



SAFE USE

The word 'SAFE' is written in large, bold, black, sans-serif capital letters. The letter 'U' in 'USE' is also in large, bold, black, sans-serif capital letters, but it is stylized to look like a pill capsule. The top half of the 'U' is white with a black outline, and the bottom half is filled with a solid red color, representing the bottom half of a pill.

Collaborating to reduce preventable harm
from medications

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FDA Regulatory



- Risk Evaluation and Mitigation Strategy (REMS)
 - Measure impact
- Labeling changes
- Advisory committee
- Require new studies to assess observed safety signals
- Drug safety communications
- Develop guidance documents

FDA Safe Use

- Convene stakeholders:
 - Identify drug safety issue (s)
 - Discuss barriers
 - Propose interventions
- Create voluntary collaborative efforts
 - Implement interventions
 - Measure impact
- Federal, non-federal partners (private)
- Join ongoing drug safety activities
- Support literacy, adherence, HIT activities

FDA Opioid REMS

(Risk Evaluation and Mitigation Strategy)

- **Directly affects** - Manufacturers of Long Acting (LA) and Extended Release (ER) opioid products
 - Create a single shared system to implement REMS
 - Revise/Develop medication guide and ensure its availability for patients
 - Provide training/education to healthcare providers (CME)
 - Provide assessment of:
 - training/education
 - patient understanding
 - Drug utilization, changes in prescribing



Safe Use - Opioids

strategies to reduce preventable harm

- Collaborative/voluntary approach to developing strategies – enlist those who will use and be affected
 - Discuss
 - Design
 - Develop
 - Disseminate
 - Educate
 - Implement
 - Evaluate
 - Revise
- Focus on all opioids - LA/ER as well as short-acting/immediate release



Safe Use

Patient and Prescriber

- Define the issues that lead to preventable harm from opioids
 - Drug choice
 - Abuse recognition
 - Number of pills being prescribed (dose and schedule)
 - Level of information given to patient
 - Patient taking too many
 - Patient sharing
 - Patient being afraid to take

Patient Provider Agreements (PPA)

aka - Controlled Substance Agreement or Pain Treatment Contract

- 41 PPA culled from web*
 - All had violation emphasis
 - 61% mention safe storage
 - Less than half mention
 - Prescriber responsibilities
 - Patient should inform prescriber of side effects or other medications
 - Gender specific effects e.g. pregnancy and newborn withdrawal

*Mark Collen. 2009. Analysis of Controlled Substance Agreements from Private Practice Physicians. J of Pain & Palliative Care Pharmacotherapy Vol. 23(4) p357-364

PPA Quotable Quotes

- Any evidence of drug hoarding, acquisition of any opioid medication or adjunctive analgesia.....
- Addiction is a primary, chronic neurobiologic disease...
- I will actively participate in RTW activities.....
- ...other chronic pain treatment modalities....
- ...side effects...sedation, somnolence, respiratory depression
- ...you will be prescribed a titrating dose of medication...
- The use of alcohol and opioid medications is contraindicated
- I am aware that the government has warned that the improper use of these medications can cause addiction and kill

Patient Provider Agreements

Positives

- Provide tool for discussion
- Increase patient awareness
 - Appropriate use
 - Benefit/Risk
 - Storage/Sharing
- Reference tool for at home
- Develop health plan/re-evaluate therapy
- Clarify prescriber's & patient's roles and responsibilities

Negatives

- Health Literacy - difficulty reading/understanding
- Patient provider trust
- Emphasis on patient compliance
- Lack prescriber responsibilities
- Inadequate highlighting benefit & risk
- Can be long
- Limited data on effectiveness

Patient Provider Agreements Essential Elements

- Importance to a patient
- Both Patient and Provider agree to their responsibilities
- Why using this medication
- Appropriate and Safe use
- Proper storage and disposal
- Benefits/Risks/Limitations

PPA: Areas for Collaboration

- PPA Implementation
 - Developing Model PPA
 - Piloting PPA – prescribers and patients
 - Disseminating PPA for use
 - Providing information and training on use of PPA

- PPA Metrics
 - Adoption of PPA in practice
 - Shift in Knowledge, Attitudes and Behaviors
 - Reduction in ER visits for Rx opioid misuse/overuse
 - Reduction in notifications of multiple medications, early refills, and/or doctor shopping
 - Reduction in medical claims associated with Rx opioids

Prescribers

DEA Hall of Infamy – action against doctors providing scheduled drugs illegally (85 pages 2003-11) – looked at 1st 51 pages

What are the ages of doctors convicted

20-29 – 1

30-39 – 5

40-49 – 36

50-59 – 44

60-69 – 23

70-79 – 11

80-89 - 1

Education of Prescribers

- Educate the older prescribers but start education in schools and residency and training programs –
- Making checking the PDMP the new norm
- Provide general training on PDMPs – the basics (CME?) and specific training for each state
- Make it about patient safety and public health and being an informed prescriber

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