Nurse Practitioner Healthcare Foundation
Improving Health Status and Quality of Care through Nurse Practitioner Innovations

Oral Testimony on Draft Report on the Standardization of Risk Evaluation And Mitigation Strategies (REMS) [Docket No. FDA-2013-N-0502]

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NPHF Recommendations to the FDA Regarding REMS: ER/LA Opioids

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This testimony was prepared with consultation from Dr. Paul Arnstein and Dr. Barbara St. Marie, national experts in the area of pain management.

The U.S. is facing two significant and interrelated public health crises - the rise in the number of individuals who experience chronic pain as a result of their health conditions, and the drug abuse epidemic. Healthcare providers confront a dilemma. Many patients with serious conditions experience chronic pain and deserve safe and effective treatment to achieve a reasonable quality of life. Some of these patients require the use of opioids to effectively manage their pain. At the opposite end of the spectrum is the drug-seeking individual who may abuse, misuse or divert opioid medications. In the middle are patients who began with legitimate opioid therapy but who have become addicted to their medication and are now drug-seeking patients. The clinician has to make a series of complex clinical decisions each step of the way, balancing safety, efficacy, and harm-reduction. And, healthcare professionals are not adequately prepared to address these patient care conundrums.

The term "medical signature" is used to describe "the way you have always done it"- meaning that you have adopted usual ways of practicing, or in this case, prescribing. Most medical signature is congruent with our training as clinicians and most of the time it's a good thing- where the "usual way" you care for your patient is evidence-based, safe, and meets guidelines for best practice. But medical signature gets you into trouble when it is based upon a practice that is outdated or incorrectly applied to the case being considered. Then "medical signature" leads to incorrect care or "medical error." To prevent such errors, we need to replace outmoded or inaccurate medical signatures with new, more appropriate ones that will lead to better clinical practice. Education is absolutely the key to converting to a new, more appropriate medical signature. Especially with a

clinical issue as dangerous and complex as opioids, significant, varied, consistent, and ongoing interprofessional educational efforts are required. Through our educational programs, NPHF has educated thousands of NPs on just these clinical issues. The result has been relearned "medical signatures" and improved clinical practice. Prescribing behavior, practice protocols, and systems of care delivery have been upgraded and monitoring has been put into place. The result has been improved quality and safety of care for patients on opioid therapy.

With this background, the Nurse Practitioner Healthcare Foundation offers the following comment and recommendations:

Comment

The ER/LA Opioid REMS have been a positive step for changing practice. It has propelled healthcare professionals to examine their practices, and adopt new practice patterns. The REMS have not been an undue burden and have not limited access to these medications for those who require opioid therapy. CE/CME is an effective method of achieving learner engagement, and practice change. When provided by peer experts CE is one of the most effective approaches to breaking poor medical signature and adopting safe and effective practice patterns. Although we are well on the way to achieving a new, safer, and more effective "medical signature" in opioid management, all our efforts must continue.

Recommendations

However, NPHF recommends the following changes to enhance the effectiveness of the ER/LA Opioid REMS program:

1. The immediate release/short acting (IR/SA) opioids should be included in a blueprint that addresses both ER/LA opioids and IR/SA opioids. A particular education point would be the role of opioids as part of a multimodal therapeutic approach.
2. Chronic pain management is most often an interdisciplinary team effort, not the sole responsibility of the prescriber. Therefore, education should include all appropriate healthcare team members.

3. The FDA Blueprint should be incorporated into the pharmacologic curriculum of health professional education across disciplines. Resources such as the CO*RE curriculum could be used to achieve rapid implementation of this recommendation. In addition, **it may be helpful to work with program accrediting agencies to align curriculum with national guidelines.** This is consistent with tactics called for in recent federal legislation, National Drug Policy initiatives, and the National Pain Strategy.

4. Currently, a number of opioid education programs are done outside of the RPC-funded mechanism and these efforts are not reported to the FDA. The tracking and reporting system should be modified to include these learners. Also, it is important to streamline the process, as the current system is quite burdensome.

Thank you for your time and attention.