



June 3, 2016

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: FDA–2016–N–0820, Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments on the ER/LA Opioid Analgesics REMS Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. The AANA shares the US Food and Drug Administration's (FDA's) concern about the increase in opioid drug use, abuse and deaths and is committed to collaboratively working toward a common solution to help curb the opioid epidemic in the US.

Background of AANA and CRNAs

The AANA is the professional association representing more than 49,000 Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists in the United States. More than 90 percent of the nation's nurse anesthetists are members of the AANA. CRNAs are advanced practice registered nurses who personally administer more than 40 million anesthetics to patients each year in the United States. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

Recommendations

The AANA makes the following recommendations regarding the ER/LA Opioid Analgesics REMS Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics:

- **Patient engagement should be a central component of pain management.**

Patient-centered care offers the patient greater transparency, understanding, and engagement in their care. Using a shared decision making model facilitates collaborative care through planning and discussion of risks and benefits of the pain management plan, encourages the patient to express his or her preferences and values, and jointly establishes realistic goals for the patient's well-being and quality of life. In the treatment of pain, patients and their caregivers should understand the etiology of pain, treatment plans and goals, treatment options and alternatives, as well as consequence to non-adherence to the pain management plan. For chronic pain management, particularly if opioids are prescribed in the treatment, the clinician should enter into a pain management treatment agreement with the patient.

- **Acute and chronic pain management involves a multidisciplinary approach; therefore education should extend to all members of the multidisciplinary team and be aligned with national guidelines.**

The AANA supports provider education regarding alternative non-pharmacologic and pharmacologic modalities for pain management that minimize the use of opioids. Many clinicians across numerous specialties, such as primary care, anesthesia, addiction, pain, emergency, and palliative care, are involved in the management of acute and chronic pain. Interprofessional education should be evidence-based and align with national guidelines, such as the Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain*. The AANA has many resources related to acute and chronic pain management which can be applied to patient care settings, such as [Chronic Pain Management Guidelines](#) and [Regional Anesthesia for Surgical Procedures and Acute Pain Management, Practice Considerations](#), and the AANA would be happy to serve as a resource on this effort.

- **A multimodal approach to pain management should be considered as part of the patient-specific treatment plan and can lessen the need for opioid use.**

For surgical pain, a preemptive, often multimodal, approach to acute pain management integrating regional anesthesia techniques has been shown to be advantageous in a wide array of surgical specialties. Preemptive analgesia may improve the patient's postoperative acute pain experience, minimize the transition to a chronic pain state and have a positive, long-term effect. The use of an enhanced recovery after surgery (ERAS) protocol, to include multimodal pain management, may reduce the patients' stress response to surgery, minimize use of opioids, and accelerate the return to normal daily function.

Chronic pain management may also incorporate a multimodal treatment approach. Non-pharmacologic treatment modalities may decrease pain and when appropriate should be considered as part of the plan of care. When a pharmacologic approach, including opioid medications, is used, the treatment should be tailored to the patient's level of pain, functionality, and response.

- **REMS should incorporate immediate release (IR) opioid medications.**

AANA recommends that the ER/LA Opioid Analgesics REMS be expanded to include IR opioids. IR opioids may be prescribed postoperatively and have the potential for addiction. Consistent, standardized clinician education and patient monitoring for the treatment of acute pain using IR opioids may mitigate opioid addiction or transition to ER/LA opioid formulations.

- **Engage with professional organizations, such as the AANA, to support all stakeholders' needs in the development of any standardized REMS resources and tools.**

Many physician and nursing organizations, patient advocacy groups, and governmental agencies share the common concern of increased opioid use, abuse, and deaths in the US. The AANA recommends that the FDA collaborate with all interested parties, including the AANA and relevant professional education, certification, and accrediting bodies, in the further refinement of the current ER/LA opioid REMS and any future resource or recommendation development (e.g., IR

opioid medications). Many clinicians, including CRNAs, regularly manage patients who suffer from acute and chronic pain. Engagement with various stakeholder groups will increase awareness of FDA's educational tools and resources and foster commitment to the common goal of more judicious use of opioids among all clinicians on the multidisciplinary patient care team.

We thank you for the opportunity to comment and further partner with the FDA on this important issue. Please do not hesitate to contact Lynn Reede, DNP, MBA, CRNA, FNAP, Senior Director, Professional Practice, at (847) 655-1136 or lreede@aana.com if you have any questions or comments.

Sincerely,

A handwritten signature in black ink that reads "Juan F. Quintana". The signature is written in a cursive, flowing style.

Juan F. Quintana, DNP, MHS, CRNA
AANA President

cc: Wanda O. Wilson, PhD, MSN, CRNA, AANA Executive Director/Chief Executive Officer
Lynn Reede, DNP, MBA, CRNA, FNAP, AANA Senior Director, Professional Practice