

# What is REMS?

## REMS = Risk Evaluation and Mitigation Strategy

**REMS are FDA-mandated requirements to minimize the risks associated with certain medications. REMS can be mandated for any medication or class of medication, and certain opioids have been included in this mandate.**

### Components of REMS

<b>Medication Guide/PPI*</b>	Educational tools provided to each patient when drug is prescribed/dispensed
<b>Communication Plan</b>	For example, letters to healthcare providers, communications to professional societies, professional education, etc.
<b>Elements to Assure Safe Use</b>	Special requirements or restrictions to optimize safe use of products
<b>Implementation System</b>	System to monitor, evaluate, and improve elements to assure safe use
<b>Timetable for Assessment</b>	Minimum FDA requirement 18 months, 3 years, and 7 years after REMS approval (only compulsory element for all REMS programs)

\*PPI: Patient package insert.

***“REMS already exist in other therapeutic areas—opioids aren’t being singled out”***

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#### Reference

1. Title IX of the FDAAA: REMS Authorities, March 2009. <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM163674.pdf>. Accessed August 2010.