

Opioid analgesic REMS Assessment plan: additional approaches

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OA REMS Goals


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.

Evaluation of educational intervention



Knowledge

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- Prescriber behavior
 - Patient outcomes

Health care provider knowledge

- Pre- and post-CE activity testing
- Long-term follow-up evaluation of participants to assess retention of knowledge

These evaluations inform Objective 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

Patient knowledge and experiences

- Evaluation of patient understanding (knowledge surveys)
- Evaluation on patient experiences around pain management (focus groups)

These evaluations inform Objective 2 - Informing patients about their roles and responsibilities regarding their pain treatment plan, risks, and safe use of opioid analgesics.



Prescriber behavior and patient outcomes

- **The approval letter specified that the RPC should:**
 - Use an appropriate **control group** (i.e., providers who have not completed REMS-compliant CE), and rigorous **control for confounding** to allow assessment of whether any observed changes in prescriber behaviors or patient outcomes can be attributed to the CE
 - **Development and use of metrics** that assess prescriber behaviors and patient outcomes relating to key messages in the Blueprint
 - Should also include evaluation of potential **unintended adverse patient outcomes** resulting from changes in prescribing practices

These metrics inform the aspirational goals/intent of education and will be the focus of our discussion today

**ARE THERE *ADDITIONAL* EVALUATIONS THAT
INFORM GOALS/OBJECTIVES OF THE OPIOID
ANALGESIC REMS?**

Focus on Knowledge



- Identification of specific knowledge that is most associated with desired changes in prescriber behavior

Prescribing/patient management



- Evaluation of prescribing patterns and/or patient monitoring practices
 - Identify specific practices and evaluate changes since 2010, for example:
 - Use of urine drug screens
 - Opioid prescribing for third molar extractions
 - Opioid dispensing from EDs
 - Opioid co-prescribing with benzos,
 - Increased prescribing of opioid with naloxone

Required CE



- Impact of State or health system-required CE
 - Expectations/evaluation of state-mandated CE
 - Impact of REMS-CE on requirements for other CE

Determinants of effective CE



- REMS or other pain/opioid CE
 - Widespread availability of CE
 - Multiple formats
 - High quality CE activities

“Drivers” of prescribing



- Examination of drivers of prescribing
 - Determine which interventions have had the greatest impact on prescribing such as:
 - Prescription Drug Monitoring Programs
 - Required continuing education
 - Opioid analgesic prescribing limits
 - Academic detailing
 - Prescriber dashboards and reminders
 - Others?



Evidence for state, community and systems-level prevention strategies to address the opioid crisis

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ABSTRACT

Background: Practitioners and policy makers need evidence to facilitate the selection of effective prevention interventions that can address the ongoing opioid overdose epidemic in the United States.

Methods: We conducted a systematic review of publications reporting on rigorous evaluations of systems-level interventions to address provider and patient/public behavior and prevent prescription and illicit opioid overdose. A total of 251 studies were reviewed. Interventions studied included 1) state legislation and regulation, 2) prescription drug monitoring programs (PDMPs), 3) insurance strategies, 4) clinical guideline implementation, 5) provider education, 6) health system interventions, 7) naloxone education and distribution, 8) safe storage and disposal, 9) public education, 10) community coalitions, and 11) interventions employing public safety and public health collaborations.

Results: The quality of evidence supporting selected interventions was low to moderate. Interventions with the strongest evidence include PDMP and pain clinic legislation, insurance strategies, motivational interviewing in clinical settings, feedback to providers on opioid prescribing behavior, intensive school and family-based programs, and patient education in the clinical setting.

Conclusions: Although evidence is growing, further high-quality research is needed. Investigators should aim to identify strategies that can prevent overdose, as well as influence public, patient, and provider behavior. Identifying which strategies are most effective at addressing prescription compared to illicit opioid misuse and overdose could be fruitful, as well as investigating synergistic effects and unintended consequences.

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Considerations

Given that pain management is being affected by multiple interventions delivered at multiple levels

Can a one-time pain management CE be the sole driver of prescriber behavior change?

If patient outcomes and prescriber behavior are improving, can we assume that REMS CE contributed?



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Session 3: Alternative study approaches

- Discuss whether there might be suitable additional or alternative studies for evaluating the impact of other similar interventions and whether any lessons learned from these could be applied to the evaluation of REMS-compliant CE on prescriber behaviors and patient outcomes