

As a Healthcare Provider, How Do I Integrate Opioid Risk Evaluation and Mitigation Strategies (REMS) into My Practice?

What do we know about opioid REMS?

- > REMS are the latest step in the evolution of risk mitigation
- > While there are different components of REMS, an individual program does not have to include all of these:
 - **Medication Guide/Patient Package Insert:** educational tools provided to each patient when a drug is prescribed/dispensed
 - **Communication Plan:** for example, letters to healthcare providers, communications to professional societies, professional education, etc
 - **Elements to Assure Safe Use:** special requirements or restrictions to optimize safe use of products
 - **Implementation System:** system to monitor, evaluate, and improve elements to assure safe use
 - **Timetable for Assessment:** minimum FDA requirement 18 months, 3 years, and 7 years after REMS approval. Each REMS must contain a timetable for assessment to periodically check its effectiveness
- > The two components that are most relevant to prescribers are:
 - **Medication Guide/Patient Package Insert**
 - **Elements to Assure Safe Use:** to mitigate serious risks via such measures as training/certification of prescribers/pharmacists, restrictions on dispensing, evidence of patient safe-use conditions, patient monitoring, and/or enrollment of patients
- > REMS can be mandated for any medication or class of medication
- > As of August 2011, there are 140 approved REMS
 - See <http://1.usa.gov/Xs1f6> for a continually updated list of FDA-approved REMS

FDA and opioid REMS update

- > FDA has defined a unified “class-wide REMS” for long-acting opioids (LAOs) and extended-release (ER) opioids
- > See <http://1.usa.gov/km4y7Y> for a list of LAO/ER opioids required to have a REMS
- > Other opioid REMS are product specific
- > When a new opioid REMS is approved, **you may not be able to prescribe or dispense that opioid until you meet the REMS requirements**
- > Therefore, opioid REMS must be integrated into your practice in order to maintain access to these pain medications for appropriate patients
- > **Note:** REMS for opioids add to, but do not replace, existing state and federal regulations

What can you do now to prepare?

Coordinate your office/clinic/pharmacy

- Review current standard operating procedures for REMS compliance
- Review staff roles, train staff, and monitor their performance
- Prepare for potential new documentation requirements

Enhance communication with your patients

- Educate them about REMS and the potential implications (eg, there may be changes in processes for dispensing their medications)
- Assess their ability to understand the requirements of the REMS
- Actively educate them on the risks of opioid medications—misuse, abuse, overdose, and diversion—and explain that REMS are designed to minimize those risks while maintaining access
- Advise them on safe storage and disposal of opioid medications

Ensure that you

- Know the federal and state regulations for prescribing opioids
- Review your current prescribing habits to ensure standards of care continue
- Evaluate your current patient communications
- Talk to your colleagues and peers to find out how they are getting ready

Stay informed via

- FDA - www.fda.gov
- List of Approved REMS - <http://1.usa.gov/Xs1f6>
- List of Long-Acting and Extended-Release Opioids Required to have a REMS - <http://1.usa.gov/km4y7Y>
- Questions and Answers on REMS for Long-Acting and Extended-Release Opioids - <http://1.usa.gov/j1qLaM>
- DEA - www.justice.gov/dea
- Federation of State Medical Boards - www.fsmb.org
- American Academy of Pain Medicine - www.painmed.org
- American Academy of Pain Management - www.aapainmanage.org
- American Society of Pain Educators - www.paineducators.org
- American Pain Society - www.ampainsoc.org
- American Pharmacists Association - www.pharmacist.com
- American Society of Health System Pharmacists - www.ashp.org
- American Chronic Pain Association - www.theacpa.org
- American Pain Foundation - www.painfoundation.org
- **Ready for REMSSM** - www.ReadyForREMS.com