

*Blueprint for Health Care Providers  
Involved in the Treatment and  
Monitoring of Patients with Pain:*

## An Overview

LCDR Mark A. Liberatore, PharmD, RAC  
Deputy Director for Safety

Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP)  
FDA/CDER/OND/ON

# Why a *Blueprint*?



- FDA regulates drug companies
- Provider education is important
- FDA authority to require a Risk Evaluation and Mitigation Strategy (REMS):
  - Allows for Elements to Assure Safe Use (ETASU)
  - One element = provider training
- The Blueprint was established to provide a guide as to what must be covered in the CE
- The Blueprint is part of the REMS, which is required of the application holders, but the application holders are not the CE providers
- Application holders are obligated to abide by the terms of the REMS, but do not develop the continuing education (CE) themselves
- CE providers can independently develop CE based on this document

# 2012 and 2018 Version Comparison



## 2012

- Extended-Release and Long-Acting Opioid Analgesics *only*
- Focused on product-specific information
- Targeted mainly to prescribers

## 2018

- Expanded to include all opioid analgesics intended for use in the outpatient setting
- Focuses on fundamental concepts of pain management
- Targets *all* health care providers involved in the treatment and monitoring of patients with pain

# Why Health Care Provider Education is Important



- Adverse outcomes of addiction, unintentional overdose, and death remain a major public health problem
- Inappropriate prescribing, misuse, and abuse continues to contribute to these outcomes
- Critical that HCPs understand the risks associated with opioid analgesics, as well as from a public health perspective

*Blueprint available at:*

[https://www.accessdata.fda.gov/drugsatfda\\_docs/remis/Opioid\\_Analgesic\\_2019\\_11\\_14\\_FDA\\_Blueprint.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/remis/Opioid_Analgesic_2019_11_14_FDA_Blueprint.pdf)

# Data Behind the *Need* for Education

- Millions of Americans suffer from chronic pain
- Many patients visiting an emergency department (for acute pain) still receive an analgesic
- Many people who use prescription “nonmedically” report obtaining them from friends or family
- Undertreated pain carries with it a lot of adverse consequences
- Proper treatment of pain while using best practices to ensure patient safety is critical
- Having a broad knowledge about how to manage patients with pain (including non-pharmacologic options) can help contribute to national efforts to address and reduce opioid misuse and abuse

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# Purpose of the REMS Educational Effort



- Fundamental concepts of pain management
- How to assess patients in pain
- Identify risk factors for abuse and addiction
- Range of therapeutic options
- Managing acute and chronic pain, including initiation, titration, and discontinuation (proper tapering)
- How to counsel patients
- When to refer to pain specialist
- Fundamental elements of addiction medicine, including identification and management of patients with opioid use disorder

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# Focus Section 1: The Basics of Pain Management



- The Need for Comprehensive Pain Education
  - Reinforcement of the purpose
- Definitions and Mechanisms of Pain
  - Taking into consideration biological significance, acute/chronic, nociceptive/neuropathic pain
- Assessing Patients in Pain

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# Focus Section 2: Creating The Pain Treatment Plan

- I. Components of an Effective Treatment Plan
- II. General Principles of Non-pharmacologic Approaches
- III. General Principles of Pharmacologic Analgesic Therapy**
- IV. Managing Patients on Opioid Analgesics**
- V. Addiction Medicine Primer

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# III. General Principles of Pharmacologic Analgesic Therapy

## Non-opioid Medications

- Mechanism of action
- Indications and uses
- Routes of administration
- Initiation, titration, tapering
- Contraindications
- Adverse events
- Drug interactions

## Opioid Analgesic Medications

- Knowledge of all the same points covered under non-opioid options, *plus*:
  - Opioid-specific risks (i.e., misuse, abuse, addiction)
  - Respiratory depression, overdose, death
  - Use successfully as a *component* of pain management

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### III. b. Opioid Analgesic Medications

1. General Precautions
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
6. Initial Dosing, Dose Titration, Dose Tapering (when appropriate) for Analgesia
7. Contraindications
8. Adverse Events
9. Drug Interactions
10. Key Safety Strategies for Use with Opioid Medications

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## IV. Managing Patients on Opioid Analgesics

- Appropriate use
- Acute and chronic pain
- Balance of benefits and risks
- Serious outcomes of overdose and death

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## 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 Opioid Use Disorder
- F. When to Consult a Pain Specialist
- G. Medically Directed Opioid Tapering
- H. Importance of Patient Education

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# Addiction Medicine Primer



- Knowledgeable about the basic elements of addiction medicine
- Usage of non-stigmatizing language
- Be familiar with:
  - Neurobiology of OUD
  - Use of Screening Tools
  - Management of OUD

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# Summary



- The Blueprint is an FDA-approved document designed to facilitate development of continuing educational programs
  - It is not, itself, an continuing education program
- The new Blueprint and CE developed from it targets all health care providers, not just prescribers
  - No longer contains product-specific information
- The Blueprint contains a high-level outline of core educational messages that must be included in CE
  - CE can be **customized** depending on the target audience, medical specialty, or health care profession
- In addition to relaying important information related to the treatment and monitoring of patients with pain, the document also contains an “addiction medicine primer” so that HCPs are educated on the basic elements of addiction medicine



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