 3) it includes a knowledge assessment of all of the sections of the FDA Blueprint, and 4) it is subject to independent audit to confirm that conditions of the REMS training have been met.
 - b. The NDA/ANDA holders of ER/LA opioid analgesic products (“NDA/ANDA holders”) will ensure that REMS-compliant training is made available to prescribers of ER/LA opioid analgesics and will achieve the following performance goals:
 - i. Not later than March 1, 2013, the first REMS-compliant training will be made available.
 - ii. Within two years from the time the first REMS-compliant training becomes available, 80,000 prescribers (based on 25% of the 320,000 active prescribers in 2011) will have been trained;
 - iii. Within three years from the time the first REMS-compliant training becomes available, 160,000 prescribers (based on 50% of the 320,000 active prescribers in 2011) will have been trained;
 - iv. Within four years from the time the first REMS-compliant training becomes available, 192,000 prescribers (based on 60%

of the 320,000 active prescribers in 2011) will have been trained.

- c. The content of the REMS-compliant training will be based on the learning objectives established by the [FDA Blueprint](#). The FDA Blueprint contains core messages to be conveyed to prescribers in the training about the risks and appropriate prescribing practices for the safe use of ER/LA opioid analgesics. The NDA/ANDA holders will direct providers of REMS-compliant training to the FDA Blueprint, via the REMS website (www.ER-LA-opioidREMS.com), and via its Request for Grant Applications. No less than annually, NDA/ANDA holders will direct providers of REMS-compliant training to consult the FDA Blueprint for possible revisions (e.g., changes to the drug specific information).
- d. NDA/ANDA holders will ensure that independent audits of the educational materials used by the providers of REMS-compliant training are conducted. The audits must:
 - i. Be conducted by an auditor independent of the NDA/ANDA holders. (Accreditation bodies of CE providers would be considered independent of the NDA/ANDA holders and would be eligible to conduct the audits.)
 - ii. Evaluate:
 - 1. whether the content of the training covers all components of the [FDA Blueprint](#) approved as part of the REMS;
 - 2. whether the knowledge assessment measures knowledge of all sections of the FDA Blueprint; and
 - 3. for training conducted by CE providers, whether the training was conducted in accordance with the standards for CE of the Accreditation Council for Continuing Medication Education[®] (ACCME[®]), or of another CE accrediting body appropriate to the prescribers' medical specialty or healthcare profession.
 - iii. Be conducted on a random sample of 1) at least 10% of the training funded by the NDA/ANDA holders, and 2) REMS-compliant training not funded by the NDA/ANDA holders but that will be counted towards meeting the performance goals in section [B.1.b](#).
- e. To facilitate prescriber awareness of the availability of the REMS and REMS-compliant training, within 30 calendar days of the approval of the REMS, the NDA/ANDA holders will make available, and then

maintain a web site that will contain information about the REMS specified below (www.ER-LA-opioidREMS.com):

- i. A current list of the REMS-compliant training that is supported by educational grants from the NDA/ANDA holders, when this information becomes available.
 - ii. A copy of the Patient Counseling Document (PCD) on Extended-Release/Long-Acting Opioid Analgesics.
 - iii. A copy of the Prescriber Letters 1, 2, and 3 (when mailed and for at least one year thereafter) (see section B.1.f).
- f. To make prescribers aware of the existence of the REMS and the prescriber training that will be made available under the REMS, the NDA/ANDA holders will electronically deliver (email or fax), or directly mail letters to all DEA-registered prescribers who are registered to prescribe Schedule II and III drugs:
 - i. [Prescriber Letter 1](#) will be sent not later than 60 days after the initial approval of this REMS, notifying prescribers of the existence of the REMS and the fact that prescriber training will be offered, and providing a copy of the [Patient Counseling Document \(PCD\)](#).
 - ii. [Prescriber Letter 2](#) will be sent not later than 30 days before the first prescriber REMS-compliant training required by the REMS is offered by providers and will notify prescribers of the imminent upcoming availability of accredited REMS CE courses.
 - iii. The prescribers will be identified via the DEA Registration Database.
 - iv. At least annually from the date of initial approval of the REMS, the DEA Registration Database will be reviewed and [Prescriber Letter 3](#) will be sent to all newly DEA-registered prescribers who are registered to prescribe Schedule II and III drugs to inform them of the existence of the REMS, provide them the [Patient Counseling Document \(PCD\)](#), and notify them of the availability of the REMS-compliant training and how to find REMS-compliant courses.
- g. To further ensure that prescribers are aware of the existence of the ER/LA Opioid Analgesic REMS and the prescriber training that will be made available under the REMS, the NDA/ANDA holders will electronically deliver (email or fax), or directly mail the following two letters to the professional organizations and state licensing entities listed in section [B.1.g.iii](#) with a request that the information be disseminated to their members:

- i. [Professional Organization/Licensing Board Letter 1](#) will be sent not later than 60 days after the approval of this REMS, notifying prescribers of the existence of the REMS and the fact that prescriber training will be offered, and providing a copy of the [Patient Counseling Document \(PCD\) on Extended-Release/Long-Acting Opioids](#).
- ii. [Professional Organization/Licensing Board Letter 2](#) will be sent not later than 30 days before the first prescriber REMS-compliant training required by the REMS is offered by providers and will notify prescribers of the imminent upcoming availability of accredited REMS CE courses.
- iii. The letter and enclosures referenced above, will be sent to the following entities:
 - a) State Licensing Boards of:
 - 1) Medicine (allopathic and osteopathic)
 - 2) Nursing
 - 3) Dentistry
 - b) Associations of State Licensing Boards:
 - 1) Federation of State Medical Boards
 - 2) National Council of State Boards of Nursing
 - 3) American Association of Dental Boards
 - c) Learned Societies and Professional Associations, including, but not limited to:
 - 1) American Academy of Addiction Psychiatry
 - 2) American Academy of Family Physicians
 - 3) American Academy of Hospice and Palliative Medicine
 - 4) American Academy of Neurology
 - 5) American Academy of Nurse Practitioners
 - 6) American Academy of Nursing
 - 7) American Academy of Orofacial Pain
 - 8) American Academy of Pain Management
 - 9) American Academy of Pain Medicine
 - 10) American Academy of Physical Medicine and Rehabilitation
 - 11) American Academy of Physician Assistants

- 12) American Association of Colleges of Osteopathic Medicine
- 13) American Association of Colleges of Nursing
- 14) American Association of Poison Control Centers
- 15) American Board of Medical Specialties
- 16) American Board of Orofacial Pain
- 17) American College of Nurse Practitioners
- 18) American College of Osteopathic Family Physicians
- 19) American College of Physicians
- 20) American College of Rheumatology
- 21) American Dental Association
- 22) American Dental Education Association
- 23) American Medical Association
- 24) American Medical Directors Association
- 25) American Nurses Association
- 26) American Nurses Credentialing Center
- 27) American Osteopathic Association
- 28) American Osteopathic Association of Addiction Medicine
- 29) American Pain Society
- 30) American Society of Addiction Medicine
- 31) American Society for Pain Management Nursing
- 32) American Society of Anesthesiologists
- 33) American Society of Pain Educators
- 34) Association of American Medical Colleges
- 35) Council of Medical Specialty Societies
- 36) Hospice and Palliative Nurses Association
- 37) National Association of Managed Care Physicians
- 38) National Association of State Controlled Substances Authorities
- 39) National Commission on Certification of Physician Assistants
- 40) National Hospice and Palliative Care Organization
- 41) American College of Emergency Physicians

42) Society of Emergency Medicine Physician Assistants

- h. NDA/ANDA holders will ensure that an interim single toll-free number call center is implemented no later than July 23, 2012, and a fully operational centralized call center is implemented no later than 90 calendar days after the approval of the REMS.

The following materials are part of the ER/LA Opioid Analgesic REMS and are appended:

- [Patient Counseling Document \(PCD\) on Extended-Release/Long-Acting Opioid Analgesics](#)
- [FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics](#)
- [Prescriber Letter 1](#)
- [Prescriber Letter 2](#)
- [Prescriber Letter 3](#)
- [Professional Organization/Licensing Board Letter 1](#)
- [Professional Organization/Licensing Board Letter 2](#)
- [ER/LA Opioid Analgesic REMS website \(www.ER-LA-opioidREMS.com\)](#)

II. Implementation System

The ER/LA Opioid Analgesic REMS can be approved without the Elements to Assure Safe Use specifically described under FDCA 505-1(f)(3) (B), (C), and (D) of the Act; therefore an implementation system is not required.

III. Timetable for Submission of Assessments

REMS assessments will be submitted to the FDA at 6 months and 12 months after the initial approval date of the REMS (July 9, 2012), and annually thereafter. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment. The NDA holders will submit each assessment so that it will be received by the FDA on or before the due date based on the initial approval date of the REMS.