

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214044Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document

Opioid Analgesic REMS Program

The Opioid Analgesic REMS Program includes all opioid analgesics used in the outpatient setting and not covered by other REMS programs.

I. Administrative Information

Initial Shared System REMS Approval: 07/2012

Most Recent REMS Update: 09/2018

II. REMS Goal

The Opioid Analgesic REMS is an educational effort and one of a number of national efforts that are designed to address the epidemic of prescription opioid abuse.

The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. The education provided through the REMS program is based on the [Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#). Through better education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with nonpharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies which is intended to assist healthcare providers in reducing adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse. The REMS will accomplish this goal by:

1. Ensuring that training based on the [FDA Blueprint](#) is effective in educating prescribers and other healthcare providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and appropriate use of opioid analgesics.
2. Informing patients about their roles and responsibilities regarding their pain treatment plan, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and [Patient Counseling Guide](#) for opioid analgesics.

III. REMS Requirements

Opioid Analgesic Applicants must make training available to healthcare providers who prescribe and healthcare providers involved in the treatment and monitoring of patients who receive opioid analgesics.

The training must include all the elements of the [FDA Blueprint](#). The training must be made available to healthcare providers who prescribe or are involved in the treatment and monitoring (including pharmacists and nurses) of patients who receive opioid analgesics.

Training is compliant with the REMS if it: 1) for training provided by Continuing Education (CE) Providers, is offered by an accredited CE Provider and supported by unrestricted educational grants from the opioid analgesic applicants; 2) includes all elements of the [FDA Blueprint](#); 3) includes a knowledge assessment of

all sections of the [FDA Blueprint](#); and 4) is subject to independent audit to confirm that conditions of the REMS training have been met.

To inform healthcare providers about the REMS Program and the risks and safe use of opioid analgesics, Opioid Analgesic Applicants must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials-& Dissemination Plans
All DEA-registered prescribers, pharmacies, hospitals, and teaching institutions registered to prescribe or dispense Schedule II, III, and IV drugs	REMS Letter: Healthcare Provider Letter 1 or Professional Society/Licensing Board Letter 1 with attachment Patient Counseling Guide 1. Email within 60 calendar days of the approval (09/18/2018) of the REMS. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 2. Disseminate through the following professional societies and request the letter or content be provided to their members: a. The professional societies identified in Appendix A. 3. Disseminate through all dental, medical (allopathic and osteopathic), nursing, and pharmacy licensing boards and request the letter or content be provided to their licensed practitioners. REMS Letter: Healthcare Provider Letter 2 or Professional Society/Licensing Board Letter 2 with attachment Patient Counseling Guide 4. Email within 30 calendar days of 03/31/2019. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 5. Disseminate through the following professional societies and request the letter or content be provided to their members. a. The professional societies identified in Appendix A. 6. Disseminate through all dental, medical (allopathic and osteopathic), nursing, and pharmacy licensing boards and request the letter or content be provided to their licensed practitioners.

Target Audience	Communication Materials-& Dissemination Plans
All newly DEA-registered prescribers, pharmacies, hospitals, and teaching institutions registered to prescribe or dispense Schedule II, III, and IV drugs since the last dissemination	REMS Letter: Healthcare Provider Letter 2 with attachment Patient Counseling Guide 1. Email annually from the date of the approval (09/18/2018) of the REMS. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.

To support REMS Program operations, Opioid Analgesic Applicants must:

1. Establish and maintain a REMS Program website, www.opioidanalgesicrems.com. The REMS Program website must include a current list of training funded by the Opioid Analgesic Applicants that is REMS-compliant and the option to print the PI, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product websites.
2. Direct CE Providers to the [FDA Blueprint](#) on www.fda.gov/OpioidAnalgesicREMSBlueprint.
3. Make the REMS Program website fully operational and all REMS materials available through the website and call center within 60 calendar days of REMS approval (09/18/2018).
4. Establish and maintain a REMS Program call center for healthcare providers at 1-800-503-0784.
5. Ensure healthcare providers who prescribe or are involved in the treatment and monitoring of patients who receive opioid analgesics are able to access training by 3/31/2019
6. Notify accredited CE Providers of REMS-compliant training regarding changes to the [FDA Blueprint](#) within 10 calendar days of such changes.
7. Use independent auditors (accreditation bodies of CE Providers are considered independent and eligible to conduct the audits) to audit the educational materials used by the accredited CE Providers of REMS-compliant training of a random sample of at least 10% of the training funded by the Opioid Analgesic Applicants to evaluate (1) whether the content of the training covers all the components of the [FDA Blueprint](#), (2) whether the knowledge assessment measures knowledge of all sections of the [FDA Blueprint](#), (3) whether the training was conducted in accordance with the standards for CE of the Accreditation Council for Continuing Medication Education or of another CE accrediting body appropriate to the prescribers, dental, pharmacy, nursing, or healthcare profession.

IV. REMS Assessment Timetable

Opioid Analgesic NDA Applicants must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the approval of the REMS (09/18/2018). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date

for that assessment. Opioid Analgesic NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Opioid Analgesic REMS:

Training and Educational Materials

Healthcare Provider:

1. Healthcare Provider training available at www.opioidanalgesicrems.com

Patient:

2. Medication Guide (available at www.opioidanalgesicrems.com)
3. [Patient Counseling Guide](#)

Communication Materials

4. [Healthcare Provider Letter 1](#)
5. [Healthcare Provider Letter 2](#)
6. [Professional Society/Licensing Board Letter 1](#)
7. [Professional Society/Licensing Board Letter 2](#)

Other Materials

8. [Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \(FDA Blueprint\)](#)
9. [Opioid Analgesic REMS Program website \(www.opioidanalgesicrems.com\)](#)

Appendix A: List of Professional Societies

1. American Academy of Addiction Psychiatry
2. Council of Medical Specialty Societies
3. Academy of Integrative Pain Management
4. Academy of Managed Care Pharmacists
5. American Academy of Family Physicians
6. American Academy of Hospice and Palliative Medicine
7. American Academy of Neurology
8. American Academy of Nurse Practitioners
9. American Academy of Nursing
10. American Academy of Orofacial Pain
11. American Academy of Pain Medicine
12. American Academy of Physical Medicine and Rehabilitation
13. American Academy of Physician Assistants
14. American Association of Colleges of Nursing
15. American Association of Colleges of Osteopathic Medicine
16. American Association of Poison Control Centers
17. American Board of Medical Specialties
18. American Board of Orofacial Pain
19. American College of Clinical Pharmacy
20. American College of Nurse Midwives
21. American College of Nurse Practitioners
22. American College of Osteopathic Family Physicians
23. American College of Physicians
24. American College of Rheumatology
25. American Dental Association
26. American Dental Education Association
27. American Medical Association
28. American Medical Directors Association
29. American Nurses Association
30. American Nurses Credentialing Center
31. American Osteopathic Association

32. American Osteopathic Association of Addiction Medicine
33. American Pain Society
34. American Pediatric Association
35. American Pharmacists Association
36. American Psychiatric Nursing Association
37. American Society for Pain Management Nursing
38. American Society of Addiction Medicine
39. American Society of Anesthesiologists
40. American Society of Consultant Pharmacists
41. American Society of Pain Educators
42. Association of American Medical Colleges
43. Doctors of Nursing Practice
44. Gerontological Nursing Association
45. Hospice and Palliative Nurses Association
46. National Association of Managed Care Professionals
47. National Association of Pediatric Nurse Practitioners
48. National Conference of Nurse Practitioners
49. National League of Nursing
50. National Organization of Nurse Practitioner Faculties
51. Nurse Practitioners in Women's Health
52. Oncology Nursing Society
53. Society of Emergency Medicine Physician Assistants

What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

What are opioids?

Opioids are strong prescription medicines that are used to manage severe pain.

What are the serious risks of using opioids?

- Opioids have serious risks of addiction and overdose.
- **Too much opioid medicine in your body can cause your breathing to stop – which could lead to death.** This risk is greater for people taking other medicines that make you feel sleepy or people with sleep apnea.
- **Addiction** is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require ongoing treatment.

Risk Factors for Opioid Abuse:

- You have:
 - » a history of addiction
 - » a family history of addiction
 - You take medicines to treat mental health problems
 - You are under the age of 65 (although anyone can abuse opioid medicines)
-
- **You can get addicted to opioids even though you take them exactly as prescribed, especially if taken for a long time.**
 - If you think you might be addicted, talk to your healthcare provider right away.
 - If you take an opioid medicine for more than a few days, your body becomes physically “dependent.” This is normal and it means your body has gotten used to the medicine. You must taper off the opioid medicine (slowly take less medicine) when you no longer need it to avoid withdrawal symptoms.

How can I take opioid pain medicine safely?

- Tell your healthcare provider about all the medicines you are taking, including vitamins, herbal supplements, and other over-the-counter medicines.
- Read the Medication Guide that comes with your prescription.

- Take your opioid medicine exactly as prescribed.
- Do not cut, break, chew, crush, or dissolve your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.
- When your healthcare provider gives you the prescription, ask:
 - » How long should I take it?
 - » What should I do if I need to taper off the opioid medicine (slowly take less medicine)?
- Call your healthcare provider if the opioid medicine is not controlling your pain. Do not increase the dose on your own.
- Do not share or give your opioid medicine to anyone else. Your healthcare provider selected this opioid and the dose just for you. A dose that is okay for you could cause an overdose and death for someone else. Also, it is against the law.
 - Store your opioid medicine in a safe place where it cannot be reached by children or stolen by family or visitors to your home. Many teenagers like to experiment with pain medicines. Use a lock-box to keep your opioid medicine safe. Keep track of the amount of medicine you have.
- Do not operate heavy machinery until you know how your opioid medicine affects you. Your opioid medicine can make you sleepy, dizzy, or lightheaded.



What should I avoid taking while I am taking opioids?

Unless prescribed by your healthcare provider, you should avoid taking alcohol or any of the following medicines with an opioid because it may cause you to stop breathing, which can lead to death:

- Alcohol: Do not drink any kind of alcohol while you are taking opioid medicines.
- Benzodiazepines (like Valium or Xanax)
- Muscle relaxants (like Soma or Flexeril)
- Sleep medicines (like Ambien or Lunesta)
- Other prescription opioid medicines

What other options are there to help with my pain?

Opioids are not the only thing that can help you control your pain. Ask your healthcare provider if your pain might be helped with a non-opioid medication, physical therapy, exercise, rest, acupuncture, types of behavioral therapy, or patient self-help techniques.

What is naloxone?

- Naloxone is a medicine that treats opioid overdose. It is sprayed inside your nose or injected into your body.
- Use naloxone if you have it and call 911 or go to the emergency room right away if:
 - You or someone else has taken an opioid medicine and is having trouble breathing, is short of breath, or is unusually sleepy
 - A child has accidentally taken the opioid medicine or you think they might have
- Giving naloxone to a person, even a child, who has not taken an opioid medicine will not hurt them.

Naloxone is never a substitute for emergency medical care. Always call 911 or go to the emergency room if you've used or given naloxone.

Where can I get naloxone?

- There are some naloxone products that are designed for people to use in their home.
- Naloxone is available in pharmacies. Ask your healthcare provider about how you can get naloxone. In some states, you may not need a prescription.
- When you get your naloxone from the pharmacy, read the Patient Information on how to use naloxone and ask the pharmacist if anything is unclear.
- Tell your family about your naloxone and keep it in a place where you or your family can get to it in an emergency.

When you no longer need your opioid medicine, dispose of it as quickly as possible. The Food and Drug Administration recommends that most opioid medicines be promptly flushed down the toilet when no longer needed, unless a drug take-back option is immediately available. A list of the opioid medicines that can be flushed down the toilet is found here: <https://www.fda.gov/drugdisposal>

What things should I know about the specific opioid medicine that I am taking?

- Your healthcare provider has prescribed _____ for you. Read the Medication Guide for this medicine, which is information provided by your pharmacy.
- Remember this other important information about your opioid medicine:

Dosing instructions: _____

Any specific interactions with your medicines: _____

What if I have more questions?

- Read the Medication Guide that comes with your opioid medicine prescription for more specific information about your medicine.
- Talk to your healthcare provider or pharmacist and ask them any questions you may have.
- Visit: www.fda.gov/opioids for more information about opioid medicines.

Introduction

FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain

Background

In July 2012, FDA approved the Extended-Release and Long-Acting (ER/LA) Opioid Analgesic Risk Evaluation and Mitigation Strategy (ER/LA REMS) to ensure that the benefits of ER and LA opioid analgesics used in the outpatient setting outweigh the risks. That REMS was modified and the new *Opioid Analgesic REMS* includes, in addition to ER/LA opioid analgesics, all immediate-release (IR) opioids used in the outpatient setting that are not already covered by another REMS program. The *Opioid Analgesic REMS* is intended to support other national efforts underway to address the misuse and abuse of prescription opioid analgesics.

As part of the Opioid Analgesic REMS, all opioid analgesic companies must provide the following:

- Education for health care providers (HCPs) who participate in the treatment and monitoring of pain. For the purpose of the Opioid Analgesic REMS, HCPs will include not only prescribers, but also HCPs who participate in the treatment and monitoring of patients who receive opioid analgesics, including pharmacists and nurses.
 - Education will be offered through accredited continuing education (CE) activities. These activities will be supported by unrestricted educational grants from opioid analgesic companies.
- Information for HCPs to use when counseling patients about the risks of ER, LA, and IR opioid analgesic use.

To facilitate the development of CE educational materials and activities as part of the Opioid Analgesic REMS, FDA has also revised the education blueprint — originally designed to facilitate development of CE educational materials under the ER/LA REMS. FDA has completed the revisions to the *FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain* (FDA Blueprint), following publication of a draft version and consideration of received public comments.

The FDA Blueprint contains a high-level outline of the core educational messages that will be included in the educational programs developed under the Opioid Analgesic REMS. The FDA Blueprint focuses on the fundamentals of acute and chronic pain management and provides a contextual framework for the safe prescribing of opioid analgesics. The core messages are directed to prescribers, pharmacists, and nurses, but are also relevant for other HCPs who participate in the management of pain. The course work is not intended to be exhaustive nor a substitute for a more comprehensive pain management course.

Accrediting bodies and CE providers will ensure that the CE activities developed comply with the standards for CE of the Accreditation Council for Continuing Medical Education,^{1,2} or another CE accrediting body, depending on the target audience's medical specialty or health care profession.

FDA is making the FDA Blueprint, approved as part of the Opioid Analgesic REMS, available on the REMS@FDA Website (www.fda.gov/REMS), where it will remain posted for use by CE providers as they develop the CE materials and activities. A list of the REMS-compliant CE activities supported by unrestricted educational grants from the opioid analgesic companies to accredited CE providers will be posted at www.opioidanalgesicREMS.com as that information becomes available.

Reasons Why HCP Education Is So Important

Adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioids have emerged as major public health problems. It is critical that HCPs are knowledgeable about the risks associated with opioid analgesics as they pertain to their patients as well as from a public health perspective. The data continue to show problems associated with prescription opioid analgesics.

- In 2015, over 52,404 Americans died from drug poisonings, and of these, 24% or approximately 12,570 deaths involved opioid analgesics.³
- Based on the 2016 National Survey on Drug Use and Health (NSDUH), an estimated 11.5 million Americans aged 12 or older misused a prescription pain reliever in the past year — with hydrocodone, oxycodone, and codeine products being the most commonly reported.⁴
- The most common source of pain relievers in the 2016 NSDUH was “a friend or relative” (53%). “A physician’s prescription” was the second most common source, reported by approximately 35% of respondents.⁵

The nation is facing competing public health problems: the need to adequately treat a large number of Americans with acute and chronic pain and an epidemic of prescription opioid abuse.

¹ [Accreditation Council for Continuing Medical Education. 2016. Accreditation Requirements. Criteria for CME Providers-Accreditation Criteria.](#) Accessed July 2018.

² [Accreditation Council for Continuing Medical Education. 2016. Accreditation Requirements. Criteria for CME Providers-Standards for Commercial Support.](#) Accessed July 2018.

³ See https://www.cdc.gov/nchs/data/factsheets/factsheet_drug_poisoning.pdf. Accessed July 2018.

⁴ Substance Abuse and Mental Health Services Administration. (2017). *Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health* (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.

⁵ Ibid.

Described in the 2011 report by the National Academies of Science, Engineering, and Medicine (NASEM), *Relieving PAIN in America, A Blueprint for Transforming Prevention, Care, Education, and Research*,⁶ 100 million Americans suffer from common chronic pain conditions; fewer than half of Americans undergoing surgery report adequate pain relief; and 60% of Americans visiting the emergency department with acute painful conditions receive analgesics.

The increasing availability of prescription opioids since the 1990's has been accompanied by an epidemic of opioid addiction. The Substance Abuse and Mental Health Services Administration's *National Survey of Drug Use and Health* has shown that most people who use prescription analgesics "nonmedically" obtain them from friends or family, who it is believed obtained the drugs from a doctor's prescription.⁷

Some of the immediate consequences of untreated or undertreated pain include reduced quality of life, impaired physical function, and high economic costs. Chronic pain is associated with physical disability, fear, anger, depression, anxiety, and reduced ability to carry out the roles of family member, friend, and employee. It is critically important that HCPs have all the information they need to properly treat their patients and safely manage their pain. It is also critical for HCPs to understand when opioid analgesics are the appropriate treatment and how to implement best practices to ensure their patients' safety. A 2017 report by NASEM, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, describes the challenges of providing adequate pain management and calls for the establishment of "comprehensive pain education materials and curricula" for HCPs.⁸

Having broad knowledge about how to manage patients with pain can create the opportunity for HCPs to consider *all* options for pain management, including nonpharmacologic and non-opioid pharmacologic options, and to reserve opioids for when non-opioid options are inadequate and when the benefits of the opioids are expected to outweigh the risks. This information can also aid HCPs in identifying and intervening when encountering obstacles that may reduce access to nonpharmacological and non-opioid medication options. Fully informed HCPs can help contribute to national efforts to address opioid addiction and reduce opioid misuse and abuse.

⁶ <http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>. Accessed July 2018.

⁷ <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf>, Table 6.53A. Accessed July 2018.

⁸ <http://nationalacademies.org/hmd/Reports/2017/pain-management-and-the-opioid-epidemic.aspx>. Accessed July 2018.

FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain

Purpose of the Opioid Analgesic REMS HCP Educational Effort

Following completion of educational activities under the Opioid Analgesic REMS, HCPs should be knowledgeable about the following.

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain, identifying risk factors for abuse and addiction
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient
- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with opioid use disorder

In addition, HCPs will gain an understanding of current information about safe opioid practices and about current Federal⁹ and State regulations, national guidelines,¹⁰ and professional organization¹¹ and medical specialty guidelines on treating pain and prescribing opioids. HCPs will also become familiar with the use of naloxone and with the importance of its availability for use by patients and caregivers both in the community and in the home.

⁹ For example, see <https://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfr.htm> and <https://www.deadiversion.usdoj.gov/21cfr/21usc/829.htm>. Accessed July 2018.

¹⁰ For example, see Dowell D, Haegerich TM, Chou R. 2016. [CDC Guideline for Prescribing Opioids for Chronic Pain](#) –United States, 2016. MMWR Recomm Rep 2016; 65 (No.RR-1): 1-49. Accessed July 2018.

¹¹ For example, see [Federation of State Medical Boards' Guidelines for the Chronic Use of Opioid Analgesics](#). Accessed July 2018.

Section 1: The Basics of Pain Management

I. THE NEED FOR COMPREHENSIVE PAIN EDUCATION

The FDA Blueprint was developed with two, competing, U.S. public health concerns in mind, (1) the large number of Americans with acute and chronic pain and (2) the epidemic of prescription opioid abuse.

1. Providing health care providers (HCPs) with a thorough understanding of the risks associated with opioids can give HCPs the opportunity to consider all pain management options, including nonpharmacologic and pharmacologic options, prescribing opioids only when non-opioid options are inadequate and when the benefits of using an opioid are expected to outweigh the risks.
2. When HCPs have information about the risks of opioid misuse and abuse, they will be better able to create opportunities for patient counseling and other strategies to reduce these risks.

II. DEFINITIONS AND MECHANISMS OF PAIN

Pain can be categorized according to its duration, underlying pathophysiology of the original insult, and whether a central sensitization component has developed. An understanding of these different categorizations can help direct therapeutic decisions.

When defining, and classifying pain, the following should be taken into consideration:

1. Biological significance of pain (survival value)
2. Relationship between acute and chronic pain
3. Distinction between nociceptive and neuropathic pain

III. ASSESSING PATIENTS IN PAIN

HCPs should be knowledgeable about how to assess each patient when initiating a pain management program. When appropriate, evidence-based, standardized scales and tools can be used to document pain characteristics and guide management decisions throughout treatment, noting the strengths and weaknesses regarding specificity and sensitivity of these scales.

Important elements of an initial assessment should include the following:

1. Patient history

2. Screening tools to evaluate the known risk factors for development of chronic pain after an acute injury or disease
3. Screening tools to evaluate the known risk factors for opioid use disorder (OUD) or abuse
4. Queries of state prescription drug monitoring programs (PDMPs)
5. Pain assessment scales/tools
6. Functional assessment scales
7. Physical examination
8. Family planning, including information about use of contraceptives, pregnancy intent/status and plans to breastfeed
9. Psychological and social evaluation
10. Diagnostic studies when indicated

Section 2: Creating the Pain Treatment Plan

A comprehensive pain treatment plan should be developed and customized to the needs of the individual patient. The treatment plan should include the types of therapies planned, the goals of treatment, and an explanation of the patient and prescriber roles and responsibilities. The goals of treatment should be based on (1) expected outcomes of pain reduction; (2) improvement in functional outcomes impaired by pain (e.g., activities of daily living); and (3) quality of life.

If HCPs encounter potential barriers to managing patients with pharmacologic and/or nonpharmacologic treatment options, such as lack of insurance coverage or inadequate availability of certain HCPs who treat patients with pain, attempts should be made to address these barriers. The overall treatment approach and plan should be well documented in the patient record, including written agreements and informed consent/patient provider agreements (PPAs) that reinforce patient-provider responsibilities and avoid punitive tones.

I. COMPONENTS OF AN EFFECTIVE TREATMENT PLAN

1. The goals of treatment, including the degree of improvement in pain and function when function has been impaired by pain
2. Possible constituents of the treatment plan, including nonpharmacologic approaches and pharmacologic therapies
3. Patient/prescriber/health care team interactions, including

- Patient responsibilities/compliance with the plan
- Responsibilities of the prescriber and health care team, including patient monitoring
- Plans for reviewing functional goals
- Use of supplemental medication for intermittent increases in pain
- Use of PPAs

II. GENERAL PRINCIPLES OF NONPHARMACOLOGIC APPROACHES

Pain can arise from a wide variety of causes. There are a number of nonpharmacologic and self-management treatment options that have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain. Examples include, but are not limited to, psychological, physical rehabilitative, and surgical approaches, complementary therapies,¹² and use of approved/cleared medical devices for pain management. HCPs should be knowledgeable about the range of treatment options available, the types of pain that may be responsive to those options, and when they should be used as part of a multidisciplinary approach to pain management. HCPs should also be aware that not all nonpharmacologic options have the same strength of evidence to support their utility in the management of pain, and some may be more applicable for some conditions than others.

III. GENERAL PRINCIPLES OF PHARMACOLOGIC ANALGESIC THERAPY

A variety of analgesics, including non-opioid and opioid medications, are available for use to manage pain symptoms. HCPs should be well informed about the range of analgesics available and the types of pain that may be responsive to those analgesics.

A. Non-opioid medications

When using non-opioid medications in pain management, HCPs should be knowledgeable about the following:

1. Mechanism of action of analgesic effect
2. Indications and uses for pain management
3. Routes of administration and formulations used in pain management
4. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia
5. Contraindications
6. Adverse events, with emphasis on labeled warnings
7. Drug interactions — both pharmacodynamic and pharmacokinetic

B. Opioid analgesic medications

Opioid analgesic medications can be used successfully as a component of pain management. However, opioids carry risks not present with most non-opioid analgesics, specifically the risks

¹² For example, see <https://nccih.nih.gov>. Accessed July 2018.

of addiction, abuse and misuse, which can lead to respiratory depression, overdose and death. Therefore, it is the responsibility of HCPs to be knowledgeable, not just about the presence of such risks, but about how to weigh these risks before prescribing an opioid and about how to properly manage patients who are prescribed opioids, both for short-term and long-term use. When using opioid analgesics as part of pain management, HCPs should be knowledgeable about the following:

1. General precautions
 - a. Even at prescribed doses, opioid analgesics carry the risk of misuse, abuse, opioid use disorder, overdose, and death
 - b. Importance of the appropriate use of PDMPs¹³ and their use as a clinical decision support tool
 - c. DSM-5 (R) criteria (or the most recent version) for OUD and the concepts of abuse (taking an opioid to get high) vs. misuse (taking more than prescribed for pain or giving to someone else in pain)¹⁴
 - d. The concepts of tolerance and physiological dependence and how they differ from OUD (addiction)
 - e. Recognition that some opioid analgesics (e.g., Transmucosal Immediate Release Fentanyl products, some ER/LA products) are safe only for opioid-tolerant patients
2. Mechanism of action and analgesic effect
3. Types of opioids (full agonists, partial agonists)
4. Indications and uses for pain management
5. Range of opioid analgesic products available for pain management and their related safety concerns
 - a. Routes of administration including oral, transmucosal, transdermal
 - b. Release characteristics of immediate release (IR), extended-release (ER), long-acting (LA)
 - c. Abuse-deterrent formulations (ADFs)
 - Definition of ADF based on the FDA guidance for industry, *Abuse-Deterrent Opioids – Evaluation and Labeling*¹⁵
 - Recognition that all ADFs have the same potential for addiction and overdose death as non-abuse-deterrent opioids
 - How to understand FDA-approved ADF product labeling
6. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia
 - a. Concepts and limitations of the conversion charts in labeling and the limitations of relative potency or equianalgesic dosing tables in literature

¹³ [SAMHSA Prescription Drug Monitoring Programs: A Guide for Healthcare Providers](#). Accessed July 2018.

¹⁴ [American Psychiatric Association DSM-5-Opioid Use Disorder Diagnostic Criteria](#). Accessed July 2018.

¹⁵ See FDA guidance for industry [Abuse-Deterrent Opioids —Evaluation and Labeling](#). Accessed July 2018.

- b. Interindividual variability of response
 - c. Special populations
 - Pregnant, postpartum, breastfeeding, and neonatal opioid withdrawal syndrome
 - Renal and hepatic impairment
 - Children and adolescents
 - Genetic and phenotypic variations
 - Older adults
 - Sleep disorders
 - Common and uncommon psychiatric disorders
7. Contraindications
8. Adverse Events
- a. Medication errors
 - b. Periods of greater risk for significant respiratory depression, including at treatment initiation and with dose increases
 - c. Serious adverse drug reactions (including overdose and death)
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9. Drug interactions
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10. Key safety strategies for use with opioid medications
- a. Dosing instructions including daily maximum
 - b. Safe storage to reduce risk of accidental exposure/ingestion by household contacts, especially children/teens and to reduce risk of theft
 - c. Naloxone products for use in the home to reduce risk of overdose deaths in patients and household contacts
 - d. Proper disposal of used (e.g., transdermal systems) and unused opioids
 - e. Pain management after an opioid overdose
 - f. Driving and work safety

IV. MANAGING PATIENTS ON OPIOID ANALGESICS

HCPs should be knowledgeable about the appropriate use of opioids in patients with acute and chronic pain, including the importance of balancing potential benefits with the risks of serious adverse outcomes such as overdose and death.

A. Initiating treatment with opioids — acute pain

1. Patient selection — consider when an opioid is an appropriate option and consult the PDMP
2. Dosing — as needed vs. around-the clock dosing, prescribing an appropriate quantity based on the expected duration of pain, i.e., the least amount of medication necessary to treat pain and for the shortest amount of time
3. Naloxone for home use — prescribe and discuss the use of naloxone products and the various means of administration
4. Screening tools for risk of abuse

B. Initiating treatment with opioids — chronic pain

1. Patient selection
 - a. Differences in benefit and risk and expected outcomes for patients with chronic pain, palliative care, or end-of-life care
 - b. Differences in initiating treatment in opioid nontolerant vs. opioid-tolerant patients
2. Dosing
 - a. As needed vs. around-the-clock
 - b. How to determine a safe initial dose
 - c. Safe conversion from other opioids
3. Considerations in opioid selection
 - a. IR or ER/LA
 - b. Special precautions with methadone
 - c. Products restricted to opioid-tolerant patients
4. When and how to use an opioid or non-opioid analgesic to supplement pain management

C. Ongoing management of patients on opioid analgesics

1. Periodic review of pain and functional goals
2. Review adverse events at each visit
 - Eliciting signs or symptoms of opioid abuse
 - Screening for endocrine function may be recommended

- Importance of adverse event reporting and mechanisms to report
3. Review refill history/review PDMP
 4. How to determine when an opioid analgesic is no longer necessary/beneficial

D. Long-term management

1. Evaluation of the patient with worsening pain for changes in underlying condition and for signs of OUD before increasing opioid dosage
2. Changing opioid medications
 - Concept of incomplete cross-tolerance when converting patients from one opioid to another
 - Concepts and limitations of the conversion charts in labeling and the limitations of relative potency or equianalgesic dosing tables in literature
3. Monitoring of patient adherence to the treatment plan, especially regarding misuse and abuse:
 - Perform medication reconciliation — recognize, document, and address aberrant drug-related behavior
 - Determine if nonadherence is due to inadequate pain management
 - Understand the utility and interpretation of urine drug testing (e.g., screening and confirmatory tests) and use as indicated
 - Screen and refer for substance use disorder treatment when concerns arise

E. How to recognize and intervene upon suspicion or identification of an OUD

HCPs should understand how to monitor patients taking opioid analgesics and identify the signs and symptoms of opioid misuse, abuse, and OUD and be knowledgeable about how to begin the process of intervention upon suspicion of an OUD.

F. When to consult with a pain specialist

HCPs should be knowledgeable about when referral to a pain management specialist is indicated, including identifying patients at high risk for OUD and patients unable to achieve adequate pain management.

G. Medically directed opioid tapering

HCPs should be knowledgeable about how to safely taper opioid analgesics, including how to recognize and manage signs and symptoms of opioid withdrawal. HCPs should be knowledgeable about the particular risks associated with tapering during pregnancy.

H. Importance of patient education

HCPs should recognize their role in reducing the risks associated with opioid analgesics through patient education at initiation of an opioid and throughout long-term management.

1. Inform patients about pain management expectations and managing pain through different pharmacologic and nonpharmacologic modalities.
2. Use the *Patient Counseling Guide: What You Need to Know About Opioid Pain Medicines* as part of discussion with patients and caregivers when prescribing opioid analgesics.
3. Counsel the patient about the following:
 - a. Importance of adherence to prescribed dosing regimen
 - b. Patients should use the least amount of medication necessary to treat pain and for the shortest amount of time
 - c. The risk of serious adverse events that can lead to death
 - d. The risk of addiction that can occur even when product is used as recommended
 - e. Known risk factors for serious adverse events, including signs and symptoms of overdose and opioid-induced respiratory depression, GI obstruction, and allergic reactions, among others
 - f. The most common side effects, along with the risk of falls, working with heavy machinery, and driving
 - g. When to call the prescriber (e.g., managing adverse events, ongoing pain)
 - h. How to handle missed doses
 - i. The importance of full disclosure of all medications and supplements to all HCPs and the risks associated with the use of alcohol and other opioids/benzodiazepines
 - j. Product-specific concerns, such as not to crush or chew ER products; transdermal systems and buccal films should not be cut, torn, or damaged before use, etc.
 - k. How to safely taper dose to avoid withdrawal symptoms
 - l. Safe storage and disposal, risks of theft by family members and household visitors
 - m. Never share any opioid analgesic with another person
 - n. How and when to use naloxone products and their various means of administration
 - o. Seeking emergency medical treatment if an opioid overdose occurs
 - p. How to report adverse events and medication errors to FDA (1-800-fda-1088 or via <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>)

V. ADDICTION MEDICINE PRIMER

HCPs should be knowledgeable about the basic elements of addiction medicine and be familiar with the definition, neurobiology, and pharmacotherapy of OUDs. In particular, stigmatizing or blaming language should be replaced with language that acknowledges that addiction,

reclassified as *substance use disorder*¹⁶ in the revised Diagnostic Statistical Manual–V, is a disease. The term *opioid use disorder*¹⁷ should be used when referring to the use of opioids, rather than other substances.

It should also be noted that there may be a different approach with a patient who misuses an opioid analgesic by taking the product differently than prescribed for the purpose of managing pain, in contrast to the patient who abuses an opioid analgesic with the intent of getting high. HCPs should be familiar with the following:

1. The neurobiology of OUD (addictive cycle)
2. Use of screening tools to identify patients at risk, based on known risk factors, and to identify patients developing signs of opioid dependence or addiction as early as possible.
3. Management of OUD, including the types of pharmacologic and nonpharmacologic treatments available and when to refer to an addiction medicine specialist.

¹⁶ Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (Copyright 2013). American Psychiatric Association.

¹⁷ Id.

Dear Healthcare Provider Letter #1

FDA-Required REMS for Serious Drug Risks

Risk Evaluation and Mitigation Strategy (REMS) for opioid analgesic drug products¹ used in the outpatient setting to address their risks of misuse, abuse, addiction, and overdose.

Dear Healthcare Provider:

You are receiving this letter because you are either registered with the Drug Enforcement Administration (DEA) to prescribe Schedule II, III, IV opioid analgesics and/or you are involved in the management or support of patients with pain and their caregivers. The purpose of this letter is to inform you about the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) that is required by the U.S. Food and Drug Administration (FDA) for opioid analgesic drug products used in the outpatient setting, and to provide **two helpful resources** that are a part of the Opioid Analgesic REMS.

Under the conditions of the REMS, healthcare providers (HCPs) are strongly encouraged to:

- complete a REMS-compliant education program,
- counsel patients and/or their caregivers, with *every* prescription, on the safe use, serious risks, and proper storage and disposal of these products using the ***Opioid Analgesic REMS Patient Counseling Guide*** and the specific drug's ***Medication Guide***, and
- consider other tools to improve patient, household, and community safety.

The Opioid Analgesic REMS Patient Counseling Guide

Enclosed with this letter is a new ***Patient Counseling Guide*** that was developed under the REMS. It was specifically designed to assist **you** with conducting important conversations about safety with patients for whom an opioid analgesic may be prescribed. It contains important safety information common to the drug products subject to this REMS. The ***Patient Counseling Guide*** should be provided to the patient or their caregiver at the time of prescribing. The ***Patient Counseling Guide*** is also available on the REMS website, www.opioidanalgesicrems.com, or ordered by calling the REMS Call Center at 1-800-503-0784.

REMS-compliant Accredited Continuing Education (CE): *available starting in March 2019*

REMS-compliant training is a critical component of the Opioid Analgesic REMS and focuses on pain management and creating a pain treatment plan. The FDA developed specific core messages to be communicated to a broad range of HCPs in the ***Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain*** ("FDA Blueprint"). This "FDA Blueprint," is being used to develop training that includes accredited CE courses or training offered by academic institutions/learned societies. The "FDA Blueprint" is available at: www.fda.gov/OpioidAnalgesicREMSBlueprint

Following completion of educational activities under the Opioid Analgesic REMS, HCPs should be knowledgeable about the following.

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain, identifying risk factors for abuse and addiction
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient
- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with opioid use disorder

REMS-compliant accredited CE will be available starting in March 2019. Visit www.opioidanalgesicrems.com for a listing of available REMS-compliant training.

Adverse Event Reporting

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

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

More information about this REMS can be obtained at: www.opioidanalgesicrems.com or by calling the Opioid Analgesic REMS Call Center at 1-800-503-0784.

Sincerely,
The Opioid Analgesic REMS Program Companies

¹**The branded and generic drug products subject to this REMS include all:** a) oral dosage forms of extended-release and immediate-release opioids containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol and tramadol; b) fentanyl, butorphanol and buprenorphine-containing intranasal, buccal and transdermal delivery systems; and c) methadone tablets and solutions that are indicated for use as analgesics.

Dear Healthcare Provider Letter #2

FDA-Required REMS for Serious Drug Risks

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Dear Professional Society/Licensing Board Letter #1

FDA-Required REMS for Serious Drug Risks

Risk Evaluation and Mitigation Strategy (REMS) for opioid analgesic drug products¹ used in the outpatient setting to address their risks of misuse, abuse, addiction, and overdose.

Dear **Professional Society/Licensing Board**:

The purpose of this letter is to inform you about the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) that is required by the U.S. Food and Drug Administration (FDA) for opioid analgesic drug products used in the outpatient setting, and to provide **two helpful resources** that are a part of the Opioid Analgesic REMS. We ask you to consider the development and/or distribution of training materials for your practitioners and encourage them to utilize these resources and to successfully complete REMS-compliant training to improve their ability to prescribe these medications more safely.

Under the conditions of the REMS, healthcare providers (HCPs) are strongly encouraged to:

- complete a REMS-compliant education program,
- counsel patients and/or their caregivers with every prescription on the safe use, serious risks, and proper storage and disposal of these products using the ***Opioid Analgesic REMS Patient Counseling Guide*** and the specific drug's ***Medication Guide***, and
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RPC Website Screenshot Document

August 2018

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1. Home Page



Medication Guides

U.S. Prescribing Information

Looking for Accredited REMS CE? Click Here.

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a program to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks.

The FDA has required a REMS for opioid analgesics.

Under the conditions specified in this REMS, **providers of opioid analgesics and HCPs that provide care to patients and their caregivers are strongly encouraged to do all of the following:**

- **Educate Yourself** - Complete an [FDA REMS-compliant accredited continuing education \(CE\) program](#) offered by an accredited provider of CE for your discipline
- **Counsel Your Patients** - Discuss the safe use, serious risks, storage, and disposal of opioid analgesics with patients and/or their caregivers every time you prescribe these medicines. Click here for the [Patient Counseling Guide](#)
- **Emphasize Patient and Caregiver Understanding of 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 opioid is dispensed to them
- **Consider Using Other Tools** - In addition to the Patient Counseling Guide, there are other publicly available tools to improve patient, household and community safety, including Patient-Provider Agreement (PPA) and risk assessment instruments



[Click here for a complete list of products covered under the Opioid Analgesic REMS](#)

For additional information about the Opioid Analgesic REMS, call 800-503-0784.

Accredited CE for Healthcare Providers

REMS-Compliant CE for ER/LA Opioid Analgesics

Listing of Accredited CE REMS-Compliant Activities Supported by RPC **UPDATED**

[Accredited CE Provider Information](#)

Materials for Healthcare Providers

[Dear Healthcare Provider \(HCP\) Letter](#) **UPDATED**

[Dear Professional Society and Licensing Board \(DSL\) Letter](#) **UPDATED**

[Patient Counseling Guide](#) **UPDATED**

[Medication Guides](#)

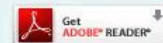
[Frequently Asked Questions for Healthcare Providers](#) **UPDATED**

[REMS Assessment Publications](#)

Materials for Patients

[Medication Guides](#)

[Frequently Asked Questions for Patient](#) **UPDATED**



2. Education Providers Page



Medication Guides

U.S. Prescribing Information

Looking for Accredited REMS CE? Click Here.

Opioid Analgesic REMS for Accredited Continuing Education Providers

The Opioid Analgesic Risk Evaluation Mitigation Strategies (REMS) was designed to ensure that the benefits of opioid analgesics used in the outpatient setting outweigh the risks (in patients whose clinicians have determined opioid analgesics to be an appropriate treatment option). The FDA has required manufacturers of opioid analgesics, known as the REMS Program Companies (RPC), to make education available for providers of these medications. RPC-supported REMS education will be provided through accredited continuing education (CE) activities supported by independent educational grants from these opioid analgesic companies. To assist in this effort, the FDA has developed an Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint") that is posted on the [FDA website](#).

To date, the RPC has completed 4 Grant cycles; see the table below for a listing of grant awardees from the 2012, 2013, 2014, and 2015 Grant cycles. As of October 2015, a detailed list of over 90 individual RPC-supported REMS-compliant accredited CE activities is available on the [CE Search Page](#). Please note that accredited CE Providers are still finalizing dates/locations for some of the activities. Check back often as this listing will be updated on a regular basis.

Grants Supported from 2017 RFA

Primary Provider	Partners	Title
Trustees of Boston University	Haymarket Medical Education, Council of Medical Specialty Societies, and 6 governmental and professional organizations	Safe and Competent Opioid Prescribing Education for Chronic Pain (SCOPE of Pain): Incorporating ER/LA Opioid Analgesics REMS into Practice
Johns Hopkins University	DKBmed	Get SMART 'Mobile'- Safe Means of Administering the Right Therapy (Get SMART Mobile)
Postgraduate Institute of Medicine	DKBmed	Safe Means of Administering the Right Therapy - Extended-Release and Long-Acting Opioids (Get SMART ER/LA Opioids)
Pri-Med Institute	American College of Physicians	SAFE Opioid Prescribing: Strategies, Assessment, Fundamentals, and Education
CO*RE	11 National & State Medical Societies, Medscape, and 50+ cooperating organizations	Opioid Prescribing Safe Practice, Changing Lives
Global Education Group	Rockpointe Corporation, PAINWeek, Primary Care Network, and FreeCME	Extension Grant: Extended-Release and Long-Acting Opioid Analgesics: Risk Evaluation and Mitigation Strategy (REMS)

Grants Supported from 2016 RFA

Links

[Request for Application \(RFA\) 090618 \(2018 Grant Review Cycle\)](#)

[Listing of Opioid Analgesic REMS Program Companies \(RPC\)](#) **NEW**

[Listing of Accredited CE REMS-Compliant Activities Supported by RPC](#) **UPDATED**

[Frequently Asked Questions regarding Continuing Education](#) **UPDATED**

[CE Grant Management System](#)

[Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#) **UPDATED**

[Press Release about MedBiquitous Standards Development](#)

Archive Links

[Request for Application \(RFA\) 080317 Extension \(2017 Grant Review Cycle\)](#)

Global Education Group

Rockpointe Corporation, PAINWeek, Primary Care Network, and FreeCME

Extension Grant: Extended-Release and Long-Acting Opioid Analgesics: Risk Evaluation and Mitigation Strategy (REMS)

*Grants Supported from 2016 RFA**Grants Supported from 2015 RFA**Grants Supported from 2014 RFA**Grants Supported from 2013 RFA**Grants Supported from 2012 RFA*

For further information on the Opioid Analgesic REMS, please refer to the [FDA website](#).

For further inquiries relating to educational grants for the Opioid Analgesic REMS, please refer to the [Continuing Education Frequently Asked Questions](#) (FAQs).

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3. List of Products Page



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Products Search

Use the filters below to search the products.

Product Type ▾	Company ▾	Drug Name / Trade Name ▾	Generic Name ▾
Search			Search Clear

	Drug Name / Trade Name	Generic Name	Company	Contact
⊖	Arymo®ER	(morphine sulfate) extended-release tablets, for oral use CII	Egalet Corporation	1-800-518-1084
	Arymo U.S. Prescribing Information			
	Arymo Medication Guide			
⊕	Belbuca®	Buprenorphine buccal film	BioDelivery Sciences International, Inc (BDSI)	1-877-579-4578
⊕	Butrans®	Buprenorphine transdermal system	Purdue Pharma L.P.	1-888-726-7535
⊕	Dolophine®	Methadone hydrochloride tablets	West-Ward Pharmaceuticals Corp.	1-800-962-8364
⊕	Duragesic®	Fentanyl transdermal system	Janssen Pharmaceuticals, Inc.	1-800-526-7736
⊕	Embeda®	Morphine sulfate and naltrexone extended-release capsules	Pfizer Inc.	1-800-438-1985
⊕	EXALGO®	Hydromorphone hydrochloride extended-release tablets	Mallinckrodt LLC	1-800-778-7898
⊕	Hysingla™ ER	Hydrocodone bitartrate extended-release tablets	Purdue Pharma L.P.	1-888-726-7535
⊕	Kadian®	Morphine sulfate extended-release capsules	Allergan Sales, LLC	1-862-261-7000
⊕	Methadose™	Methadone hydrochloride tablets	Mallinckrodt LLC	1-800-778-7898
Showing 1 to 10 of 300 entries				1 » 10 ▾

4. About Us Page



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REMS-compliant Accredited CE for Opioid Analgesics

Healthcare providers who prescribe opioid analgesics have a responsibility to help ensure the safe and effective use of opioid analgesics. The FDA REMS-compliant accredited continuing education (CE) programs will focus on the safe prescribing of opioid analgesics.

The FDA REMS-compliant accredited CE will: (a) be delivered by accredited CE providers; (b) cover all elements of the updated Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint"); (c) include a knowledge assessment; and (d) be subject to independent audit of content and compliance with applicable accrediting standards.

The FDA has developed core messages to be communicated to providers in the [Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#), which will be used by accredited CE Providers to develop the REMS-compliant accredited CE programs.

These core messages include:

- The fundamental concepts of pain management, including definitions and mechanisms of pain.
- Be familiar with how to assess patients in pain, identify risk factors for misuse, abuse, and addiction.
- Be familiar with how to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient.
- Be knowledgeable about how the range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies and when to refer to a pain specialist is appropriate.
- Know how to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics.
- Know how to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal.
- Be familiar with the fundamental elements of an addiction medicine and how to identify and manage patients with opioid use disorder.
- Be knowledgeable about how to counsel patients and caregivers about the use of naloxone for opioid overdose.

[Click here for a listing of available FDA REMS-compliant accredited CE activities supported by independent educational grants from the opioid analgesic sponsors and offered by accredited CE Providers.](#)

Links

[Listing of Accredited CE REMS-Compliant Activities Supported by RPC](#) **UPDATED**

[Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#) **UPDATED**

If you are an accredited CE Provider, [click here for more information.](#)

7. Patient Counseling Guide Page



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Patient Counseling Guide

What is the Patient Counseling Guide?

The Patient Counseling Guide on Opioid Analgesics is a tool unique to this REMS designed to facilitate important discussions with your patients for whom you select an opioid analgesic. The Patient Counseling Guide should be provided to and reviewed with the patient and/or their caregiver at the time of prescribing. It contains important safety information about the drug products subject to this REMS program and includes space for you to write additional information to help your patients use their opioid analgesic safely.

How can I obtain copies of the Patient Counseling Guide?

Printed copies of the Patient Counseling Guide (English) can be ordered either through an on-line order or via fax. Detailed instructions for both methods of ordering printed copies of the Patient Counseling Guide (English) can be found in the Patient Counseling Guide Order Form, and an electronic version of the Patient Counseling Guide (English and Spanish) is also available for download.

Materials for Download

[Patient Counseling Guide - English](#) **UPDATED**

[Patient Counseling Guide - Spanish](#) **UPDATED**

[Patient Counseling Guide Order Form](#)

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8. Letters Page



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Opioid Analgesic REMS Letters

Click on the letter title below to open a PDF version of that letter.

- [Dear Healthcare Provider \(HCP\) Letter #1](#)
- [Dear Professional Society and Licensing Board \(DSL\) Letter #1](#)

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9. FAQ Pages



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Frequently Asked Questions

[General](#)[Patient](#)[Prescriber](#)[Pharmacist](#)[Continuing Education & Grant](#)



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Note: The RPC Sponsors attest that the questions and answers on the FAQ screens will align with the FAQ document included in the submission.

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