

READY FOR REMSSM

Linking REMS with Best Practices

A Model of a Transmucosal Immediate-release Fentanyl REMS System*



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Best Practices: Prescribing

- > Awareness of risks and safety information
- > Appropriate patient selection
 - Opioid tolerance
- > Appropriate dosing
 - Conversion
- > Documentation



Best Practices: Patient Communication

- > Documented risk assessment
- > Document patient education
 - Safe use
 - Storage and disposal
- > Open dialogue with patients
- > Opioid agreement
- > Mutual responsibilities



Best Practices: Patient Support

- > Medication Guide provides:
 - Information on medication risks
 - Reference on safe use and storage for patient / family / caregiver
- > Patient encouraged to keep prescriber informed of any changes in drug regimen / schedule
- > 2-Way opioid agreement documents the understanding of and commitment to safe use and storage
- > Enrolled pharmacy provides consistent and knowledgeable contact in the community



Administrative Implications

> Additional time

- Prescriber enrollment
(eg, every 2 years)
- Potential longer patient
visit to review REMS
- Office staff training



Tip: Pre-identify a REMS expert in your office to track REMS requirements, talk with representatives, prepare patients

Resources to Help You Prepare

- > Pick up these and other resources to help you, your staff, and your patients prepare:
 - HCP REMS Implementation Guide
 - FDA/DEA handouts
 - Patient Brochure on safe use
 - TIRF patient counseling reminders
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