New Label Changes for 
Safer Outcomes with Opioid Use

The US Food and Drug Administration (FDA) has recently announced mandatory safety updates on the labeling of all long-acting (LA) and extended-release (ER) opioid pain medications amidst a growing number of overdoses and deaths related to these drugs. An analysis conducted by the Centers for Disease Control and Prevention (CDC) reported that in 2010, three out of four prescription-related deaths were linked to opioid pain relievers. This move by the FDA is highly influenced by several organizations. At the forefront of change is the opioid safety advocacy coalition, Physicians for Responsible Opioid Prescribing (PROP), whose members include pain clinicians, researchers, and health officials. Other supporting groups include the Drug Enforcement Administration (DEA), the Center for Lawful Access and Abuse Deterrence (CLAAD), the American Society of Addiction Medicine, Public Citizen’s Health Research Group, and Ryan’s Cause, to name a few. Over the recent years, there has been a push to end the tragedy of opioid misuse, dubbed an epidemic by the CDC.

The new labeling requirements are directed at LA and ER dosage forms, such as OxyContin, due to their higher doses and longer duration of action. At present, labels list an indication to relieve pain in the “moderate to severe range for patients requiring continuous, around-the-clock treatment for an extended period of time.” Soon these labels will be narrowly indicated for “the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.” Prescribers will be encouraged to order alternative immediate-release opioids or non-opioid analgesics instead. Further, LA and ER opioids will not be indicated for as-needed pain relief.

This initiative primarily highlights changes in the indication; however more labeling changes and additional requirements will take place as well. This includes:

- A new black box warning which gives more details on neonatal opioid withdrawal syndrome (NOWS);
- Changes to dosage and administration, warnings and precautions, drug interactions, and patient counseling sections;
- Manufacturer participation in long-term studies and trials of the serious risks with LA and ER pain relievers that are currently available; and
- Risk Evaluation and Mitigation Strategies (REMS) that will require access to continuing education courses for health care professionals.

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