

Getting Ready for REMS

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Disclosures: Dr Brennan will receive an honorarium from Cephalon

Disclosures

- > I'm a practising pain specialist
 - > I don't know what the full requirements of all new opioid REMS will be
 - No one does...
 - > But I'm trying to find out because I need to be ready
 - And, if you treat pain seriously, so do you...
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Getting Ready for REMS

- > Why bother?
- > Will it affect me?
- > What am I going to have to do?
- > What investment will be necessary?
- > Will it be worth it?
- > What can I do now?



Why Bother?

- > Because proceeding without REMS is not an option
 - This is mandated by the FDA
 - *“We expect all companies marketing these products to work with us [to implement REMS] expeditiously. If not, we cannot guarantee that these products will remain on the market”¹*
- Bob A. Rappaport, MD, Director
Division of Anesthesia, Analgesia and Rheumatology Products
Center for Drug Evaluation and Research
Food & Drug Administration
- Reliance on products without REMS may lead to inadvertent undertreatment of pain in appropriate patients

1. Excerpt from presentation by Rappaport BA, March 3, 2009. REMS for Opioid Analgesics: How Did We Get Here? Where are We Going? <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM163672.pdf>. Accessed September 2009.

Why Bother?

But more importantly...

- > Because REMS may help patients, our communities, and ourselves
 - > This will happen by
 - Enhancing individual patient safety
 - Increasing patients' knowledge of their treatment and its inherent risks
 - Keeping their families safer
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Why Bother?

- > Because REMS will strive to help prescribers
 - Ensure the right medications continue to be prescribed for appropriate patients
 - Facilitate the necessary dialogue with patients about abuse, misuse, and addiction
 - Improve communication with patients on taking and handling medication responsibly
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Will it Affect Me?

- > Yes it will
 - If you are here, it is likely that you are invested in pain, therefore it will affect you
- > REMS will have an impact on every key stakeholder, including
 - Physicians
 - Nurse practitioners
 - Physician assistants
 - Patients
 - Caregivers
 - Office managers
 - Pharmacists
 - Pharmaceutical manufacturers



What Am I Going to Have to Do?

> Operate within the REMS framework¹

Medication Guide/PPI

Education tools provided to each patient when 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

Distribution and/or use restrictions that mitigate a serious risk

Timetable for Assessment

Minimum FDA requirement 18 months, 3 years, and 7 years after REMS approval

PPI: patient package insert.

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

What Am I Going to Have to Do?

> Operate within the REMS framework¹

Medication
Guide/PPI

You will be providing education to each patient when drug is prescribed

Communication
Plan

For example, letters to healthcare providers, communications to professional societies, professional education, etc.

Elements to
Assure Safe Use

You will be prescribing under special requirements or restrictions to ensure appropriate and safe use

Implementation
System

Distribution and/or use restrictions that mitigate a serious risk

Timetable for
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What Am I Going to Have to Do?

> Coordinate your office/clinic

- Develop new standard operating procedures
- Train staff and monitor performance
- Prepare for new documentation requirements



> Enhance communication with your patients

- Educate them about REMS and its implications (eg, monitoring)
 - Assess their ability to understand the requirements of the REMS
 - Actively discuss overdose, abuse, misuse, and diversion
-

What Investment Will Be Necessary?

> Time

- Education
- Documentation requirements
- Developing and monitoring new processes and procedures
- Staff training



Will It Be Worth It?

> Yes

- REMS is an investment to remain committed to suffering patients and treat their pain properly
 - Individual patient safety is worth the extra effort
 - You can be part of the solution to the public health crisis of misuse and abuse of opioid medications
 - The public health crisis has fuelled the undertreatment of pain
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Will It Be Worth It?

- > REMS may offer a better opportunity to safely treat patients while at the same time protect our communities

 - > What is the cost of not following REMS?
 - Your prescribing options will be limited
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What Can I Do Now?

- > Know the federal and state regulations on prescribing opioids and where REMS can facilitate compliance with them
 - > Review your current prescribing habits to ensure your standards of care continue
 - > Ready your office/clinic
 - Review roles and responsibilities of staff
 - > Evaluate your current patient communications
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What Can I Do Now?

- > Stay informed
 - Ready for REMS: www.ReadyForREMS.com – sign up for updates
 - FDA: www.fda.gov
 - The Legal Side of Pain: www.legalsideofpain.com
 - American Academy of Pain Medicine: www.painmed.org
 - American Pain Society: www.ampainsoc.org
 - > Talk to your colleagues and peers to find out how they are getting ready
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Summary

- > There are two public health issues
 - Untreated pain
 - Opioid misuse
 - > It's time to do the right thing – REMS are necessary
 - > REMS will ensure the right medications continue to be prescribed for the appropriate patients
 - > REMS documentation may facilitate your compliance with federal and state regulations
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Remember Your Role...

- > Stay committed to suffering patients and continue to treat their pain properly
 - > Individual patient safety is the ultimate goal
 - > Be part of the solution to the public health issues

 - > Get Ready for REMS!
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