July 10, 2017

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

RE: FDA–2017–N–1094, Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics-Exploring the Path Forward; Public Workshop; Request for Comments

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments on health care provider training related to pain management and the safe use of 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 working collaboratively toward comprehensive solutions to curb the opioid epidemic in the US.

AANA makes the following recommendations:

1. Acute and chronic pain management should utilize a multimodal, patient focused multidisciplinary team approach
2. Invite the AANA to collaborate in the development education recommendations for pain management and safe use of opioid analgesics
3. Provider education should emphasize a multimodal approach to pain management
4. Patient education for engagement in their plan of care should be a central component of acute and chronic pain management and should be emphasized in an education curriculum
5. All healthcare providers, including CRNAs, should be allowed to practice to their full scope of practice, education and licensure

Background of AANA and CRNAs

The AANA is the professional association representing more than 50,000 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 (APRNs) who personally administer more than 40 million anesthetics to patients each year in the US. 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.

Acute and chronic pain management should utilize a multimodal, patient focused multidisciplinary team approach

The AANA supports healthcare provider and patient 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. Promotion of collaborative, multidisciplinary clinician and patient education, research, and practice will have a positive impact on patients who seek and increasingly rely on acute and chronic pain management services.

Any national education framework should be in the form of recommendations that are adaptable to profession- and practice-specific requirements. Interprofessional education should also cover topics such as identification of individuals at risk of opioid abuse, signs of drug seeking behavior, acute and chronic pain management options for patients with substance use disorder or in recovery, criteria for referral to medication assisted treatment and for transfer of the patient to a specialty pain care provider. Patient education recommendation regarding multimodal pain management alternatives and related therapy should be developed to increase patient awareness for make best decisions for their plan of care for safe or no opioid use.

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 and substance use disorder which can be applied to patient care settings, such as Addressing Substance Use Disorder for Anesthesia Professionals, Chronic Pain Management Guidelines and Regional Anesthesia for Surgical Procedures and Acute Pain Management.

Many nursing and medical organizations, patient advocacy groups, and governmental agencies share the common concern of increased opioid use, abuse, and deaths in the US. The AANA encourages the use of federal and non-federal partnerships, including nursing and medical professional organizations, including the AANA, FDA, CDC, American Nurses Association, Substance Abuse and Mental Health Services Administration, and SmartTots, to support a collaborative, multidisciplinary effort in the refinement of healthcare provider education models surrounding pain management and safe opioid use. The AANA welcomes the opportunity to serve as member of the multidisciplinary collaborative.

Invite the AANA to collaborate in the development education recommendations for pain management and safe use of opioid analgesics

The AANA recognizes that solving the opioid drug epidemic is an integral part of healthcare reform, and we are committed to collaboratively working toward a common solution to this issue. CRNAs provide holistic anesthesia and pain related care for patients of all ages in all communities across the US. From entry into practice education and certification through ongoing education and skills acquisition throughout their career, CRNAs provide robust, patient-centered acute and chronic pain management services. The Council on Accreditation of Nurse Anesthesia Programs (COA) requires acute and chronic pain management content in the curriculum of the 116 accredited nurse anesthesia education programs. The AANA, State Nurse Anesthetist Associations, universities and other stakeholders play an active role in CRNA education and professional development, reinforcing how to safely integrate and, when appropriate, eliminate opioids in acute and chronic pain management. Professional development opportunities include educational webinars, online continuing education, conferences, and peer reviewed publications.

CRNAs have for many decades and continue to provide access to acute and chronic pain management services in their community. To continue the profession’s excellence, the AANA offers advanced pain management workshops that include comprehensive patient focused, holistic, multimodal pain management education content and skills, and also offers content for safe prescribing and management of the risk of opioid dependence and
disorder. Consistent with the recommendation to increase access to pain management services in the 2011 National Academies of Medicine report “Relieving Pain in America,” the AANA is partnering with academia and the COA to offer accredited fellowships in Acute Surgical Pain Management and Advanced Pain Management. The National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA) offers a voluntary nonsurgical pain management (NSPM) subspecialty certification for CRNAs.

In addition to the education efforts by the AANA, the FDA could also leverage efforts developed by the greater APRN community. The AANA, along with the American Association of Colleges of Nursing and other APRN organizations, developed a joint online educational series that serves as a resource for practicing nurses, faculty, and students on the current need to address opioid use disorder and overdose, integration of timely content into education program curricula, and the CDC’s opioid prescribing guidelines.

To further interdisciplinary collaboration, AANA has recently endorsed the Emergency Nurses Association and the International Nurses Society on Addictions joint position statement, Substance Use Among Nurses and Nursing Students.

**Provider education should emphasize a multimodal approach to pain management**

Pain is a personal experience that, if left undertreated or mismanaged, can radically change an individual’s quality of life and impact important relationships. At a time when there is an increase of patients suffering from chronic pain, CRNAs are poised to be part of the solution. As members of the interprofessional pain management team and direct providers of pain management services, CRNAs are uniquely skilled to provide both acute and chronic pain management in a patient-centered, compassionate and holistic manner. 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 or eliminate use of opioids, and accelerate the return to normal daily function. As AANA highlights in the position statement, A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment, “Management occurs from pre-procedure to post discharge using opioid sparing techniques such as regional anesthesia, peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures. ERAS pathways use multimodal pain management to reduce the use of opioids and shorten overall hospital length of stay. Careful assessment and treatment of acute pain, which may include appropriate opioid prescribing, can decrease the risk of acute pain transitioning to chronic pain or the probability of the development of opioid dependency and abuse.”

Chronic pain management may also incorporate a patient specific, 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.

**Patient education for engagement in their plan of care should be a central component of acute and chronic pain management and should be emphasized in an education curriculum**

Patient-centered care offers the patient greater transparency, understanding, and engagement in their care for desired outcomes. 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 discuss the risk of dependence and opioid use disorder, as well as enter into a pain management treatment agreement with the patient.

All healthcare providers, including CRNAs, should be allowed to practice to their full scope of practice, education and licensure

To meet the increasing need for pain management services, there needs to be a comprehensive effort to remove artificial, unnecessary barriers at the practice, state and federal levels. CRNAs are appropriately educated and trained to handle every aspect of the delivery of anesthesia services including general and regional anesthesia and acute, chronic, and interventional pain management services. The ability for CRNAs and all healthcare providers to care for patients to their full scope of practice will increase the excellence and availability of important, multidisciplinary pain management services for all patients. Unintended consequences of any initiative or policy limiting patients’ access to care must be considered and addressed.

We thank you for the opportunity to comment and further partner with the FDA on prescriber education initiatives. 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,

Cheryl Nimmo, DNP, MSHSA, 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