American Association of
NURSE ANESTHESIOLOGY

April 7, 2022

Theresa Wells
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Ms. Wells,

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on the draft guidance entitled ‘‘Development of Non-Opioid Analgesics for Acute Pain.” The AANA shares the U.S. 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. Our comments include the following:



## I. Background of the AANA and CRNAs

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 59,000 CRNAs and SRNAs, representing about 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 50 million anesthetics to patients each year in the United States and are among the nation's most trusted professions according to Gallup[1]. Nurse anesthetists have provided anesthesia in the United States for 150 years, and high-quality, cost-effective CRNA services are in high demand. CRNAs are Medicare Part B providers and since 1989 have billed Medicare directly for 100 percent of the physician fee schedule amount for services. CRNAs also play an essential role in assuring that rural America has access to critical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many necessary procedures.

[1] Gallup “U.S. Ethics Ratings Rise for Medical Workers and Teachers (December 22, 2020), https://news.gallup.com/poll/328136/ethics-ratings-rise-medical-workers-teachers.aspx

CRNAs are involved in every aspect of anesthesia services including a pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery and recovery. CRNAs also provide acute, chronic, and interventional pain management services. 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. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Services. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

Numerous peer reviewed studies have shown that CRNAs are safe, high quality and cost effective anesthesia professionals who should practice to the full extent of their education and abilities. According to a May/June 2010 study published in the journal *Nursing Economic$*, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.[2] An August 2010 study published in *Health Affairs* showed no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.[3] Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration, the internationally recognized authority on evidence-based practice in healthcare.[4] Most recently, a study published in *Medical Care* (June 2016) found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.[5]

The importance of CRNA services in rural areas was highlighted in a recent study which examined the relationship between socioeconomic factors related to geography and insurance type and the distribution of anesthesia provider type.[6] The study correlated CRNAs with lower-income populations and correlated anesthesiologist services with higher-income populations. Of particular importance to the implementation of public benefit programs in the U.S., the study also showed that compared with anesthesiologists, CRNAs are more likely to work in areas with lower median incomes and larger populations of citizens who are

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[2] Paul F. Hogan et al., "Cost Effectiveness Analysis of Anesthesia Providers." *Nursing Economic$.* 2010; 28:159-169. http://www.aana.com/resources2/research/Documents/nec_mj_10_hogan.pdf

[3] B. Dulisse and J. Cromwell, "No Harm Found When Nurse Anesthetists Work Without Physician Supervision." *Health Affairs*. 2010; 29: 1469-1475. http://content.healthaffairs.org/content/29/8/1469.full.pdf

[4] Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients. *Cochrane Database of Systematic Reviews* 2014, Issue 7. Art. No.: CD010357. DOI: 10.1002/14651858.CD010357.pub2. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010357.pub2/abstract

[5] Negrusa B et al. Scope of practice laws and anesthesia complications: No measurable impact of certified registered nurse anesthetist expanded scope of practice on anesthesia-related complications. *Medical Care* June 2016, http://journals.lww.com/lww-medicalcare/Abstract/publishahead/Scope_of_Practice_Laws_and_Anesthesia.98905.aspx.

[6] Liao CJ, Qurashi JA, Jordan LM. Geographical Imbalance of Anesthesia Providers and its Impact on the Uninsured and Vulnerable Populations. Nurs Econ. 2015;33(5):263-270. http://www.aana.com/resources2/research/Pages/NursingEconomics2015.aspx

unemployed, uninsured, and/or Medicaid beneficiaries.[7] This information highlights the importance of CRNAs who provide high-quality, evidence-based care to millions of Americans living and working in rural and underserved areas. Allowing them to participate in rural emergency hospitals will increase needed access to care for patients who live in these areas.

## II. Use of Non-Opioid Alternatives, Such as Multi-Modal Pain Management ERAS® Protocols, Do Lead to a Decrease in Prescription Opioid Use and Addiction

The AANA appreciates the opportunity to comment on strategies CRNAs use to more effectively address the opioid epidemic and we also support the agency's goal of engaging healthcare providers to address both substance use disorder and mental health needs of individuals, families, and communities. CRNAs have been on the front lines of developing novel non-opioid based treatments for both chronic and acute pain and we support maximum flexibility in allowing pain treatment plans that rely on the clinical judgment of the practitioner directing care.

As a main provider of pain management services in all types of settings, CRNAs are uniquely skilled to provide both acute and chronic pain management in a patient centered, compassionate and holistic manner across the pain continuum in all clinical settings.[8] Furthermore, the approach that CRNA pain management practitioners employ when treating their chronic pain patients may reduce the reliance on opioids as a primary pain management modality, thus aiding in the reduction of potential adverse drug events related to opioids.

As the risk of opioid dependence and addiction begins with the first exposure, we recommend that FDA promote comprehensive multimodal pain management and ERAS® protocols as a non-opioid alternative to treat pain in all clinical settings. ERAS® is a patient-centered, evidence-based, pain management strategy employed by CRNAs to reduce the need for opioids, improve patient outcomes and reduce costs.[9] Using specific protocol-driven enhanced recovery after surgery pathways improves patient outcomes by reducing the patient's stress response to surgery, shortening the overall hospital length of stay, and accelerating the return to normal daily function.

CRNAs play a critical role by ensuring proper anesthesia services management which can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings. Interventional pain management involves the use of invasive techniques, such as joint injections, nerve blocks, spinal cord stimulation, and other procedures, to reduce pain. Such techniques are best performed in the context of a multimodal treatment regimen, including physical therapy to maximize functional restoration. There has

[7] Liao, op cit.

[8] AANA Chronic Pain Management Guidelines, November 2021, available at: https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/professional-practice-manual/chronic-pain-management-guidelines.pdf, AANA Regional Anesthesia and Analgesia Techniques - An Element of Multimodal Pain Management Guidelines, https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1_6, and AANA Guidelines on A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/a-holistic-approach-to-pain-management-integrated-multimodal-and-interdisciplinary-treatment.pdf?sfvrsn=f40049b1_4

[9] AANA Enhanced Recovery After Surgery, http://www.future-of-anesthesia-care-today.com/pdfs/eras-info.pdf.

been a significant increase in the volume of certain interventional procedures over the past 10 years, much of it focused on low back and neck pain with or without radiation to the hip and other lower extremities.[10]

Using a multimodal approach and specific protocol-driven ERAS® pathways improves patient outcomes by reducing the patient's stress response to surgery, shortening the overall hospital length of stay, and accelerating the return to normal daily function. The anesthesia professional plays a pivotal role in patient/family education by engaging the patient as an active participant in his or her care and the recovery process.[11] Anesthesia professionals continue to build on these activities throughout the Prehospital/Preadmission Phase through patient assessment and evaluation to identify unique elements of the patient's health, pain and anesthesia history that may require modification of the ERAS® pathway to coordinate development of the plan of care with the patient and their primary care and specialty team, as appropriate. The patient's pain management plan of care begins pre-procedure and continues through post-discharge using opioid-sparing techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures. Collaboration with the patient's advanced pain management team and utilizing multi-modal pain management strategies can improve outcomes, especially for patients with difficult to control pain (e.g., chronic pain patient, substance use disorder).[12,13,14]

The evidence is quite clear that careful assessment, evaluation, and treatment of acute pain may prevent access to unused opioids and development of opioid dependency and abuse in the following AANA documents: Chronic Pain Management Guidelines (2021); Analgesia and Anesthesia for the Substance Use Disorder Patient (2019); Ketamine Infusion Therapy for Psychiatric Disorders and Chronic Pain Management (2019); Regional Anesthesia and Analgesia Techniques - An Element of Multimodal Pain Management (2018); A Holistic Approach to Pain Management Integrated Multimodal and Interdisciplinary Treatment (2016); Enhanced Recovery after Surgery, Considerations for Pathway Development and Implementation (2017). In addition, organizations such as SOFA (the Society for Opioid Free Anesthesia), a nonprofit organization formed to research, promote and educate anesthesia professionals and the general public on opioid free pain management techniques, may also have additional data regarding evidence-based non-opioid pain management therapies used in the outpatient and ASC setting. All of this evidence shows that CRNAs play a critical role by ensuring proper anesthesia services management which can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings.

The AANA appreciates the opportunity to comment to this guidance. We thank you for the opportunity to comment and further partner with the FDA on development of non-opioid analgesics for acute pain

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[10] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse; Phillips JK, Ford MA, Bonnie RJ, editors. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. Washington (DC): National Academies Press (US); 2017 Jul 13. 2, Pain Management and the Intersection of Pain and Opioid Use Disorder. Available from: https://www.ncbi.nlm.nih.gov/books/NBK458655/

[11] Brady KM, Keller DS, Delaney CP. Successful Implementation of an Enhanced Recovery Pathway: The Nurse's Role. *AORN J.* Nov 2015;102(5):469-481.

[12] Vadivelu N, Mitra S, Kaye AD, Urman RD. Perioperative analgesia and challenges in the drug-addicted and drug-dependent patient. *Best Pract Res Clin Anaesthesiol.* Mar 2014;28(1):91-101.

[13] Shah S, Kapoor S, Durkin B. Analgesic management of acute pain in the opioid-tolerant patient. *Curr Opin Anaesthesiol.* Aug 2015;28(4):398-402.

[14] Pulley DD. Preoperative Evaluation of the Patient with Substance Use Disorder and Perioperative Considerations. *Anesthesiol Clin.* Mar 2016;34(1):201-211.

initiatives. Should you have any questions regarding our comments, please feel free to contact the AANA Senior Director of Federal Government Affairs, Ralph Kohl, at 202-741-9080 or rkohl@aanadc.com.

Sincerely,

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AANA President

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