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Safe and effective
anesthesia



March 13, 2018

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

RE: FDA–2017–N–6502, Opioid Policy Steering Committee: Prescribing Intervention–Exploring a Strategy for Implementation; Public Hearing; Request for Comments

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments to the Opioid Policy Steering Committee regarding prescribing interventions. 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 52,000 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 recommendations in response to the following questions posed:

The Steering Committee requests input from the public on whether, in addition to, or in conjunction with the above described prescriber intervention, and to the extent consistent with its statutory authority, the Agency should consider requiring sponsors to create a system that utilizes a nationwide prescription history database to facilitate safe use of opioid analgesics.

A nationwide prescription history database is critical to facilitate safe use and prescribing of opioid analgesics. Access to a comprehensive medication history, integrated with the patient’s health history and evaluation, is important to patient safety and creation of a multimodal pain management plan that minimizes or eliminates the need to administer and prescribe opioids. Multimodal pain management, incorporating alternative therapies, may decrease or eliminate the need to administer or prescribe opioids for acute and chronic pain management.

CRNAs provide patient-centered acute and chronic pain management services that offer comprehensive pain management options to decrease or eliminate the need for opioids. When managing surgical pain, a preemptive multimodal approach, such as an enhanced recovery after surgery (ERAS) protocol, integrates regional anesthesia techniques, when appropriate, with non-opioid medications. Enhanced recovery pathways decrease variability of care to improve outcomes and has been shown to be advantageous in a wide array of surgical specialties to minimize or eliminate the use of opioids during the perioperative period to the patient's return home. Preemptive analgesia has been shown to improve the patient's postoperative acute pain experience for recovery and to minimize the risk of enduring pain that may trigger the transition to a chronic pain state. These same opioid-sparing practices can be utilized for non-surgical acute and chronic pain.

The proposed Opioid Analgesics REMS includes a Medication Guide and a Patient Counseling Document to educate patients. It also includes a "Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain" that contains information on counseling patients and caregivers about the safe use of opioid analgesics. Consistent with its statutory authority, should FDA require sponsors to take additional measures to ensure that health care providers, their patients, and patient caregivers and family members are educated on safe storage and disposal and the risks of misuse, abuse, and addiction associated with opioid analgesics (e.g., a public health campaign targeted at these groups)?

Prescribing and educating the patient on the proper use of non-opioid analgesics and a rescue opioid decreases the dose required and limits the amount of opioid prescribed, thus decreasing the risk of excess opioids available in the home for diversion. Clear verbal and written instructions given at discharge and when the prescription is dispensed should describe the safe storage of current medications and the proper disposal of unused medications.

A targeted public health campaign can raise awareness to educate patients and their families on the potential for opioid misuse and addiction. Any public health campaign can also educate patients on the alternatives to opioids, as many patients and healthcare providers may not be aware that non-pharmacologic and non-opioid options available to them for acute and chronic pain management. Many nursing and physician organizations, patient advocacy groups, and governmental agencies share the common concern of increased opioid use, abuse, and deaths in the US. The AANA encourages and participates in collaborative, interprofessional dialogue to improve clinician and public awareness of opioid misuse, abuse, and addiction. 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 clinicians.

Should the Agency consider additional measures intended to improve the safety of patient storage and handling of opioid analgesics?

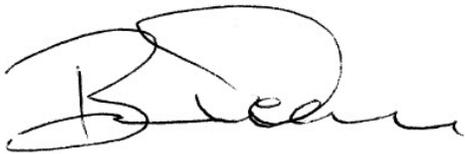
Decreasing the administration and prescription of opioids will improve safety. The opioid crisis is complex and requires a multipronged public health strategy across the healthcare system to address. There is significant opportunity to educate prescribers that integration of multimodal opioid-sparing pain management for all patients, not just surgical or chronic pain patients, decreases or eliminates the prescription of opioids in our communities and homes, thus helping mitigate the risk of opioid misuse, abuse, and addiction. Prescribers have opportunity to select the appropriate drugs that may or may not include opioids in the correct dose and amount to meet the unique pain needs of each patient. Clinicians must continue to understand each patient's unique pain experience and educate the patient and their caregiver(s) about reasonable pain expectations, thus presenting a realistic goal for pain and post-procedure pain

management. Facilities and pharmacies can look at novel new approaches to aid patients in storing and disposal of opioid medications. An example is providing a drug disposal packet, which turns unused prescriptions into a biodegradable gel.

In summary, patient-centered care is the hallmark of nurse anesthesia practice. CRNAs will continue to play a significant role in addressing the widespread opioid drug crisis and engage in clinical practice that eliminates or decreases the use of opioids through multimodal pain management techniques. In addition to the elements described in the Blueprint, patient and caregiver education should include age- and condition-appropriate information and establishment of realistic pain goals. Non-opioid pharmacologic and non-pharmacologic pain management modalities should be discussed to minimize the need and use of opioids.

The AANA and its members look forward to collaborating with our healthcare colleagues to develop and implement multimodal pain management initiatives that reduce our nation's dependence on opioids. 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, Chief Clinical Officer, at (847) 655-1136 or lreede@aana.com if you have any questions or comments.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Weiner". The signature is fluid and cursive, with a large, stylized initial "B" and a long, sweeping underline.

Bruce A. Weiner, DNP, MSNA, CRNA
AANA President

cc: Randall D. Moore, DNP, MBA, CRNA, AANA Chief Executive Officer
Lynn Reede, DNP, MBA, CRNA, FNAP, AANA Chief Clinical Officer