

**Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes--Exploring the Path Forward for Assessment:  
Public Workshop  
December 11, 2020**

**Topics for Panel Discussion**

**Session 1: Measurable outcomes to evaluate the effectiveness of Opioid Analgesic REMS training**

1. Considering the goals of the OA REMS and the content of FDA blueprint, discuss what could be meaningful measures of good pain management practice and appropriate use of opioid analgesics:
  - a. For prescribers?
  - b. For other members of the healthcare team?
2. Similarly, what are measurable patient outcomes or behaviors that could be expected to change following completion of OA REMS CE by their provider(s) and healthcare team?

**Session 2: Feasibility of studying the specific impact of the OA REMS education on prescriber behavior and patient outcomes**

1. Discuss the value and feasibility of various approaches to evaluate the impact of OA REMS CE on healthcare provider behavior and/or patient outcomes:
  - a. Is there a role for large observational studies based on administrative or dispensing claims? If so, what could be learned from such studies?
  - b. What about observational or interventional studies using EHR data and/or prospectively collected data?
  - c. Are there non-traditional or mixed-methods study designs or other innovative approaches that may be valuable?
2. Discuss various design and analysis considerations, such as study setting and sample selection, sample size/power, data linkages, outcome ascertainment and follow-up duration, and control of confounding and isolating REMS CE effects from other influences on practice behavior and patient outcomes.
3. Discuss how to address the heterogeneity in REMS CE program formats, target audiences, and exact content.
4. Discuss the value, objectives, and important features of a pilot study.

**Session 3: Alternative study approaches to broadly evaluate the impact of CE on prescriber behaviors and patient outcomes**

1. Discuss whether inferences can be made about the effectiveness of OA REMS CE programs based on evidence of the effectiveness of CE programs more generally
2. Discuss approaches that could inform our understanding of the contribution of CE, *in general*, to improving pain management practice and patient outcomes.