

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

213426Orig1s000

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: 04/2021

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)
 - d. Labeled warnings
 - e. Common adverse drug reactions
9. Drug interactions
- a. Pharmacokinetic interactions based on metabolic pathway
 - b. Pharmacokinetic and pharmacodynamic interactions with alcohol
 - c. Concerns with particular drug–drug interactions, including, but not limited to:
 - Benzodiazepines and other central nervous system depressants, including alcohol
 - Monoamine oxidase inhibitors
 - Antidiuretic hormone drugs
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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available at:

www.accessdata.fda.gov/drugsatfda_docs/remis/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf

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
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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,
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RPC Website Screenshot Document

March 2021

Table of Contents

1	Home Page	3
2	Education Providers Page	5
3	List of Products Page	7
4	About Us	8
5	Terms of Use.....	9
6	Education Page.....	12
7	Patient Counselling Guide	13
8	Letters Page.....	14
9	FAQ Pages	15
9.1	General	15
9.2	Patient	18
9.3	Healthcare Provider.....	21
9.4	Pharmacist.....	27
9.5	Continuing Education & Grant.....	30
10	GMS Landing Page	35
11	CE Activity Search Page.....	36
12	Contact Page.....	37
13	Help Page	38
13.1	Bottom of Help Page	38
14	FAQs Page	39

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

Accredited CE for Healthcare Providers

[REMS-Compliant CE for 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 \(PSLB\) Letter](#) **UPDATED**

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

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

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

[View a complete safety and](#)

[Licensing Board \(PSLB\)](#)

[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 Patients](#) **UPDATED**



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2 Education Providers Page



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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 to make education available for providers of these medications. These manufacturers have developed and are implementing this REMS through a consortium known as the REMS Program Companies (RPC). RPC-supported REMS education is provided through accredited continuing education (CE) activities supported by independent educational grants from the RPC. 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")* on which the content of these accredited CE activities is based.

To date, the RPC has completed eight CE grant cycles - see the table below for a listing of grantees. All accredited CE activities from the 2012-2017 CE Grant Cycles have been completed. A list of 46 ongoing RPC-supported REMS-compliant accredited CE activities as of January 2021 is available on the [CE Activity Search Page](#). Please note that certain accredited CE provider grantees are still finalizing dates/locations for some of the activities. Check back often as this listing is updated on a regular basis.

Links

- [CE Request for Application \(RFA\) 110121 \(2021 CE Grant Cycle\)](#)
- [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](#)
- [CE Grant Management System **UPDATED**](#)
- [Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\) **UPDATED**](#)

Archive Links

2019 Grantees (0 out of 12 activities completed)

Primary Provider	Title
American Society of Health System Pharmacists	Protecting Our Patients: An Opioid Analgesic REMS-compliant Accredited CE Initiative for Pharmacists
Trustees of Boston University	Safer/Competent Opioid Prescribing Education – SCOPE of Pain Educating the Healthcare Team
Massachusetts Medical Society	NEJM Knowledge+ Pain Management and Opioids, with additional learning resources
AKH Inc., Advancing Knowledge in Healthcare	Managing Opioid Risk on the Front Lines: Focus on Active Military Service Members and Veterans
USF Health Professions Conferencing Corporation	Evidence-based Pain Management: Addressing the Growing Role of Nurse Practitioners and Physician Assistants in Managing Patients with Acute and Chronic Pain
Pri-Med Institute	Strategies for Effective Pain Management
CME Outfitters	Heeding the Call for Safe and Responsible Pain Management in Our Communities
Howard University	Howard University Second Opioid Symposium and Naloxone Administration Training for Pharmacy Professionals
Horizon CME	Avoiding Risks While Managing Pain: Following the REMS Blueprint for Pain

Archive Links

- [Request for Application \(RFA\) 100619 \(2019 Grant Cycle\)](#)

Horizon CME	Avoiding Risks While Managing Pain: Following the REMS Blueprint for Pain Management
Medicus Consultants in Education	It Takes a Group: Utilizing a Group-Based Model to Drive Completion of a REMS-Compliant Curriculum at Jefferson Health and Hackensack Meridian Health
Postgraduate Healthcare Education	Building Pharmacist Skills in Opioid Analgesic Therapy: The Power-Pak C.E. Opioid Analgesic Therapy Certificate Program for Pharmacists
University of Kentucky	Pain COACH: Pain Assessment Interventions Needed when Considering Older Adult Care for Healthcare providers

2018 Grantees (11 out of 13 activities completed)

2017 Grantees (6 out of 6 activities completed)

2016 Grantees (6 out of 6 activities completed)

2015 Grantees (9 out of 9 activities completed)

2014 Grantees (7 out of 7 activities completed)

2013 Grantees (7 out of 7 activities completed)

University of Kentucky	Pain COACH: Pain Assessment Interventions Needed when Considering Older Adult Care for Healthcare providers
-------------------------------	---

2018 Grantees (11 out of 13 activities completed)

2017 Grantees (6 out of 6 activities completed)

2016 Grantees (6 out of 6 activities completed)

2015 Grantees (9 out of 9 activities completed)

2014 Grantees (7 out of 7 activities completed)

2013 Grantees (7 out of 7 activities completed)

2012 Grantees (5 out of 5 activities completed)

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 [Frequently Asked Questions](#) regarding Continuing Education.

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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
Acetaminophen and Codeine	Acetaminophen and Codeine Phosphate Tablet 300mg/15mg	Par Pharmaceutical, Inc.	1-800-828-9393
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablet 300mg/15mg (ANDA # 089997)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablet 300mg/30mg (ANDA # 089998)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablet 300mg/60mg (ANDA # 089999)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Oral Solution USP 120 mg/12mg per 5 mL (ANDA # 085861)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen And Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Amneal Pharmaceuticals	1-877-835-5472
Acetaminophen And Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablets	SpecGx LLC	1-800-778-7898

Drug Name / Trade Name	Generic Name	Company	Contact
Acetaminophen and Codeine	Acetaminophen and Codeine Phosphate Tablet 300mg/15mg	Par Pharmaceutical, Inc.	1-800-828-9393
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablet 300mg/15mg (ANDA # 089997)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablet 300mg/30mg (ANDA # 089998)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablet 300mg/60mg (ANDA # 089999)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Oral Solution USP 120 mg/12mg per 5 mL (ANDA # 085861)	Teva Pharmaceuticals USA, Inc.	1-888-838-2872
Acetaminophen And Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Amneal Pharmaceuticals	1-877-835-5472
Acetaminophen And Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablets	SpecGx LLC	1-800-778-7898
Acetaminophen and Codeine Phosphate	Acetaminophen and Codeine Phosphate Tablets, USP, 300mg/15mg, 300mg/30mg, and 300mg/60mg	WES Pharma Inc.	1 410-661-6444
Acetaminophen and Codeine Phosphate Oral Solution USP 120 mg/12 mg per 5 mL CV	Acetaminophen and Codeine Phosphate Oral Solution USP 120 mg/12 mg per 5 mL CV	Pharmaceutical Associates, Inc.	1-800-845-8210
Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12mg per 5mL	Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12mg per 5mL	Akorn, Inc.	1-800-932-5676

Showing 1 to 10 of 308 entries

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4 About Us



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6 Education Page



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U.S. Prescribing Information

Looking for Accredited REMS CE? Click Here.

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.

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.

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 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.](#)

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7 Patient Counseling Guide



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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 by emailing ask.kadena@cenveo.com. 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 Healthcare Provider \(HCP\) Letter #2](#)
- [Dear Professional Society and Licensing Board \(PSLB\) Letter #1](#)
- [Dear Professional Society and Licensing Board \(PSLB\) Letter #2](#)

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9 FAQ Pages

9.1 General



Medication Guides

U.S. Prescribing Information

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Frequently Asked Questions

General

Patient

Healthcare Provider

Pharmacist

Continuing Education & Grant

Search

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What is a REMS and what is this REMS?

REMS stands for "Risk Evaluation and Mitigation Strategy". A REMS is a risk management program required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. The FDA has determined that a single, shared REMS, referred to as the Opioid Analgesic REMS, is required for all brand and generic opioid analgesics that are intended for use in the outpatient setting and not covered under another REMS.

Which pain medicines are included in this REMS?

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

- Oral dosage forms containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol
- Intranasal buprenorphine

Which pain medicines are included in this REMS?

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

- Oral dosage forms containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol
- Intranasal buprenorphine
- Fentanyl transdermal delivery systems, buprenorphine buccal film and transdermal delivery systems indicated for use as pain medicines
- Methadone tablets or liquid that are indicated for use as pain medicines

What is the goal of this REMS?

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:

- 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.
- 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.

What are the principal components of this REMS?

The principal components of this REMS are:

- REMS-compliant accredited CE for Healthcare Providers (HCPs), which includes all healthcare providers who prescribe or are involved in the management of patients with pain

Reference ID: 4873257

➤ What are the principal components of this REMS?

The principal components of this REMS are:

- a. REMS-compliant accredited CE for Healthcare Providers (HCPs), which includes all healthcare providers who prescribe or are involved in the management of patients with pain.
- b. the Opioid Analgesics REMS Patient Counseling Guide, and
- c. a Medication Guide for each opioid analgesic drug product.

For additional information visit the Opioid Analgesic REMS website at www.opioidanalgesicrems.com

➤ Who can I call if I need to speak with someone about questions I have on this REMS?

You can call the Opioid Analgesic REMS toll-free number at 1-800-503-0784 for information regarding the most commonly asked questions regarding this REMS. If your specific question is not addressed, please leave a message, and a representative will return your call.

➤ Who can I call if I have questions about a specific product?

You can talk to your pharmacist or call the individual opioid analgesic manufacturer directly for product-specific questions. A listing of companies and products is on the Opioid Analgesic REMS website available at www.opioidanalgesicrems.com.

➤ What REMS materials are available for patient education? and how can I access them?

There are two documents available for patient education: the product-specific Medication Guide and the Patient Counseling Guide. The Medication Guides can be obtained from the pharmacy; accessed via a link on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com; or by contacting the manufacturer of the specific product directly. The Patient Counseling Guide is available via a link on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com.

➤ Do I need to receive training about the safe use of opioid analgesics?

The FDA strongly encourages healthcare providers who prescribe or are involved in the management of patients with pain to complete a REMS-compliant accredited CE activity or other appropriate training in order to prescribe, dispense, or otherwise manage the use of opioid analgesics more safely.

➤ How should an adverse event(s) associated with opioid analgesics be reported?

➤ How should an adverse event(s) associated with opioid analgesics be reported?

You are strongly encouraged to report all suspected adverse reactions associated with the use of the covered opioid analgesics by contacting either:

- 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 manufacturer that markets the specific product (Manufacturer contact information available on the Opioid Analgesic REMS website <click [here](#) for listing of products and manufacturer contact information>) Or, you may contact the Opioid Analgesic REMS call center at 1-800-503-0784 and leave a message and a call center representative will return your call

➤ Privacy Statement -- What happens to the information I give you?

Call Center Communicators will take steps to safeguard any information you share with us and will not intentionally otherwise use or disclose any of your personally identifiable information, except to the extent reasonably necessary:

- I. to correct technical problems and malfunctions, to technically process your information and to determine the effectiveness of our program;
- II. to protect the security and integrity of our call center;
- III. to protect our rights and property and the rights and property of others;
- IV. to take precautions against liability;
- V. to the extent required by law or to respond to judicial process; or
- VI. to the enforcement agencies or for an investigation on a matter related to public safety or potential adverse event/product complaint, as applicable.

➤ How can I obtain literature related to this REMS or the products in this REMS?

The REMS materials can be accessed via the Opioid Analgesic REMS website at www.opioidanalgesicrems.com Requests for literature for specific products may be made by contacting the pharmaceutical manufacturer that markets the specific product (Manufacturer contact information available on the Opioid Analgesic REMS website <click [here](#) for listing of products and manufacturer contact information>)

➤ What is your confidentiality protocol?

The information that you provide to us is treated in a confidential manner. If necessary, the information may be transferred to member

What is your confidentiality protocol?

The information that you provide to us is treated in a confidential manner. If necessary, the information may be transferred to member companies and the FDA as required by law.

Who owns this website?

This website is maintained by the Opioid Analgesic REMS Program Companies ("RPC"), which is a collaboration of drug product companies to implement a single shared REMS. The content on this website is determined by, hosted on behalf of, and is financially supported by the RPC.

Is this website accessible through all search engines?

This website is publicly available and should be searchable by most popular search engines.

Why is this website required by the FDA?

This website is required by the FDA to meet the REMS requirements.

Who do I call if I have questions, comments, or concerns about this website?

Contact the Opioid Analgesic REMS call center at 1-800-503-0784. You will have the option to leave a message, and a representative will return your call.

Where do I go to view the Medication Guides for the products covered under this Opioid Analgesic REMS?

The Opioid Analgesic REMS website at www.opioidanalgesicrems.com or call the manufacturer. Medication Guides are available on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com or by calling the product manufacturer.

Where do I go to view the Prescribing Information for the products covered under this Opioid Analgesic REMS?

The Opioid Analgesic REMS website at www.opioidanalgesicrems.com or call the manufacturer. Medication Guides are available on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com or by calling the product manufacturer.

How do I access, save or print any of the class-wide materials on the website?

How do I access, save or print any of the class-wide materials on the website?

Click on the link to the material and select "print" or "save" in your web browser.

What materials are available on the website?

The REMS materials available on the website are the Patient Counseling Guide, the Patient Counseling Guide Order Form, the Dear Healthcare Provider letters, and the Dear Professional Society and Licensing Board (PSLB) Letters. The REMS website has links to other documents, such as the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#) and the US Prescribing Information and Medication Guide for each drug included in the REMS.

What browsers and platforms are supported by this website?

The browsers supported by this website are Internet Explorer 8 or 9, Google Chrome v19, Safari 5, and Firefox v13. The platforms supported by this website are: Apple Mac OSX, Windows 7 PC, Android, iPhone OSX, and iPad OSX.

What do I do if I can't view some documents on the website?

To view the Patient Counseling Guide, the Patient Counseling Guide Order Form, the "Dear Healthcare Provider" letter, or the "Dear Professional Society and Licensing Board (PSLB)" letter, you need to download the Adobe Acrobat viewer. This can be found at <https://get.adobe.com/reader>

[BACK TO TOP](#)

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Last Updated: March 24, 2021

9.2 Patient



Medication Guides

U.S. Prescribing Information

Looking for Accredited REMS CE? Click Here.

Frequently Asked Questions

General

Patient

Healthcare Provider

Pharmacist

Continuing Education & Grant

Search



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What should I do if I take too much of my pain medicine?

Call 911 or your local emergency service right away if:

- you take too much medicine,
- have trouble breathing or shortness of breath, or
- a child has taken this medicine.

As a patient, what am I required to do for this REMS?

Your responsibility is to discuss with your healthcare provider the safe use, and proper storage and disposal of your pain medicine as described in the Patient Counseling Guide; and to read the Medication Guide that you will receive with your prescription at the pharmacy.

As a patient, what am I required to do for this REMS?

Your responsibility is to discuss with your healthcare provider the safe use, and proper storage and disposal of your pain medicine as described in the Patient Counseling Guide; and to read the Medication Guide that you will receive with your prescription at the pharmacy.

What is the Patient Counseling Guide?

The Patient Counseling Guide explains how to safely use, properly store, and dispose of your pain medicine. It also explains what to do if you are having any problems with your pain medicine. This guide should be given to you by your healthcare provider when they are writing you a prescription for a pain medicine.

What is the Medication Guide for this REMS?

The Medication Guide is a document that explains how to safely use and dispose of your used or unused pain medicine. The Medication Guide includes important information specific to the pain medicine you were prescribed. This document is given to you when you receive your prescription from the pharmacy.

What is the additional information following some of the Medication Guides?

Some, but not all, pharmacies provide patients with additional information on how to safely use their medicine. This is known as the "Instructions for Use" and is generally provided to you with the Medication Guide.

Where can I get another copy of the Instructions for Use?

Instructions for Use or, IFU, can be accessed via Opioid Analgesic REMS website, under the "Medication Guides" tab. IFUs can also be requested by contacting the pain medicine manufacturer directly. A listing of companies and products is on the Opioid Analgesic REMS website available at www.opioidanalgesicrems.com. <click here for listing of products and manufacturer contact information>

Do I need to enroll in this REMS?

No, there is no enrollment required for patients.

Will this REMS affect my ability to get my pain medicine?

This REMS should not affect your ability to receive your pain medicine that your healthcare provider has prescribed for you. One of the goals of this REMS is to help you understand how to use, store, and dispose of your pain medicine safely.

Will this REMS affect my ability to get my pain medicine?

This REMS should not affect your ability to receive your pain medicine that your healthcare provider has prescribed for you. One of the goals of this REMS is to help you understand how to use, properly store, and dispose of your pain medicine safely.

Who should I contact if I develop a side effect from my pain medicine?

If you are experiencing a life-threatening medical emergency, dial 911 or your local emergency provider. If you experience a side effect, you should contact your healthcare provider for medical advice. You are strongly encouraged to report all side effects by contacting either of the following: the pharmaceutical manufacturer that markets the specific product www.opioidanalgesicrems.com or the Food and Drug Administration at 1-800-FDA-1088.

How will this REMS improve the safe use of these pain medicines in my home?

This REMS helps to educate patients on the safe storage and disposal of their pain medicine in order to prevent anyone else from taking the medicine that your healthcare provider has prescribed only for you. This information is available in the Patient Counseling Guide.

How will this REMS reduce the risk of accidental overdose of prescription pain medicines?

This REMS will help you understand how to use your medication properly. The REMS also includes important information about how to safely store and dispose of your medicine in order to avoid accidental overdose by others in the home.

I have difficulty swallowing pills. Is it okay to crush my pain medicine?

There are some pain medicines that should **never** be broken, chewed, crushed, dissolved, or injected. If you cannot swallow your medicine whole, talk to your healthcare provider.

Is it okay to cut my pain medicine patch?

No. Pain medicine patches containing opioid analgesics should **never** be cut.

Is it really okay to flush my unused pain medicine down the toilet?

According to the FDA, flushing certain medicines down the toilet is currently the safest way to immediately and permanently remove the risk of harm from the home. An alternative to flushing is to dispose of the expired/unwanted/unused medicines through a medicine take back

Is it really okay to flush my unused pain medicine down the toilet?

According to the FDA, flushing certain medicines down the toilet is currently the safest way to immediately and permanently remove the risk of harm from the home. An alternative to flushing is to dispose of the expired/unwanted/unused medicines through a medicine take back program. When a medicine take-back activity isn't immediately available, the FDA believes that any potential risk to people and the environment from flushing pain medicines is outweighed by the real possibility of life-threatening harm from accidental ingestion of these medicines. You should contact your city or county government's household trash and recycling services to see if there is a medicine take-back activity in your community and learn about any special rules regarding which medicines can be taken back. The FDA posts the dates for national take-back day at: <https://www.fda.gov/drugdisposal>

For additional information on the safe disposal of specific medications please contact the FDA at 1-888-463-6332 and visit the FDA's website at: <https://www.fda.gov/drugdisposal>

What is the best way to dispose of my unused pain medicine?

Please visit this FDA website for updated information on the **safe disposal of opioids**: <https://www.fda.gov/drugdisposal>

Who should I contact if I see that my medication looks or smells different (i.e., broken pills, tear in patch, unusual smell/color)?

You should contact the pharmacy that dispensed the medication.

Does the REMS require that my healthcare provider be certified to prescribe pain medicine for me?

No, at this time this REMS does not require your healthcare provider to complete any certification to prescribe pain medicine. However, all healthcare providers that prescribe opioids must be registered by the Drug Enforcement Administration (DEA) and may have to meet other license requirements in their State.

What is the difference between extended release, long-acting, and immediate release pain medicines and their involvement in this REMS?

According to the FDA description, immediate-release (IR) opioid analgesics are formulated to release the drug over a shorter time period so they generally require more frequent dosing compared to extended-release opioid analgesics. Extended-release (ER) opioid analgesics are formulated to provide a longer time period of drug release so that they can be taken less frequently. Examples of opioid analgesics formulated as both IR and ER products include hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, and tapentadol. Long-acting (LA) opioid analgesics, such as methadone, have a longer period of action because of the inherent characteristics of the drug substance, which stays longer in the body, and not because of the formulation of the finished product. The amount of opioid analgesic contained in an ER tablet can be much more than the amount of opioid analgesic contained in an IR tablet, because ER tablets are

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On September 28, 2017, the FDA announced that IR opioids used in the outpatient setting are to be subject to the same REMS requirements as ER/LA opioid analgesics. Please refer to the FDA website at <https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems> for additional information.

 How will this REMS affect my methadone or buprenorphine prescription for treatment of addiction?

It will not affect those prescriptions at all.

[BACK TO TOP](#)

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Last Updated: March 24, 2021

9.3 Healthcare Provider



Medication Guides

U.S. Prescribing Information

Looking for Accredited REMS CE? Click Here.

Frequently Asked Questions

General

Patient

Healthcare Provider

Pharmacist

Continuing Education & Grant

Search



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What opioid analgesics are involved in this REMS?

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

- Oral dosage forms containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol or tramadol
- Intranasal buprenorphine
- Fentanyl transdermal delivery systems, buprenorphine buccal film and transdermal delivery systems indicated for use as pain medicines
- Methadone tablets or liquid indicated for use as pain medicines

Can you tell me more about the opioid analgesic education intended for healthcare providers, such as myself?

REMS-compliant accredited CE for healthcare providers is offered by accredited CE Providers. You are strongly encouraged to complete a

Can you tell me more about the opioid analgesic education intended for healthcare providers, such as myself?

REMS-compliant accredited CE for healthcare providers is offered by accredited CE Providers. You are strongly encouraged to complete a REMS-compliant accredited CE activity from an accredited provider of CE to increase your knowledge in prescribing opioid analgesic products more safely. CE credits are available for these activities. A listing of REMS-compliant accredited CE activities can be found at: search.opioidanalgesicrems.com. This listing is updated regularly as CE Providers notify the RPC of new activities.

What important safety information will the opioid analgesic education contain?

REMS-compliant, independent, accredited CE includes information on the basics of pain. The CE is based on the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#). The core messages include:

- 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

How can I find out more about available REMS-compliant accredited CE and how to complete it?

REMS-compliant, independent, accredited CE activities supported by educational grants from the RPC are listed in a searchable table on the Opioid Analgesic REMS website at search.opioidanalgesicrems.com, as they become available.

Other REMS-compliant accredited CE may also be offered by academic institutions or professional societies independent of RPC-related funding.

How can I find out more about available REMS-compliant accredited CE and how to complete it?

REMS-compliant, independent, accredited CE activities supported by educational grants from the RPC are listed in a searchable table on the Opioid Analgesic REMS website at search.opioidanalgesicrems.com, as they become available.

Other REMS-compliant accredited CE may also be offered by academic institutions or professional societies independent of RPC-related funding.

Healthcare providers (HCPs) who prescribe opioid analgesics and/or provide care to patients and their caregivers are in a key position to balance the benefits of prescribing opioid analgesics to treat pain against the risks of adverse outcomes. As such, healthcare providers are strongly encouraged to complete REMS-compliant accredited education offered by accredited CE Providers.

Can you tell me more about the opioid analgesic education available for patients?

The Patient Counseling Guide is designed to assist healthcare providers in having important conversations with patients for whom you prescribe an opioid analgesic. The Patient Counseling Guide 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 opioid analgesic safely. The Patient Counseling Guide should be provided to your patient or their caregiver at the time you prescribe an opioid analgesic to patients. The patient should also be given the specific drug's Medication Guide when they pick up their prescription at the pharmacy.

Where can I obtain additional copies of the Patient Counseling Guide?

Access to the Patient Counseling Guide and additional information or how to request multiple copies of the Patient Counseling Guide is available on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com. <click [here](#) for Patient Counseling Guide or Patient Counseling Guide order form >

Why should I be interested in this REMS - what does it mean for me and my patients?

Opioid misuse and abuse, resulting in injury and death, has emerged as a major public health problem in the US. The goal of this 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 [FDA 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

Why should I be interested in this REMS - what does it mean for me and my patients?

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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.

Are there mandatory components associated with the Opioid Analgesic REMS that I must complete (e.g., enrollment, education), to allow me to continue providing care or prescribing opioid analgesics to my patients?

Under this REMS, pharmaceutical companies that manufacture or market opioid analgesics are required to make training available to all opioid analgesic prescribers and members of the broad healthcare team who provide care for patients and their caregivers. The companies are meeting this requirement by providing educational grants to accredited CE providers. While completion of REMS-compliant accredited CE is not mandatory under this REMS, all healthcare providers are STRONGLY encouraged to successfully complete a REMS-compliant training program from an accredited provider of CE. Doing so may help to promote safe use of these drugs.

How are "Providers" defined in the Opioid Analgesic REMS?

Providers as referenced in this REMS are prescribers such as physicians, nurse practitioners, physician assistants, dentists, or any other healthcare providers authorized by the Drug Enforcement Administration or their State to prescribe scheduled II, III, and IV opioid analgesics. Providers also include members of the broad healthcare team who care for patients and/or their caregivers, such as nurses and pharmacists.

Do I need to complete more than one REMS-compliant accredited CE if I prescribe multiple opioid analgesics?

All opioid analgesic products intended for outpatient use are covered by this REMS. All the REMS-compliant, independent, accredited CE activities offered by or through the RPC will cover the full [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers](#).

Do I need to complete more than one REMS-compliant accredited CE if I prescribe multiple opioid analgesics?

All opioid analgesic products intended for outpatient use are covered by this REMS. All the REMS-compliant, independent, accredited CE activities offered by or through the RPC will cover the full [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#). All healthcare providers who prescribe opioid analgesics should take the necessary training they need to help ensure the safe use of opioid analgesics.

What if I have previously completed a/an [opioid, TIRF, Butrans, Embeda, Exalgo, Opana, OxyContin] REMS education? Do I still need to complete additional education for the Opioid Analgesic REMS?

There has been new, updated training developed for this REMS. Healthcare providers are in a key position to balance the benefits of prescribing opioid analgesics against the risks of serious adverse outcomes. As such, you are strongly encouraged to complete a REMS-compliant accredited CE activity that is based on the updated [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#). The "FDA Blueprint" includes content on pain management, including non-opioid alternatives. This includes principles related to management of acute and chronic pain; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). The "FDA Blueprint" also covers information about the safe use of opioids and basic information about addiction medicine and opioid use disorders.

How often should healthcare providers participate in the Opioid Analgesic REMS-compliant accredited CE?

Taking a REMS-compliant accredited CE annually is strongly recommended. However, note that you will not receive CE credit for repeating the same CE course within the reporting period.

How many CE credits will Healthcare Providers receive for completing the REMS accredited continuing education and how long will it take to complete?

The number of CE credits for any particular activity will be determined by the accredited CE Provider. The number of credits and the length of time to complete the activity will depend on the scope and design of the educational activity.

What areas of education are contained in the FDA's Opioid Analgesic REMS "Blueprint"?

The [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#) contains core messages for the safe use of these medications. Topics include:

Section 1: The Basics of Pain

- I. Definitions and Mechanisms of Pain
- II. Assessing Patients in Pain

Section 2: Creating the Pain Treatment Plan

What areas of education are contained in the FDA's Opioid Analgesic REMS "Blueprint"?

The [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#) contains core messages for the safe use of these medications. Topics include:

Section 1: The Basics of Pain

- I. Definitions and Mechanisms of Pain
- II. Assessing Patients in Pain

Section 2: Creating the Pain Treatment Plan

- I. Components of an Effective Treatment Plan
- II. Non-Pharmacologic Therapies
- III. General Principles of Pharmacologic Analgesic Therapy
 - A. Non-opioid analgesics and adjuvant medications
 - B. Opioid Analgesics
- IV. Managing Patients on Opioid Analgesics
 - A. Initiating Treatment with Opioids - acute pain
 - B. Initiating Treatment with Opioids - chronic pain
 - C. Ongoing management of patients on opioid analgesics
 - D. Long-term management
 - E. How to recognize and intervene upon suspicion or identification of an opioid use disorder (OUD)
 - F. When to consult a pain specialist
 - G. Medically directed opioid tapering
 - H. Importance of patient education
- V. Addiction Medicine Primer

A link to the "FDA Blueprint" is available at: [FDA Blueprint](#)

What are the responsibilities of the companies of opioid analgesics as it pertains to healthcare provider education?

The Opioid Analgesic REMS requires that the manufacturers of opioid analgesics make training available to prescribers of these medications and other members of the healthcare team who provide care to patients and their caregivers. The companies are meeting this requirement by providing educational materials to accredited CE providers. All companies involved in this REMS created accredited CE...

What are the responsibilities of the companies of opioid analgesics as it pertains to healthcare provider education?

The Opioid Analgesic REMS requires that the manufacturers of opioid analgesics make training available to prescribers of these medications and other members of the healthcare team who provide care to patients and their caregivers. The companies are meeting this requirement by providing educational grants to accredited CE providers. All companies involved in this REMS supported accredited CE will adhere to the Standards of Commercial Support and, as such, the only involvement in the education will be as a grantor to support the REMS-compliant accredited CE consistent with the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#).

Who is funding the REMS-compliant accredited CE?

REMS-compliant, independent, accredited education is funded through educational grants by the REMS Program Companies (RPC), comprised of the companies who currently manufacture or market opioid analgesic products.

Where and how is REMS-compliant accredited CE offered?

Detailed information about REMS-compliant accredited CE activities, including the location and format, is available via the Opioid Analgesic REMS website at <https://search.opioidanalgesicrems.com>. A broad range of formats and venues for REMS compliant accredited CE activities are being offered through the accredited CE Providers.

In addition to the CE credits is there any "advanced or additional certification" associated with the completion of this education?

The Opioid Analgesic REMS does not require advanced or additional certification associated with the REMS-compliant accredited CE.

What happens if I do NOT participate in REMS-compliant accredited CE?

Under this REMS, the manufacturers of opioid analgesics are required to make independent, accredited CE available to all opioid analgesics prescribers and healthcare providers who provide care to patients and their caregivers. While completion of REMS-compliant accredited CE is not mandatory, all healthcare providers are STRONGLY encouraged to successfully complete a REMS compliant CE activity from an accredited provider of CE. Doing so may help to promote safe use of these drugs.

Who is the target audience for the Opioid Analgesic REMS?

At this time, the FDA has directed the Opioid Analgesic REMS accredited CE towards healthcare providers. This includes other members of the healthcare team who are involved in the management or support of patients with pain, such as nurses and pharmacists. "Prescribers," as referenced in this REMS, encompasses physicians, nurse practitioners, pharmacists, physician assistants, dentists, or any other healthcare providers authorized by the Drug Enforcement Administration or their State to prescribe scheduled II, III, and IV opioid analgesic.

Who is the target audience for the Opioid Analgesic REMS?

At this time, the FDA has directed the Opioid Analgesic REMS accredited CE towards healthcare providers. This includes other members of the healthcare team who are involved in the management or support of patients with pain, such as nurses and pharmacists. "Prescribers," as referenced in this REMS, encompasses physicians, nurse practitioners, pharmacists, physician assistants, dentists, or any other healthcare providers authorized by the Drug Enforcement Administration or their State to prescribe scheduled II, III, and IV opioid analgesic.

How much will it cost to participate in the REMS-compliant accredited CE?

The FDA expects that REMS-compliant accredited CE consistent with the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#) has been developed by independent accredited CE Providers, and is offered to prescribers and members of the broad healthcare team who care for patients and their caregivers at no or nominal cost via educational grants supported by the RPC. Here is a link to the list of current accredited CE in a variety of platforms: <https://search.opioidanalgesicrems.com>.

Will the education content be the same regardless of format?

Yes, all REMS-compliant, independent, accredited CE supported by the companies involved in this REMS must address all the elements of the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain \("FDA Blueprint"\)](#).

How long will the education be available?

REMS-compliant accredited CE will continue to be provided as long as the Opioid Analgesic REMS is in effect.

Is there a deadline to complete the education?

While there is no deadline, you are encouraged to participate in the REMS-compliant accredited CE as soon possible in order to help positively impact this important patient safety and public health issue.

Where may I get a copy of my CE credit?

The learner should contact the accredited CE Provider for information on obtaining copies of CE credits.

How will the Opioid Analgesic REMS affect patient access to medications?

➤ How will the Opioid Analgesic REMS affect patient access to medications?

The Opioid Analgesic REMS does not impact patient access; the REMS does not impose any restrictions on prescribing or dispensing. The intent of this REMS is not to limit patient access to medication, but rather reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of opioid analgesic products.

➤ What is the difference between extended-release, long-acting, and immediate-release opioid analgesics? When were IR opioids added to the Opioid Analgesic REMS?

According to the FDA description, immediate-release (IR) opioid analgesics are formulated to release the drug over a shorter time period so they generally require more frequent dosing compared to extended-release opioid analgesics. Extended-release (ER) opioid analgesics are formulated to provide a longer time period of drug release so that they can be taken less frequently. Examples of opioid analgesics formulated as both IR and ER products include hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, and tapentadol. Long-acting (LA) opioid analgesics, such as methadone, have a longer period of action because of the inherent characteristics of the drug substance, which stays longer in the body, and not because of the formulation of the finished product. The amount of opioid analgesic contained in an ER tablet can be much more than the amount of opioid analgesic contained in an IR tablet because ER tablets are designed to release the opioid analgesic over a longer period.

On September 28, 2017, the FDA announced that IR opioids used in the outpatient setting are to be subject to the same REMS requirements as ER/LA opioid analgesics. Please refer to the FDA website at <https://www.fda.gov/drugs/information-drug-class/opioid-analg-eric-risk-evaluation-and-mitigation-strategy-rems> for additional information.

➤ Will this REMS affect the prescribing and dispensing of methadone or buprenorphine indicated for treatment of opioid dependence?

No. This REMS only applies to methadone and buprenorphine products indicated for the treatment of pain.

➤ Will healthcare providers be required to be certified under this REMS to continue prescribing opioid analgesics?

No. At this time, there is no certification requirement or connection to any state certification or requirements.

➤ Will the content of accredited CE activities be applicable to veterinarians?

The Opioid Analgesic REMS accredited CE activities focus on the safe prescribing of opioid analgesics and consist of core content as defined in the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint"). While the primary target of this content is prescribers of opioid analgesics and healthcare providers who provide care to patients and their caregivers as specified by the FDA, the content may also be relevant for other healthcare providers (e.g., veterinarians). The accredited CE Provider determines the target audience based on the needs assessment they conduct.

➤ Will the content of accredited CE activities be applicable to veterinarians?

The Opioid Analgesic REMS accredited CE activities focus on the safe prescribing of opioid analgesics and consist of core content as defined in the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint"). While the primary target of this content is prescribers of opioid analgesics and healthcare providers who provide care to patients and their caregivers as specified by the FDA, the content may also be relevant for other healthcare providers (e.g., veterinarians). The accredited CE Provider determines the target audience based on the needs assessment they conduct.

➤ Will the content of accredited CE activities be applicable to EMTs?

The Opioid Analgesic REMS accredited CE activities focus on the safe prescribing of opioid analgesics and consist of core content as defined in the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint"). While the primary target of this content is prescribers of opioid analgesics and healthcare providers who provide care to patients and their caregivers as specified by the FDA, the content may also be relevant for other healthcare providers (e.g., emergency medical technicians). The accredited CE Provider determines the target audience based on the needs assessment they conduct.

➤ How do I report a Prescriber who miss-prescribes / over-prescribes Opioid Analgesics?

If you have any concerns regarding a Prescriber, please contact your state's medical board or other local professional governing body (e.g., state pharmacy board) for assistance.

➤ Where can I locate the documents mentioned in the Healthcare Provider Survey?

For inquiries regarding the Healthcare Providers Survey, please call the Survey Vendor at 1-800-497-9511.

➤ How do I obtain an update on compensation from the Healthcare Provider Survey?

For inquiries regarding the Healthcare Providers Survey, please call the Survey Vendor at 1-800-497-9511.

➤ How do I update / remove my address for REMS mailings from the RPC?

Please call the Opioid Analgesic REMS call center at 1-800-503-0784 and leave a message with your name, current address, action you wish to take, and new address (if applicable). If required, a Call Center Agent will return your call.

For inquiries regarding the Healthcare Providers Survey, please call the Survey Vendor at 1-800-497-9511.

➤ [How do I obtain an update on compensation from the Healthcare Provider Survey?](#)

For inquiries regarding the Healthcare Providers Survey, please call the Survey Vendor at 1-800-497-9511.

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Please call the Opioid Analgesic REMS call center at 1-800-503-0784 and leave a message with your name, current address, action you wish to take, and new address (if applicable). If required, a Call Center Agent will return your call.

➤ [Why did I receive / not receive the Dear Healthcare Provider Letter from RPC?](#)

The letter was first distributed to healthcare providers within 60 calendar days of the approval of the REMS on 9/2018 and will be distributed to healthcare providers annually on the date of REMS approval moving forward. To be added / removed from the mailing list, please call the Opioid Analgesic REMS call center at 1-800-503-0784.

➤ [Are there Spanish versions of the Patient Counseling Guide or Medication Guides available?](#)

At this time, only the Patient Counseling Guide is available in Spanish. To access the Spanish version of the Patient Counseling Guide, please visit the Opioid Analgesic REMS website at www.opioidanalgesicrems.com.

[BACK TO TOP](#)

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Last Updated: March 24, 2021

9.4 Pharmacist



Medication Guides

U.S. Prescribing Information

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Frequently Asked Questions

General

Patient

Healthcare Provider

Pharmacist

Continuing Education & Grant

Search



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Are there components of this REMS that impact outpatient or mail-order pharmacy practice?

The central component of the Opioid Analgesic REMS is REMS-compliant accredited CE for healthcare providers who prescribe these products and other healthcare providers who provide care to patients and their caregivers including pharmacists. Product-specific Medication Guides are a component of the Opioid Analgesic REMS. Pharmacists in the outpatient and mail-order pharmacy setting are required to provide patients and/or their caregivers with the product-specific Medication Guide when dispensing an opioid analgesic. Medication Guides provide information in patient friendly language about the drug's risks and how to use the drug safely.

Are there components of this REMS that impact inpatient or long-term care pharmacy practice?

No. There is no component of this REMS that specifically applies to inpatient or long-term care pharmacies. However, product-specific Medication Guides should be available and provided to inpatients, upon request.

Did this REMS impact the Medication Guides?

Did this REMS impact the Medication Guides?

Distribution of a product's Medication Guide has not changed as a result of this REMS. The product-specific Medication Guides are an element of the REMS and are part of approved product labeling. The Medication Guides can be used to facilitate communicating about aspects of safe use of opioid analgesics. Pharmacists in the outpatient and mail-order pharmacy setting are required to provide patients and/or their caregivers with the product-specific Medication Guide when dispensing an opioid analgesic.

Am I required to provide the "Instructions for Use" with the Medication Guide?

Distribution of a product's "Instructions for Use" (IFU) has not changed as a result of this REMS. The IFU is part of approved product labeling. For products that have additional IFU, the IFU follows the Medication Guide available on the Opioid Analgesic REMS website. The IFU should also be available in the product-specific packaging. Specific questions on a product's IFU should be directed to the manufacturer of the opioid analgesic. A listing of companies and products is on the Opioid Analgesic REMS website available at www.opioidanalgesicrems.com. <click [here](#) for listing of products and manufacturer contact information>

Where can I get a copy of the Instructions for Use?

Instructions for Use (IFU) can be accessed via the Opioid Analgesic REMS website, via the "Medication Guides" tab. IFUs can also be requested by contacting the opioid analgesic manufacturer directly. A listing of companies and products is on the Opioid Analgesic REMS website available at www.opioidanalgesicrems.com. <click [here](#) for listing of products and manufacturer contact information>

Will pharmacists be required to complete accredited CE, enrollment, or verification to dispense these opioid analgesic products?

No. This REMS does not require pharmacists in any pharmacy setting to complete accredited CE, enrollment, or verification to dispense opioid analgesic products. While completion of REMS-compliant accredited CE is not mandatory, all healthcare providers who provide care to patients and their caregivers, including pharmacists and nurses, are STRONGLY encouraged to successfully complete a REMS-compliant activity from an accredited provider of CE. Outpatient or mail-order pharmacies are required to provide patients and/or their caregivers with the product-specific Medication Guide when dispensing an opioid analgesic.

Does this REMS require pharmacists to counsel patients on the safe use of opioid analgesics?

The Opioid Analgesic REMS does not introduce new requirements for pharmacists. Pharmacists should continue to counsel patients in the same manner and follow existing state-specific regulations regarding patient counseling.

Is there a single, shared Medication Guide we can use for all opioid analgesics?

➤ Is there a single, shared Medication Guide we can use for all opioid analgesics?

No. Even though the FDA has required common language in the Medication Guides for the opioid analgesics, the Medication Guides for the opioid analgesics subject to this REMS each contain product-specific risk information. Therefore, the appropriate and most current FDA-approved product-specific Medication Guide must be dispensed to the patient and/or caregiver with each specific opioid analgesic product.

➤ How can pharmacists obtain the product-specific Medication Guides?

Each manufacturer is responsible for providing Medication Guides in sufficient numbers to pharmacies in order to provide a Medication Guide to each patient receiving a prescription for the dispensed drug product. If additional Medication Guides are needed they can be accessed via:

- the Opioid Analgesic REMS website at www.opioidanalgesicrems.com
- contacting the Opioid Analgesics REMS toll-free # at 1-800-503-0784 (a call center agent will then transfer you to the appropriate pharmaceutical manufacturer), or
- contacting the opioid analgesic manufacturer directly as referenced on this Opioid Analgesic REMS website <click [here](#) for a listing of products and manufacturer contact information>

➤ How can I determine which product-specific Medication Guide is the correct one to dispense?

The existing process for identifying the appropriate Medication Guide to dispense to a patient receiving any medication that has a Medication Guide has not changed. Each product-specific Medication Guide will continue to include the name of the manufacturer or distributor of the opioid analgesic.

➤ Can manufacturer-generated drug information or consumer medication information (CMI) be provided to patients in place of the FDA approved Medication Guides?

No. Manufacturer-generated drug information or Consumer Medication Information (CMI) provided with your medication does not take the place of the Medication Guide. Pharmacists are responsible for providing patients and/or their caregiver with the product-specific FDA-approved Medication Guide for the opioid analgesic product dispensed.

➤ Does a Medication Guide need to be provided with each subsequent opioid analgesic prescription dispensed to the same patient, for the same product?

Yes. Each opioid analgesic prescription must include a current product specific Medication Guide with EVERY prescription, regardless of

➤ Does a Medication Guide need to be provided with each subsequent opioid analgesic prescription dispensed to the same patient, for the same product?

Yes. Each opioid analgesic prescription must include a current product specific Medication Guide with EVERY prescription, regardless of whether the patient has previously received the same medication. This is important because information may have changed since their last prescription.

➤ If patients want to learn more about the safe use of opioid analgesics, where can we refer patients?

Patients should have received and reviewed the Patient Counseling Guide with their healthcare provider, which contains important safety information common to opioid analgesics. Pharmacists have product-specific Medication Guides to provide safe use information to patients. If patients are seeking additional information, they should be referred to their healthcare provider who prescribed the medication and/or their pharmacist. Patients can also visit the Opioid Analgesic REMS website at www.opioidanalgesicrems.com for a review of Frequently Asked Questions for Patients or the FDA's Opioid Medications website at: www.fda.gov/opioids. However, this should not take the place of speaking with their healthcare provider if they have a prescription for an opioid analgesic.

➤ How is the Patient Counseling Guide different from the product specific Medication Guides?

The Patient Counseling Guide reviews important safety information common to opioid analgesics and is provided by the healthcare provider to the patient at the time of prescribing the medication. Medication Guides are product-specific and include both common language regarding opioid risks and risks specific to the product. The Medication Guide is provided to the patient and/or their caregiver at the time the opioid analgesic is dispensed.

➤ Where should pharmacists report adverse events associated with opioid analgesics?

You are strongly encouraged to report all suspected adverse reactions associated with the use of the covered opioid analgesics by contacting either:

- 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 manufacturer that markets the specific product (Manufacturer contact information available on the Opioid Analgesic REMS website (<click [here](#) for a listing of products and manufacturer contact information>)

➤ What do healthcare providers and patients need to know about this REMS?

The central component of the Opioid Analgesic REMS is REMS-compliant accredited CE for healthcare providers who prescribe these products and other healthcare providers who provide care to patients and their caregivers including pharmacists. Dispensers and the other

 What do healthcare providers and patients need to know about this REMS?

The central component of the Opioid Analgesic REMS is REMS-compliant accredited CE for healthcare providers who prescribe these products and other healthcare providers who provide care to patients and their caregivers including pharmacists. Prescribers and the other healthcare providers are strongly encouraged to complete a REMS-compliant accredited CE activity from an accredited provider of CE. The REMS also includes an education component for patients, and/or their caregivers. The REMS includes a Patient Counseling Guide that healthcare providers who prescribe these drugs can review and provide to patients to help them understand safe use and their responsibilities associated with using these products. Additionally, product-specific Medication Guides are a component of the Opioid Analgesic REMS. Pharmacists in the outpatient and mail-order pharmacy setting are required to provide patients and/or their caregivers with the product-specific Medication Guide when dispensing an opioid analgesic. Medication Guides provide information in patient friendly language about the drug's risks and how to use the drug safely.

 Will our distributors and wholesalers of opioid analgesics be affected by the REMS?

No. Distributors and wholesalers of opioid analgesics will not need to do anything new or different due to this REMS.

 What if pharmacists are interested in reviewing REMS-compliant accredited CE? Can we also receive CE credit?

The FDA has directed that the Opioid Analgesic REMS education should be targeted towards prescribers, and other healthcare providers who care for patients and their caregivers (e.g., pharmacists and nurses).

The RPC recognizes that pharmacists are important members of the patient care team, and as such, supports broadly-accessible online REMS-compliant accredited educational activities. Details are posted on the RPC's listing of REMS-compliant accredited educational activities on the Opioid Analgesic REMS website at <https://search.opioidanalgesicrems.com>. Please check with your accrediting organization to find out about receiving CE credits.

[BACK TO TOP](#)

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Last Updated: March 24, 2021

9.5 Continuing Education & Grant



Medication GuidesU.S. Prescribing Information

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Frequently Asked Questions

GeneralPatientHealthcare ProviderPharmacistContinuing Education & Grant

Search

☒ Expand all

Where and how is REMS-compliant accredited CE offered?

Detailed information about REMS-compliant accredited CE activities, including the availability, location, and format, is available via the Opioid Analgesic REMS website at <https://search.opioidanalgesicrems.com>. A broad range of formats and venues for REMS-compliant accredited CE activities are being offered through the accredited CE Providers.

Is the education mandatory?

While completion of REMS-compliant accredited CE is not mandatory, healthcare providers are **STRONGLY** encouraged to successfully complete a REMS-compliant activity from an accredited provider of CE. Doing so may help to promote safe use of these drugs.

How many CE credits will a Healthcare Provider receive for completing the REMS education and how long will it take to complete?

The number of CE credits for any particular activity will be determined by the accredited CE Provider. The number of credits and the length of time to complete the activity depend on the scope of the educational activity.

How many CE credits will a Healthcare Provider receive for completing the REMS education and how long will it take to complete?

The number of CE credits for any particular activity will be determined by the accredited CE Provider. The number of credits and the length of time to complete the activity depend on the scope of the educational activity.

What education topics are covered in the FDA's Opioid Analgesic REMS 'Blueprint'?

The FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint") contains core messages for the safe use of these medications. Topics include:

Section 1: The Basics of Pain Management

- I. The Need for Comprehensive Pain Education
- II. Definitions and Mechanisms of Pain
- III. Assessing Patients in Pain

Section 2: Creating the Pain Treatment Plan

- I. Components of an Effective Treatment Plan
- II. General Principles of Nonpharmacologic Approaches
- III. General Principles of Pharmacologic Analgesic Therapy
 - A. Non-opioid analgesics and adjuvant medications
 - B. Opioid Analgesics
- IV. Managing Patients on Opioid Analgesics
 - A. Initiating Treatment with Opioids - acute pain
 - B. Initiating Treatment with Opioids - chronic pain
 - C. Ongoing management of patients on opioid analgesics
 - D. Long-term management
 - E. How to recognize and intervene upon suspicion or identification of an opioid use disorder (OUD)
 - F. When to consult a pain specialist
 - G. Medically directed opioid tapering
 - H. Importance of patient education

V. Attribution: Martina Primavera

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A. Non-opioid analgesics and adjuvant medications

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IV. Managing Patients on Opioid Analgesics

A. Initiating Treatment with Opioids - acute pain

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C. Ongoing management of patients on opioid analgesics

D. Long-term management

E. How to recognize and intervene upon suspicion or identification of an opioid use disorder (OUD)

F. When to consult a pain specialist

G. Medically directed opioid tapering

H. Importance of patient education

V. Addiction Medicine Primer

A link to the "FDA Blueprint" is available at: [FDA Blueprint](#)

Who is funding the REMS-compliant, independent, accredited CE?

REMS-compliant, independent, accredited CE is funded through educational grants by the opioid analgesic drug companies.

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REMS-compliant, independent, accredited CE is funded through educational grants by the opioid analgesic drug companies.

Will the independent, accredited, CE content be the same regardless of format?

Yes, all REMS-compliant accredited CE supported by the companies involved in this REMS must address all of the elements of the FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint").

Who can submit a grant application to support independent, accredited Opioid Analgesic REMS healthcare provider education?

Any accredited CE Provider may apply by submitting a grant application that complies with the FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint") and the educational standards in the Request for Application (RFA) located on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com. The accredited CE Provider may choose to collaborate with Educational Planner(s) to assist in the development and/or execution of an educational activity. All information related to the grant application process can be accessed at www.opioidanalgesicrems.com.

If I am an accredited CE Provider, what is the process for applying for grant monies?

All information related to the grant application process can be accessed at the Opioid Analgesic REMS website at www.opioidanalgesicrems.com.

Is there a limit on the amount of funding for each grant request?

There will be a finite pool of resources available each year. Pages 8-9 of the 2018 Request for Application (RFA) contain additional information about the budget.

Are the FDA and the REMS Program Companies (RPC) interested in being informed about non-RPC supported accredited REMS compliant activities? If so, what is the process for a CE Provider who is interested in sharing information on a non-RPC supported REMS-compliant activity with the FDA and RPC?

Yes, the FDA and the RPC are interested in being informed about all non-RPC supported REMS-compliant accredited activities. Information is available at www.opioidanalgesicrems.com on how to submit information to the REMS Program Companies (RPC).

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Yes, the FDA and the RPC are interested in being informed about all non-RPC supported REMS-compliant accredited activities. Information is available at www.opioidanalgesicrems.com on how to submit information to the REMS Program Companies (RPC).

- How do I become an accredited CE Provider so that I can provide Opioid Analgesic REMS education?

Go to the specific Accreditor's website for detailed information on the accreditation process. An alternative for participating in the provision of Opioid Analgesic REMS education may be to partner with an accredited CE Provider.

- Which healthcare provider specialties should be included in the REMS-compliant accredited CE?

The accredited CE activities focus on the safe prescribing of opioid analgesics and consist of core content as defined in the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint"). While the primary target of this content is prescribers of opioid analgesics and healthcare providers who provide care to patients and their caregivers as specified by the FDA, the content may also be relevant for other healthcare providers (e.g., veterinarians or emergency medical technicians). The accredited CE Provider determines the target audience based on needs assessment they conduct.

- What qualifies as an equivalent accrediting body?

For purposes of qualification to request or receive an educational grant from the RPC, a provider must demonstrate that their enterprise is accredited by an organization recognized by the professional group for which credits are issued, that the accrediting body has standards they impartially employ to approve providers, and that the credits granted are accepted by appropriate licensing bodies for those professionals to recertify or maintain license. The accrediting body must agree to provide reports of its activities to the third-party database aggregator in the format defined by the Association of American Medical Colleges (formerly known as MedBiquitous) for periodic reporting to the FDA.

- What is the status of the MedBiquitous standards that are designed to support the reporting of REMS CE data?

Please reference the related MedBiquitous Specifications for a full list of REMS-related definitions, developed by the MedBiquitous Metrics Working Group, which has been updated as of January 28, 2019, and can be downloaded by registering or logging in to the following link: https://medbq.org/download_standards_and_guidelines#Activity_Report.

Additional resources on activity reporting implementation guidelines and standards can be found via: https://medbq.org/activity_report or https://medbq.org/sites/default/files/files/REMS_ImplementationGuidelines_2019_05_21.pdf, which are now managed by the Association of

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- When will the REMS be ready to accept grant applications?

The Grant Management System (GMS) will be updated periodically as new information is available from the FDA. The GMS can be accessed via the Opioid Analgesic REMS website: Go to www.opioidanalgesicrems.com, and click "If you are an accredited Continuing Education Provider" link at the bottom of the right column.

- Who is responsible for verifying the percentage of healthcare providers who complete the accredited CE?

Accredited CE Providers will report information on the number of participants to their respective Accrediting Body.

- How will the REMS Program Companies (RPC) prove to the FDA the number of healthcare providers who completed the education?

Accredited CE Providers will report information on the number of participants to their respective Accrediting Body.

- Is RPC-supported continuing education (CE) funding available for military installations?

Yes, organizations meeting RPC eligibility requirements who provide accredited CE to HCP's serving any branch of the US Armed Forces can apply for grant support for educational programming relevant to the Opioid Analgesic REMS.

- May CE RFA response submissions be submitted by an accredited CE Provider as long as the submitter has, as a joint sponsor or subcontracted partner, an organization that is engaged in or represents healthcare providers who provide direct patient care?

An accredited CE Provider may partner/sponsor with an organization that is engaged in/represents healthcare providers who provide direct patient care.

However, the grant request application must be submitted by the organization that is engaged in/represents healthcare providers who

- May CE RFA response submissions be submitted by an accredited CE Provider as long as the submitter has, as a joint sponsor or subcontracted partner, an organization that is engaged in or represents healthcare providers who provide direct patient care?

An accredited CE Provider may partner/sponsor with an organization that is engaged in/represents healthcare providers who provide direct patient care.

However, the grant request application must be submitted by the organization that is engaged in/represents healthcare providers who provide direct patient care.
- Are there any exclusions from participation in and receipt of a certificate of completion for any CE program supported under this initiative for healthcare providers who are federal healthcare personnel?

There are no exclusions from participation by federal healthcare personnel. Certificates of completion may be provided upon request to the accredited provider of education.
- Is it acceptable to have an associate from Canada as part of an application since the application process states that only providers from the US and its possessions may apply?

The RPC eligibility requirements apply only to the primary accredited CE Provider submitting the application.

The eligible accredited CE Provider who submits the application selects partner(s) at its own discretion.
- Are there time requirements for the REMS-compliant accredited CE? That is, may education last more than 3 hours?

The duration of REMS-compliant accredited CE is at the discretion of the CE Provider; hence, there are no specific time limits on the education. The only requirement is that the education must address all elements of the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint").
- Is there a limit on the number of pages associated with the CE Grant Proposal? Are there certain requirements for the proposal as to font, layout, etc.?

Grant requests/proposals should include any information required to succinctly and sufficiently convey all elements of the grant proposal. The Grant Management System specifications require that attachment files must be less than 10MB each; it is also recommended that grant proposals be formatted for printing on 8.5"x11" paper.
- Is there a points system of any kind for approving grants?

While all RPC-supported accredited CE must be REMS-compliant, and will be evaluated based on all criteria outlined in the CE RFA that

- Is there a points system of any kind for approving grants?

While all RPC-supported accredited CE must be REMS-compliant, and will be evaluated based on all criteria outlined in the CE RFA that was published for a given CE Grant Cycle, there are several criteria that are particularly important for CE Providers to consider.

Essential Elements

 - Compliance with accredited CE Provider eligibility requirements
 - Alignment – clear "mapping" of proposed activity to the updated [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint") components

Elements of High Importance

 - Needs assessment specific to audiences proposed by the accredited CE Provider
 - Number of healthcare providers expected to complete activity/activities covering full updated "FDA Blueprint" plus completion of post-activity assessment
 - Qualifications of accredited CE Provider and partners
 - Educational design/methods (may include one or more)

Additionally, accredited CE Providers must agree to uniform data submission procedure in accordance with current MedBiquitous Specifications.

Please reference the related MedBiquitous Specifications for a full list of REMS-related definitions developed by the MedBiquitous Metrics Working Group, which has been updated as of January 28, 2019, and can be downloaded by registering or logging in to the following link: https://medbiq.org/download_standards_and_guidelines#Activity_Report.

Additional resources on activity reporting implementation guidelines and standards can be found via: https://medbiq.org/activity_report or https://medbiq.org/sites/default/files/files/REMS_ImplementationGuidelines_2019_05_21.pdf, which are now managed by the Association of American Medical Colleges.
- May the FDA Blueprint Elements be covered over multiple CE segments rather than in one CE activity?

Yes. While the entire content of the [FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) ("FDA Blueprint") must be addressed by the REMS-compliant accredited CE, Providers are encouraged to design CE programs that align with optimal adult learning principles and practices.
- How much grant money is available?

How much grant money is available?

Total grant funding available will not be disclosed.

Are CE Providers allowed to print the Patient Counseling Guide and/or the FDA Blueprint for use in education materials?

Yes, the FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint") and Patient Counseling Guide are available for educational use by healthcare providers who are involved in the dispensing of opioid analgesics. These documents are available on the Opioid Analgesic REMS website at www.opioidanalgesicrems.com.

How can I get updates regarding the REMS-compliant accredited CE?

The best way to stay updated on the REMS-compliant accredited CE activities is through the Continuing Education page on the Opioid Analgesic REMS website www.opioidanalgesicrems.com.

Is a CE Provider able to provide REMS education to healthcare providers without applying for a grant?

A CE Provider is free to develop and offer education on this topic as well as others and does not need a grant from the RPC to do so. In order for the accredited CE to be REMS-compliant, education should contain all of the core content as defined in the FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint"), be provided by an accredited CE Provider, and may be subject to an audit.

Are there particular applications that should be used to meet the qualifications for reporting of RPC-funded accredited CE activities? What about for non-RPC funded activities?

Accredited CE Providers receiving RPC grants under this REMS are required to report data utilizing the MedBiquitous Specifications. It is not within the RPC's purview to advise on particular systems. For non-RPC supported CE, accredited Providers are encouraged to utilize the MedBiquitous Specifications to allow the data to be collected, aggregated and reported (Please also reference CE FAQ #14, as appropriate).

When will the revised MedBiquitous standard, which will enable the exchange of Opioid Analgesic REMS accredited CE outcomes data, be completed?

Please reference the related MedBiquitous Specifications for a full list of REMS-related definitions developed by the MedBiquitous Metrics Working Group, which has been updated as of January 28, 2019, and can be downloaded by registering or logging in to the following link: https://medbq.org/download_standards_and_guidelines#Activity_Report.

Accredited CE Providers receiving RPC grants under this REMS are required to report data utilizing the MedBiquitous Specifications. It is not within the RPC's purview to advise on particular systems. For non-RPC supported CE, accredited Providers are encouraged to utilize the MedBiquitous Specifications to allow the data to be collected, aggregated and reported (Please also reference CE FAQ #14, as appropriate).

When will the revised MedBiquitous standard, which will enable the exchange of Opioid Analgesic REMS accredited CE outcomes data, be completed?

Please reference the related MedBiquitous Specifications for a full list of REMS-related definitions developed by the MedBiquitous Metrics Working Group, which has been updated as of January 28, 2019, and can be downloaded by registering or logging in to the following link: https://medbq.org/download_standards_and_guidelines#Activity_Report.

Additional resources on activity reporting Implementation guidelines and standards can be found via: https://medbq.org/activity_report or https://medbq.org/sites/default/files/files/REMS_ImplementationGuidelines_2019_05_21.pdf, which are now managed by the Association of American Medical Colleges.

I represent a Medical Education Communication Company (MECC) and wish to be involved with REMS-compliant accredited CE grants. What are the ways I can do this?

Medical Education Communication Companies (MECCs) are encouraged to partner with an eligible accredited CE Provider, organization, or group of CE Providers/organizations and contribute to the REMS education through active collaboration. The RPC appreciates all interest in REMS-compliant accredited CE. We recognize that all CE Providers have a valuable contribution to make to this patient safety/public health initiative.

[BACK TO TOP](#)

10 GMS Landing Page



[Help](#) [FAQ](#) [Privacy Policy](#)

[Forgot your password?](#)

Grant Management System (GMS)

Welcome to the Opioid Analgesic REMS GMS homepage provided by the Opioid Analgesic REMS Program Companies (RPC).

Grant submissions for Request for Application (RFA) 110121 are no longer being accepted.



Important Information for CE providers:

CE providers should reference the approved FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain, and are encouraged to reference the MedBiquitous website periodically for updates to the REMS definitions. To learn more about the Opioid Analgesic REMS, please click here. For additional questions regarding grant applications, please reach out to the Grant Coordinator at grants@opioidanalgesicrems.com.

The RPC has adopted a policy under which any member or observer company personnel, outside panel members, experts, or other third parties designed to participate in its REMS-compliant accredited continuing education grant application review process are requested to disclose any potential "conflicts of interest" (as defined by the RPC) relating to applicants seeking RPC-funded grants and/or applicant-identified education partners. In the event that such a potential conflict of interest is disclosed, the disclosing individual shall refrain from participating in the review of the grant application that is the subject of the potential conflict of interest is disclosed.

Thank you,
The RPC

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[Cookies](#)

11 CE Activity Search Page



CE ACTIVITY SEARCH

[OPIOIDANALGESICREMS.COM](https://opioidanalgesicrems.com)

CONTINUING EDUCATION ACTIVITY SEARCH

Use the filters below to search the activities.

ACTIVITY TYPE ▼

CREDIT TYPE ▼

CE PROVIDER ▼

STATE ▼

START DATE ▼

END DATE ▼

SEARCHING FOR...



SEARCH

CLEAR

04/12/2019 - 03/31/2021



**Get SMART - Safe Means
of Administering the Right
Therapy Module 1**

Web

04/12/2019 - 03/31/2021



**Get SMART - Safe Means
of Administering the Right
Therapy Module 2**

Web

04/12/2019 - 03/31/2021



**Get SMART - Safe Means
of Administering the Right
Therapy Module 3**

Web

12 Contact Page



REMS Opioid Analgesic Education
risk education and
prescription monitoring
FDA REMS-Compliant
CE for Opioid Analgesics

[Help](#) [FAQ](#) [Privacy Policy](#)

Forgot your password?

Sign In

Grant Management System (CMS)

Contact

Welcome to the Opioid Analgesic REMS

Grant submissions for Request for Application

Important Information for CE providers:

CE providers should reference the appropriate updates to the REMS definitions. To learn more, click here.

The RPC has adopted a policy under which no individual shall be requested to disclose any potential "conflict of interest" information unless the individual is requested to refrain from participating in the grant application review process. If a conflict of interest is disclosed, the disclosing individual shall refrain from participating in the grant application review process.

Thank you,
The RPC

Copyright 2018

For any inquiries regarding the Opioid Analgesic REMS Program Companies (RPC) Grant Management System (GMS) or funding requests, please feel free to contact the Grant Coordinator at grants@opioidanalgesicrems.com

MedBiquitous website periodically for updates to the REMS definitions. To learn more, click here.

on grant application review process are of interest is disclosed, the disclosing individual shall refrain from participating in the grant application review process.

13 Help Page

The screenshot shows the login page for the Opioid Analgesic REMS Grant Management System (GMS). At the top left is the REMS logo with the text "Opioid Analgesic Education" and "FDA REMS-Compliant CE for Opioid Analgesics". Navigation links for "Help", "FAQ", and "Privacy Policy" are at the top right. Below these are input fields for a username (containing "mbender") and a password (masked with asterisks), a "Forgot your password?" link, and a "Sign In" button. A "Guest Help" popup window is open, displaying the following content:

Welcome
The Login Screen is your entry point for the **Opioid Analgesic REMS GMS**. Enter your Email and Password and then click "Log In" button. Your email address will be your username.

Registration
If you are a new user of the system, click "Register", review the Compliance Commitment, click the acknowledgment box, then click "Submit." If you do not agree with the Compliance Commitment, you will not be able to register with the Grants Management System.

By clicking "Submit", you will be directed to the Profile Registration page where you can enter your contact information and choose your email and password.

For fields where the question mark icon (?) appears, place your cursor over the icon for information regarding that field.

Organization Legal Name - Enter your organization's legal name. Do not use abbreviations or acronyms.

Valid characters:

1. Upper and lower case alphabetic characters
2. All numeric characters (0 through 9)
3. Comma(,), Period (.), Apostrophe ('), Ampersand (&), Space, Hyphen (-), Colon(:)

Tax ID - For organizations / institutions in the US, enter your Federal Employer Identification Number (FEIN), assigned by the Internal Revenue Service.

Organization Tax Status - Choose the appropriate Federal tax status of your organization from the dropdown menu.

Password

1. 8-12 characters

The background of the page features a blue-tinted image of laboratory glassware. On the right side, there is a vertical text block: "MedBiquitous website periodically for esicrems.com" and "on grant application review process are of interest is disclosed, the disclosing". The bottom left corner of the page has a "Copyright 20" notice.

13.1 Bottom of Help Page

This screenshot shows the bottom portion of the same login page. The "Guest Help" popup window is open, displaying the following content:

with the Compliance Commitment, you will not be able to register with the Grants Management System.

By clicking "Submit", you will be directed to the Profile Registration page where you can enter your contact information and choose your email and password.

For fields where the question mark icon (?) appears, place your cursor over the icon for information regarding that field.

Organization Legal Name - Enter your organization's legal name. Do not use abbreviations or acronyms.

Valid characters:

1. Upper and lower case alphabetic characters
2. All numeric characters (0 through 9)
3. Comma(,), Period (.), Apostrophe ('), Ampersand (&), Space, Hyphen (-), Colon(:)

Tax ID - For organizations / institutions in the US, enter your Federal Employer Identification Number (FEIN), assigned by the Internal Revenue Service.

Organization Tax Status - Choose the appropriate Federal tax status of your organization from the dropdown menu.

Password

1. 8-12 characters
2. Must Contain any three of the Complexities (Upper Case / Lower Case / Numerals / Special Characters)

Once all the information has been completed, click "Submit." If your registration is accepted, you will be taken to a confirmation page. If your registration is not accepted, you will be directed to contact RPC.

Once on the confirmation page, click "Continue" to be directed to your Grant Management System Home Page.

The background and side text are identical to the previous screenshot. The "Copyright 20" notice is visible at the bottom left.

14 FAQs Page

The screenshot displays the REMS Opioid Analgesic Education website. At the top left is the REMS logo with the text "risk evaluation and mitigation strategy" and "FDA 2010-Compliant CE for Opioid Analgesics". To the right are links for "Help", "FAQ", and "Privacy Policy". Below these is a login section with a username field containing "mbender", a password field with masked characters, a "Forgot your password?" link, and a "Sign In" button.

The main content area is titled "Grant Management System (GMS)" and includes a "Guest FAQ" pop-up window. The pop-up window has a close button (X) in the top right corner. The text inside the pop-up is as follows:

Information about our on-line application process

This page may help to answer some of the questions you have regarding the Grant Management System (GMS) application process. First, please ensure that you have read the Grant Request Instructions page included at the beginning of the application form instructions page. If you have additional questions or would like to know more about how the process works, we encourage you to browse through the following Frequently Asked Questions (FAQs).

How can I obtain additional information about the REMS program?

Please visit the Opioid Analgesic REMS website (www.opioidanalgesicrems.com) for more details. The website also contains a FAQs page which provides answers to common questions about the REMS program.

FDA Blueprint Mapping Document

Click [here](#) to download.

Technical

- [What if I cannot remember my Username or Password?](#)
- [Why was I prevented from registering?](#)
- [Why was I unable to login?](#)
- [What if I do not receive e-mail notifications?](#)

Funding Application

At the bottom of the page, there is a "Copyright 20" notice.

Please see the REMS GMS FAQ – 2021 PDF document for the full FAQ

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FDA Blueprint Mapping Document

Click [here](#) to download.

Technical

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Funding Application

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[What is a Request for Additional Information and how much time do I have for completion?](#)

[Can I complete part of the online request and come back to it later?](#)

[How do I save an application once I have started it?](#)

[I saved an application but I have decided to start a new one. Is this a problem?](#)

[Should I telephone to verify that my request has been received?](#)

[Do the Opioid Analgesic REMS Companies accept requests by mail, fax or telephone?](#)

[When will I hear if our request has been approved?](#)

[I made a mistake in my submission. Can I correct the information in my application?](#)

Funding Request - After the Decision

[What is the Final Update Report?](#)

Miscellaneous

[Can I request funding for an activity that has already occurred?](#)

[Does previous support of my activity by RPC guarantee future support?](#)

[Will the information I provide be kept private?](#)

[I prefer the personal touch. Why can't I explain my proposal in person?](#)

[Our organization doesn't have a computer. Can we make a funding request?](#)

[I'm not comfortable with computers. How can I make use of the Grant Management System?](#)

[As a CE stakeholder involved in the FDA REMS development process, I already have worked with RPC.](#)

[Can I contact them directly about my request?](#)

[This on-line grant submission process takes some time to complete. Is it worth the effort?](#)

[Our organization does not have an e-mail address. The application form will not let me proceed without entering one. What do I do?](#)

Technical

What if I cannot remember my Username or Password?

You may request to have your Username or Password emailed to your registered email address by clicking on the “Forgot your username?” And “Forgot your password?” links provided on the login page.

Why was I prevented from registering?

Common reasons include:

1. Some of the information entered as part of your registration was not valid – please see the error message and re-enter corrected information.
2. You entered an email address during your registration that has already been registered with the Grant Management System. Please choose a different email address.
3. If you have registered previously, please click on reset password to receive a temporary password.
4. If you have not registered previously, please contact the Grant Coordinator at grants@opioidealgesicrems.com.

Why was I unable to login?

Common reasons include:

1. Your account may have been disabled due to inactivity. Please contact the Grant Coordinator by email at grants@opioidealgesicrems.com and request that your account be reactivated.
2. Your account has been temporarily disabled due to five repeated unsuccessful attempts to log in. Please contact the Grant Coordinator at grants@opioidealgesicrems.com to reactivate your account.

What if I do not receive e-mail notifications?

In Microsoft Outlook, please perform the following actions:

1. Check SPAM and/or Junk e-mail folders – once located, right-click on the e-mail and select the option under “Junk E-mail” to “Add Sender’s Domain to Safe Senders list”.
2. Alternatively, you can also manually add grants@opioidealgesicrems.com to the safe senders list by taking these steps:
 1. Click on Actions, then locate the “Junk E-mail Options”
 2. Click on the tab for “Safe Senders”
 3. Click “Add”, type in grants@opioidealgesicrems.com, and click “OK”

Application pages are taking a long time to load and appear on my screen very slowly.

Depending on the connection speed of your computer, some pages may take a minute or two to load as the information you have submitted is being processed. This is normal. If you would like pages to load faster, try submitting from a computer with a faster wireless connection speed or turn off your wireless adapter and plug your computer into the internet via an Ethernet cable - you can still enter the same e-mail address, to which we will send confirmation and update emails. While pages are processing, please do not click the Back button on your web browser, as it may cause information to be submitted twice.

The application form will not load.

The browser you are using may not be supported by this application. Valid browsers are Internet Explorer 11 - Chrome 66 - Firefox 60 - Safari Mac 11.1 - Safari iPad 11.3.

I can't move from one question to the next question.

Use the **Tab** key to move from question to question, or simply point and click on the next question with your mouse.

Please Note: The **Enter** key will NOT move you from question to question, but can be used to go to the next page or to submit the request.

I can't move onto the next page. I get a warning message and am returned to the current page.

To move from page to page, use the **Save & Continue** button at the bottom of the current page. The application form won't let you move to the next page until all required questions have been answered appropriately and completely. An error message will be displayed on top of the page if required fields are missing or incomplete.

I am having trouble returning to a previous page.

To navigate forwards and backwards through the application form you must use the **Save & Back** and **Save & Continue** buttons located at the bottom of the application form. Please do not use the browser buttons to navigate through the application.

When I enter a telephone number, I get an error message.

Telephone numbers must include the area code and be entered in the following format: 444-555-6666. The application form will only accept telephone numbers entered in this format.

I submitted an application, but have received no confirmation of receipt.

You should receive an e-mail notification within 15 minutes of submitting an application, but it can sometimes take longer. Ensure that you entered your entire e-mail address correctly on the application. (Check the copy you printed for your records to make sure.) If you entered the e-mail address correctly, contact your Information Technology (IT) department or your Internet Service Provider (ISP) (e.g., AOL, Sympatico, Rogers, etc.), as your internet may temporarily be out-of-service. If you entered an incorrect e-mail address, please contact the Grant Coordinator at grants@opioidanalgesicrems.com.

I am having difficulty printing the completed application form for my records.

Do not try to print individual pages. After you complete all pages of the application form, you will come to a summary page, which shows your fully completed form. Print this page using the print function of your web browser for your records.

After I submit the completed form, I receive an "Error Saving Information" message.

The connection to your Internet Service Provider (ISP) may have been interrupted or there may have been too long of a delay between when you began the application form and when you tried to submit it. If you have read through the guidelines and collected the information required to fill out the form, it should take approximately 30 minutes to complete. If for some reason, you cannot complete the application form once you have started it, don't worry. Simply click on the **Save** button at the bottom of the page. You can begin again where you had left off, and submit the completed form another time.

Funding Application**What if my descriptions, agenda, and budget etc. do not fit into the allotted space?**

You will have the opportunity to upload supporting documentation at the end of the Request Form. Please use this function to upload lengthier documents. Note there is a document upload size limit of 10 MBs.

What is a Request for Additional Information (RAI) and how much time do I have for completion?

An RAI is made when more information is needed to consider your grant request. You will receive an email containing the items that are required or items requiring clarification. You will then have to access your grant request in order to provide the necessary information. If your response to the RAI has not been received after seven days, you will receive a reminder email from the GMS. If your response to the RAI has not been received within 14 days, the Grant Coordinator will attempt to contact you via telephone. If your response to the RAI has not been received within 21 days, your grant request will be cancelled.

Can I complete part of the online request and come back to it later?

Yes, if you are unable to complete your request in one sitting, you may save the grant request and come back to it later by clicking **Save** at the bottom of the page. At any time before the submission of a grant request, you will have the opportunity to come back and make changes to the request.

How do I save an application once I have started it?

You may save work by clicking **Save** at the bottom of the page. Also, when you move from one page to the next using **Save & Continue**, all information entered to that point will be saved. If you leave the application form without clicking on one of these buttons or if your computer or browser malfunctions, some information may be lost.

I saved an application but I have decided to start a new one. Is this a problem?

No, simply click on "**Submit new request**" from your GMS homepage.

Should I telephone to verify that my request has been received?

No, upon submission of your on-line application, you will receive an e-mail notification confirming receipt. Please rest assured we review every grant request submitted through our GMS. Due to the large numbers of requests that we receive, we are unable to confirm receipt of individual requests by telephone. You may also log into the GMS, where the **Requestor Home page** will be displayed. This is also called the "**My Funding Requests**" page. In this section you will find detailed information about each of your grant requests. The status column will provide a brief description of where your grant request is in the review process, and the actions column will inform you if an action is required to complete your grant request. To view a specific request, click on the appropriate Program Title.

Do the Opioid Analgesic REMS Companies GMS requests by mail, fax or telephone?

No, grant requests are only permitted through our GMS. We are unable to accept or respond to requests sent by mail, fax, or telephone. There are many reasons why we have chosen to employ an on-line GMS, including having a centralized grant request database, proper and timely processing of all grant requests, greater compliance with regulations and enabling accurate financial monitoring and reporting.

When will I hear if our request has been approved?

When you submit a grant request, you will receive an e-mail notification confirming successful submission. We strive to evaluate proposals in a timely manner. Please remember that due to the large volumes of requests, we are unable to respond to any inquiries regarding the status of individual requests. You may also log into the GMS, where the **Requestor Home page** will be displayed. This is also called the "**My Funding Requests**" page. In this section you will find detailed information about each of your grant requests. The status column will provide a brief description of where your grant request is in the review process, and the actions column will inform you if an action is required to complete your grant request. To view a specific request, click on the appropriate **Program Title**.

I made a mistake in my submission. Can I correct the information in my application?

No, once you have submitted a grant request application, the information within it cannot be changed. We recommend that you contact the Grant Coordinator by email at grants@opioidanalgesicrems.com and request that your application be canceled. You can then submit your corrected grant request.

Funding Request - After the Decision

What is the Final Update Report?

At the conclusion of the funded activity/initiative, RPC-supported CE providers will be required to submit program details and materials, financial documentation, and evaluation and educational outcomes to verify the funding was used as intended and to show effectiveness of the programming. You will receive an email notification when the Final Update Report is available (after the second to last milestone payment). Upon submission of the report, if the RPC deems that the information provided is sufficient and satisfactory, the final payment of your request will be released. The final payment will not be released until the Final Update Report has been completed in its entirety.

Miscellaneous

Can I request funding for an activity that has already occurred?

No, grant support may not be considered for activities that have already occurred. Grant requests must be successfully submitted at least 90 days prior to the date of the first activity.

Does previous support of my activity by RPC guarantee future support?

No, each grant request submitted will be evaluated based on its individual merit. No grant request should be considered approved until you receive written confirmation from the GMS.

Will the information I provide be kept private?

Yes, subject to our Transparency Policy where we may be required to publish the Payee/Requestor's name, the date of grant support, the activity/initiative being supported, and the amount of grant support, the information you provide will only be accessed by the **Opioid Analgesic REMS Program Companies** and organizations authorized to have access to the information you provide to us. The database where the information is kept is password protected. With respect to the protection of personal information, please refer to the Privacy Policy.

I prefer the personal touch. Why can't I explain my proposal in person?

By requiring that all requests be submitted through our on-line GMS, we ensure that every proposal is assessed on its merits, and that there can be no real or perceived influence on the educational activity being proposed.

As a CE stakeholder involved in the FDA REMS development process, I already have worked with RPC. Can I contact them directly about my request? No, the GMS must be utilized for all grant requests, so that a request can be properly, fairly and consistently handled, and assessed on its merits, with no real or perceived influence of the Requestor.

This on-line grant submission process takes some time to complete. Is it worth the effort?

Most well-prepared applicants successfully complete the on-line grant request submission process in 30 minutes or less. While we are unable to provide details with regard to the support decision-making process,

there is grant funding available for qualified grant requests. You must make the decision whether or not to submit.

If you have read the FAQs above but still have a question about our GMS, or if you would like to provide us with feedback, please send us an email outlining your questions and/or comments at grants@opioidalgesicrems.com. Explain the situation as clearly as possible so we can respond with appropriate assistance. Our technical support staff will contact you in a timely manner.

IMPORTANT: Due to the volume of requests we receive, we are unable to accept telephone, e-mail or faxed inquiries regarding the status of specific requests.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

RIGOBERTO A ROCA
10/15/2021 02:22:39 PM