

Introduction

FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain March 2026

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. In September 2018, the ER/LA REMS was modified to the *Opioid Analgesic REMS*, which includes, in addition to ER/LA opioid analgesics, all immediate-release (IR) opioid analgesics used in the outpatient setting that are not already covered by another REMS program.

The Prescribing Information (PI) for opioid analgesics (OA) contains a boxed warning that includes the risks of addiction, abuse, and misuse, which can lead to overdose and death. The goal of the Opioid Analgesic REMS is to mitigate these risks. The Opioid Analgesic REMS is one of many national, state, and local efforts to address the risks of prescription opioid analgesics.

FDA approved labeling for OA products define misuse, abuse, and addiction in the following ways:

- Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed.
- Abuse is the intentional non-therapeutic use of a prescription drug, even once, for its rewarding psychological or physiological effects.
- Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than to other activities and obligations), and possible tolerance or physical dependence.

FDA recognizes that certain language can be perceived negatively, which in turn can perpetuate stigma and negative bias toward individuals with substance use disorders and create barriers to effective treatment. For example, the term “abuse” has been identified as having a strong association with negative judgments and punishment. FDA is committed to reducing stigma, expanding therapeutic options, and ensuring access to evidence-based treatment for individuals with substance use disorders. Therefore, in this blueprint, the Agency uses the term “**nonmedical use**” to refer to use of a medication in a way other than as directed by a health care provider, including both misuse and abuse, as defined above. This blueprint has also been updated in places to use the medical terms “substance use disorder” and “opioid use disorder” rather than “addiction.”

The Introduction section of this document and the attached FDA Blueprint is revised to include information on safe disposal options, update terminology, and provide updated statistics on the public health crisis involving opioid use disorder and overdoses.

As part of the Opioid Analgesic REMS, all opioid analgesic manufacturers must make available the following:

- Training for health care providers (HCPs) who prescribe and/or participate in the treatment and monitoring of patients who receive opioid analgesics.
 - 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.
- Safe disposal options to dispose of unused opioid analgesics

The FDA Blueprint contains a high-level outline of the core 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 and disposal 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 developed based on the FDA Blueprint 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 this FDA Blueprint for 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.

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.

Reasons Why HCP Education Is So Important

Adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing and nonmedical use of opioid analgesics continue to contribute to the public health crisis involving opioids. Although the crisis has evolved to involve primarily illicitly manufactured synthetic opioids, it is critical that HCPs are knowledgeable about the risks associated with opioid analgesics, as data continue to show problems associated with these medications.

- In 2024, 79,384 Americans died from drug poisonings, and of these, 7,989 deaths, or approximately 10.1%, involved opioid analgesics (natural and semisynthetic opioids), while 47,735 deaths, or approximately 60.1%, involved synthetic opioids other than methadone,³ primarily illicitly manufactured fentanyl and related analogs. Many prescription opioid-involved overdose deaths additionally involved these illicitly manufactured synthetic opioids.⁴
- Based on the 2024 National Survey on Drug Use and Health (NSDUH), an estimated 2.6% of Americans aged 12 or older (7.6 million people) used a prescription opioid in the past year nonmedically— with hydrocodone, oxycodone, and codeine products most commonly reported (used nonmedically by 45.2%, 28.6%, and 26.4%, respectively, of those reporting any prescription opioid nonmedical use).⁵
- In 2024, the most commonly reported sources of prescription pain relievers (opioids or nonopioids) used nonmedically were a friend or relative (42.3%), followed by a prescription from one or more doctors (42.5%).⁶

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 overdoses, many still involving prescription opioid analgesics, often in combination with other substances. An analysis of 2019-2021 National Health Interview Survey (NHIS) data found that in 2021, an estimated 20.9% or 51.6 million adults in the United States experienced chronic pain, and 6.9% or 17.1

³ Garnett, M & Miniño, AM. Drug overdose deaths in the United States, 2023–2024. National Center for Health Statistics Data Brief, no 549. Hyattsville, MD: National Center for Health Statistics. 2026.

⁴ <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>

⁵ Substance Abuse and Mental Health Services Administration (2025). Key substance use and mental health indicators in the United States: Results from the 2024 National Survey on Drug Use and Health (HHS Publication No. PEP25-07-007, NSDUH Series H-60). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Available at: <https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health/national-releases/2024#annual-national-report>.

⁶ Ibid.

million adults in the United States experienced chronic pain that resulted in substantial restrictions to daily activities.⁷

The increasing availability of prescription opioids beginning in the 1990s was accompanied by an alarming increase in fatal overdoses involving prescription opioids. Since then, there have been numerous federal, state, and local/institutional efforts to reverse this trend by reducing unnecessary opioid analgesic prescribing.⁸ The consequences of untreated or undertreated pain can also be devastating, however, including reduced quality of life, impaired physical and psychological distress, and high economic costs. It is critically important, therefore, that HCPs have all the information they need to properly treat their patients and safely manage their patients' 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.⁹

Even at prescribed doses, opioid analgesics carry the risk of nonmedical use, OUD, overdose, and death. These risks can occur at any dosage or duration and persist over the course of therapy. Therefore, 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 ineffective, not tolerated or would be otherwise inadequate to provide sufficient management of pain and when the benefits of the opioids are expected to outweigh the risks. This information can aid HCPs in identifying and intervening when encountering obstacles that may reduce access to nonpharmacological and non-opioid medication options. Fully informed HCPs can also help contribute to national efforts to reduce nonmedical use of opioids and address the ongoing public health crisis involving opioid use disorder and overdoses.

⁷ Rikard SM, Strahan AE, Schmit KM, Guy GP Jr.. Chronic Pain Among Adults — United States, 2019–2021. *MMWR Morb Mortal Wkly Rep* 2023;72:379–385. DOI: <http://dx.doi.org/10.15585/mmwr.mm7215a1>

⁸ Seitz AE, Janiszewski KA, Guy GP Jr, Tapscott RT, Einstein EB, Meyer TE, Tierney J, Staffa J, Jones CM, Compton WM. Evaluating opioid analgesic prescribing limits: A narrative review. *Pharmacoepidemiol Drug Saf*. 2022 Jun;31(6):605-613. doi: 10.1002/pds.5425. Epub 2022 Mar 17.

⁹ <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 and identify risk factors for substance use disorders
- 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 and evaluate for functional improvement
- 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 importance and use of opioid overdose reversal agents, e.g., naloxone or nalmefene, 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 (OUD)

In addition, HCPs will gain an understanding of current information about safe opioid practices and about current Federal¹⁰ and State regulations, national guidelines,¹¹ and professional organization¹² and medical specialty guidelines on treating pain and prescribing opioids. HCPs will also become familiar with the use of opioid overdose reversal agents (e.g., naloxone, nalmefene) and with the importance of their availability for use by patients and caregivers, both in the community and in the home.

¹⁰ 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.

¹¹ 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.

¹² 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 pain and (2) nonmedical use of prescription opioids.

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 ineffective, not tolerated or would be otherwise inadequate to provide sufficient management of pain, and when the benefits of using an opioid are expected to outweigh the risks.
2. When HCPs have information about the risks of nonmedical use of opioids, they will be able to better 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 nonmedical use of opioids and OUD
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,¹³ 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

¹³ For example, see <https://nccih.nih.gov>. Accessed July 2018.

B. Opioid analgesic medications

Opioid analgesic medications can be used successfully as a component of pain management. However, opioids carry risks greater than those of most non-opioid analgesics, specifically the risks of nonmedical use, OUD, 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 nonmedical use, OUD, overdose, and death and these risks can occur at any dosage or duration and persist over the course of therapy.
 - b. Importance of the appropriate use of PDMPs¹⁴ and their use as a clinical decision support tool
 - c. Diagnosis of OUD in patients prescribed opioid analgesics for pain
 - d. The concepts of tolerance and physiological dependence and how they differ from the concepts of OUD and addiction
 - e. Recognition that some opioid analgesics (e.g., Transmucosal Immediate-Release Fentanyl products, and some doses of ER/LA opioid analgesic products) should not be prescribed for patients who are not opioid-tolerant patients
2. Mechanism of action and analgesic effect
3. Types of opioids (full agonists, partial agonists)
4. Indications and uses, (noting the differences between the indications for IR and ER/LA opioids, as well as their limitations of use)
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. Formulations with abuse-deterrent properties
 - Definition of abuse-deterrent properties based on the FDA guidance for industry, *Abuse-Deterrent Opioids – Evaluation and Labeling*¹⁵

¹⁴ [SAMHSA Prescription Drug Monitoring Programs: A Guide for Healthcare Providers](#). Accessed July 2018.

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

- Recognition that all products formulated with abuse-deterrent properties have the same potential for addiction and overdose as opioids not formulated with abuse-deterrent properties
 - How to understand FDA-approved product labeling for products with abuse-deterrent properties
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
 - b. Interindividual variability of response, including the possibility of opioid-induced hyperalgesia and allodynia
 - c. Special populations
 - Pregnant (including information on neonatal opioid withdrawal syndrome), postpartum, and breastfeeding
 - Renal and hepatic impairment
 - Children and adolescents
 - Genetic and phenotypic variations
 - Older adults
 - Sleep disorders (e.g., obstructive sleep apnea)
 - Common and uncommon psychiatric disorders
 7. Contraindications
 8. Adverse Events (with a focus on labeled Warnings and Precautions)
 - a. Addiction, abuse, misuse, life-threatening respiratory depression, overdose, and death.
 - b. Medication errors
 - c. Periods of greater risk for significant respiratory depression, including at treatment initiation and with dose increases
 - d. 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
 10. Key safety strategies for use with opioid medications
 - a. Dosing instructions including both proper titration and safe reduction or discontinuation techniques
 - b. Safe storage to reduce risk of accidental exposure/ingestion by household contacts, especially children/teens, and to reduce risk of nonmedical use

- c. Proper disposal of used (e.g., transdermal systems) and unused opioids to reduce risk of accidental exposure/ingestion by household contacts, especially children/teens, and to reduce risk of nonmedical use
- d. The availability of and access to an opioid overdose reversal agent, like naloxone and nalmefene, for the emergency treatment of opioid overdose
- 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. HCPs should also be knowledgeable about opioid overdose reversal agents (e.g., naloxone, nalmefene) for home use, recommend or prescribe an opioid overdose reversal agent as appropriate, and discuss the use of these products and the various means of administration with the patient/caregiver.

A. Initiating treatment with opioids — acute pain

1. Patient selection — consider when an opioid is an appropriate option and consult the PDMP
2. Dosing —prescribing for the shortest duration and at the lowest effective dose necessary to treat pain; and prescribing only an appropriate quantity based on the expected duration of pain
3. Screening tools for risk of nonmedical use of opioids and OUD

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 patients who are not opioid tolerant vs. opioid-tolerant patients
2. Opioid selection
 - a. IR or ER/LA, with emphasis on the differing indications (i.e., ER/LA opioids are for the management of severe and persistent pain that cannot be adequately treated with alternative options, including immediate-release opioids)
 - b. Products, and specific doses of products restricted to opioid-tolerant patients
 - c. Special precautions with methadone

3. Dosing
 - a. As needed vs. regular dosing (e.g., “every X hours” (as labeled))
 - b. How to determine a safe initial dose
 - c. Safe conversion from other opioids (often product-specific)
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 suggesting possible nonmedical use of opioids
 - 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
5. Assess for changes in patients’ psychiatric or medical conditions

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 nonmedical use of opioids:
 - 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 OUD and be knowledgeable about how to begin the process of evaluation and 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 potential harms from sudden discontinuation or rapid dose decreases in patients who are physically dependent on opioids. Providers should understand the need for shared decision-making with patients and be able 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 and caregivers about the following:
 - a. Importance of adherence to prescribed dosing regimen
 - i Patients should use the least amount of medication necessary to treat pain and for the shortest amount of time
 - ii How to handle missed doses
 - iii (For patients who may be physically dependent) Not to rapidly reduce or discontinue the medication without first discussing a tapering plan with the prescriber
 - iv When to call the prescriber (e.g., managing adverse events, ongoing pain)
 - v 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.

- vi Never sharing an opioid analgesic with another person
- b. Potential adverse events and risk factors:
 - i The risks of addiction, abuse, misuse, overdose, and death can occur even when product is used as recommended, at any dosage or duration, and persist over the course of therapy.
 - ii Known risk factors for serious adverse events, including overdose and opioid-induced respiratory depression, obstruction, and allergic reactions, among others
 - iii The risks associated with the concomitant use of benzodiazepines, alcohol, and other CNS depressants and the importance of full disclosure of all medications and supplements to all HCPs
 - iv The most common side effects, along with the risk of falls, working with heavy machinery, and driving
 - v Signs and symptoms of withdrawal and the importance of discussing a tapering plan with the prescriber prior to discontinuing a regimen.
- c. Recognizing signs and symptoms of an overdose and the importance of having access to an opioid overdose reversal agent such as naloxone or nalmefene (especially if patient or other household members or close contacts have risk factors for overdose or accidental ingestion),
 - i How to obtain an opioid overdose reversal agent (e.g., prescription, over-the-counter, community-based program)
 - ii How to use an opioid overdose reversal agent
 - iii Seeking emergency medical treatment if an opioid overdose occurs even if an opioid overdose reversal agent is administered
- d. Safe storage and disposal (e.g., flushing [for certain products], kiosks, take-back programs, mail-back envelopes), risks of accidental exposure, and risks of diversion by family members and household visitors
- e. 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 (e.g., drug abuser, addict, “clean” versus “dirty”) should be replaced with language that acknowledges that addiction, referred to as *substance use disorder*¹⁶ in the revised

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

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.

HCPs should be familiar with the following:

1. The neurobiology of OUD (addictive cycle) and difference between physical dependence and addiction.
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.

¹⁷ Id.