

The Practical and Legal Implications of REMS

Jennifer E Bolen, JD, Attorney at Law
Founder, The Legal Side of Pain®
Lenoir City, TN

Disclosures: Ms Bolen will receive an honorarium from Cephalon

Overview

- > REMS documentation in relation to compliance with good clinical practice
 - > Legal considerations
 - > Prescriber
 - > Pharmacist
 - > Patient
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Why, as an attorney, is REMS important to me?

Does FDA have the Legal Authority to Require REMS for One or All Opioids?



- > Yes
 - Food & Drug Administration Amendments Act (FDAAA)

 - > The next question is....
 - What can you do to get your practice and your patients ready for it?
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REMS Goals and Documentation

REMS Goals

- > Minimize potential for overdose, misuse, abuse, and diversion
- > Maintain access for appropriate patients

REMS Documents

- > FDA approved documentation applies to prescribers, pharmacists, and patients
 - > Certain opioid REMS “agreements” likely
 - > Agreements should facilitate compliance with good clinical practice
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REMS and Basic Legal Obligations for Prescribing



Rx for legitimate medical purpose

While acting in "usual course of professional practice"

While exercising "appropriate degree of medical supervision" over individual patient

While following other federal and state laws, clinical standards of care, and professional guidelines

DEA obligations when prescribing controlled medications

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FDA approved REMS documentation*

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Facilitates compliance with good clinical practice (subject to individual REMS requirements)

Guides practitioners in key documentation points when prescribing other controlled medications

*Check with qualified legal counsel for overall compliance requirements

REMS and the Prescriber



Organized approach to patient selection

- Facilitates patient education on medication safety
- May improve informed consent process
- Sets a new standard of care

Issues to consider

- May require minor changes to standard operating procedures
- Legal counsel

REMS and the Pharmacist



Organized approach to pharmacy processes

- Improves understanding of drug label and REMS safe use measures
- Facilitates compliance with drug utilization review requirements
- Facilitates patient education and counseling on medication safety

Issues to consider

- May require minor changes to standard operating procedures
- May be limited from participation by in-house counsel

REMS and the Patient



Organized approach to patient communication

- Facilitates communication with healthcare professionals – documents will prompt dialogue
- Facilitates patient, caregiver, and family education
- Provides documentation to support related healthcare services

Issues to consider

- Should provide documentation to substantiate medical necessity for ongoing and long-term use in appropriate cases

Summary

- > REMS documents support REMS goals
 - > REMS documentation should facilitate compliance with good clinical practice
 - > REMS provides a framework for:
 - Appropriate patient selection
 - Optimized pharmacy processes
 - Enhanced patient communication
 - > REMS adds to, but does not replace, existing state and federal regulations
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