


REMS Education Guidelines for Physicians: Strong Enough to be Effective?



In April 2011, the FDA released a statement on new guidelines for REMS (Risk Evaluation and Mitigation Strategies) to reduce the risks associated with prescribing long-acting opioids. FDA officials say they will begin with long-acting and extended-release opioids because the amount of opioids contained in these formulations is much greater than the amount contained in immediate-release drugs. Janet Woodcock, MD, Director of the FDA's Center for Drug Evaluation and Research, said drug manufacturers will be responsible for tracking how many physicians opt-in for educational programs.

According to the regulations, drug makers will provide education and pay for this plan, this is considered to be an important step in the right direction. The primary message of this communication is that training is still not mandatory for prescribers. Allowing this to be voluntary may likely cause the REMS program to be less effective in the long run. Hopefully, there will be high quality programs available to those physicians who are willing to learn more in order to prescribe more safely. The FDA has essentially changed the prescribing parameters, although voluntary for physician practice as related to prescribing of long-acting and extended-release opioids.

Chronic pain and the prescribing of opioids is especially challenging in Workers' Compensation pharmacy. Opioid misuse has become a crisis with deaths often associated with opioid prescribing. This new REMS regulation will now mandate that pharmaceutical companies provide Continuing Medical Education (CME) level activities to practitioners on prescribing and management of patients on long-acting opioids.

"REMS juxtaposes pharmaceutical companies and CME in a way that hasn't occurred before," stated Murray Kopelow, MD, Chief Executive of the Accreditation Council for Continuing Medical Education. "There will be a curriculum and companies will be accountable to the FDA." Despite the changes, Dr. Kopelow says drug makers and CME providers can expect more of the same when it comes to accreditation. "The standards we have set will still be applicable," he added, "We are honored that the government views accredited CME as a strategic asset to public health and safety initiatives."

"Any attempt to regulate only a portion of the opioid class of medications will drive prescribers, users, and misusers of these medications to the other, less stringently regulated, but often abused members of the class of medications," the statement notes. "This will not diminish abuse or misuse and will very likely result in decreased access to appropriate therapy for some legitimate patients."

In a position statement issued by the American Academy of Pain Medicine, specialists say that any new plans should cover the entire class of opioids. New educational programs will soon be launched for Morphine, Hydromorphone, Methadone, Oxycodone, Oxymorphone, Fentanyl Transdermal and Buprenorphine.

Source: FDA's Long-Awaited Opioid Plan Calls for Education; Medscape Pharmacists, WebMD, LLC. Sourced 5/11/11.

