

The Opioid Analgesic REMS Program Companies



PO Box 1730 • West Caldwell, NJ 07007

Dear Professional Society/Licensing Board Letter #1

December 2024

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 addiction, abuse, and misuse, which can lead to overdose and death.

Dear Professional Society/Licensing Board:

The purpose of this letter is to inform you about an important upcoming change to the Opioid Analgesic REMS that is required by the U.S. Food and Drug Administration (FDA) for opioid analgesic drug products¹ used in the outpatient setting.

By March 31, 2025 the Opioid Analgesic REMS Program Companies will be required to provide pre-paid drug mail-back envelopes upon request to pharmacies and other dispensers that dispense opioid analgesics for outpatient use.

Encouraging HCPs to counsel patients on the options for safe disposal of unused opioid analgesics is an important component of the Opioid Analgesic REMS to avoid nonmedical use, opioid use disorder (OUD), and overdose. In addition to pre-paid drug mail-back envelopes, other disposal options include drug take-back sites or programs. If these options are not available, the next best option is for patients to immediately flush their opioid analgesics down the toilet. More information on safe disposal methods is available at: www.fda.gov/safe-disposal-medicines.

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.

The Opioid Analgesic REIMS Program Companies

PDR

PO Box 1730 • West Caldwell, NJ 07007

**OPIOID ANALGESICS:
FDA-REQUIRED REIMS
FOR SERIOUS
DRUG RISKS**

Presorted
First-Class Mail
U.S. Postage
PAID
PDR
Distribution, LLC

RECEIVED
JAN 14 2025

W.VA. BOARD OF
PRACTICAL NURSES

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, abuse, and misuse, which can lead to overdose.
- **Too much opioid medicine in your body can cause your breathing to stop – which could lead to death.** This risk is greater if you are 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.

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.

How should I dispose of the opioid medicine?

When you no longer need your opioid medicine, dispose of it as quickly as possible to avoid any possibility of abuse or misuse by anyone else. The Food and Drug Administration recommends that you drop off your medicine at a drug take-back site or program or mail your medicine using a pre-paid drug mail-back envelope. If you cannot get to a drug take-back location or if a mail-back envelope is not available to you, your next best option is to immediately flush your medicine down the toilet.

Find more information about disposal methods here: <https://www.fda.gov/drugdisposal>

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.

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.