August 8, 2019

Brenda Destro
Deputy Assistant,
U.S. Department of Health and Human Services
Office of the Assistant Secretary of Planning and Evaluation
Office of Science and Data Policy
Attn: EPAEDEA Report Feedback
200 Independence Ave, SW, Room 434E
Washington, D.C. 20201

RE: Request for Information: Ensuring Patient Access and Effective Drug Enforcement

Dear Ms. Destro:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments to the Department of Health and Human Services’ Request for Information (RFI) on Ensuring Patient Access and Effective Drug Enforcement. The AANA is firmly committed to working with the agency and other healthcare stakeholders to help achieve our common goals of promoting choice and competition, increasing access to the highest quality healthcare, reducing regulatory burdens on providers, and making healthcare more affordable for all Americans. Our comments focus providing information on the availability of medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed. The AANA makes the following comments and recommendations:

I. Who CRNAs Are

II. CRNAs Use a Multi-Modal Pain Management Approach which may Reduce Patient Need for and Reliance on Opioids

III. Acute and Chronic Pain Management Education Should Utilize a Multimodal, Patient Focused Multidisciplinary Team Approach

IV. Invite the AANA to Collaborate in the Development of Education Recommendations for Pain Management and Safe Use of Opioid Analgesics
V. Patient Education for Engagement in their Plan of Care should be a Central Component of Acute and Chronic Pain Management

VI. Ensure That Educational Efforts Are Harmonized Across all Specialty and Care Settings to Minimize Variation in Care Across the Patient’s Healthcare Experience

VII. Ensure that Prescriber Education and Training Efforts Extend to All Members of the Multidisciplinary Team

VIII. Support Increased Patient Access to Safe, Responsible use of Medication Assisted Treatment (MAT) for the Comprehensive Treatment of Substance and Opioid Use Disorder

IX. Our Recommendations for Creating a Substance Use and Drug Diversion Policy

I. Who CRNAs Are

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 53,000 CRNAs and SRNAs, representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 45 million anesthetics to patients each year in the United States. 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 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. 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. CRNAs 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 and affording these facilities the capability to provide many necessary procedures.

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.1 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.2 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.3 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.4

II. CRNAs Use a Multi-Modal Pain Management Approach which may Reduce Patient Need for and Reliance on Opioids

The AANA shares the agency’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 United States. As a main provider of pain management services and as APRNs, 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 (e.g., hospitals,

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1 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
ambulatory surgical centers, offices, and pain management clinics). Furthermore, the holistic 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.

Suffering from acute and chronic pain is a personal experience that, if left undertreated or mismanaged, can radically change an individual’s quality of life and impact important relationships. Utilizing a patient-centered, multidisciplinary, multimodal treatment approach to pain management may reduce the reliance on opioids as a primary pain management modality, thus helping curb the prescribed opioid epidemic. The Centers for Disease Control and Prevention reports that the problem with misuse of prescription drugs is related to high levels of prescribing of such medications – for example, in 2016 prescribers wrote 66.5 opioid and 25.2 sedative prescriptions for every 100 Americans. Acute and chronic pain are best treated and managed by an interdisciplinary team that actively engages the patient to diagnose and manage their pain for improved well-being, functionality, and quality of life.

As anesthesia professionals, our goal is to decrease or eliminate the need for opioids by collaborating with the patient and the interdisciplinary team on a comprehensive plan for pain relief known as enhanced recovery after surgery (ERAS®). According to a recent AANA position statement, *A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment*, “CRNAs integrate multimodal pain management as an element of enhanced recovery after surgery (ERAS®) protocols to manage pain. Management begins pre-procedure and continues after discharge by using opioid sparing techniques such as regional anesthesia, peripheral nerve blocks, non-pharmacological approaches, and non-opioid based pharmacologic measures. 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 development of opioid dependency and abuse.”

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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. 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. The evidence is quite clear that careful assessment, evaluation, and treatment of acute pain, with appropriate prescribing of an opioid, may prevent access to unused opioids and development of opioid dependency and abuse. 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.

Many patients rely on CRNAs as their primary pain care specialist. CRNAs manage chronic pain in a compassionate, patient-centered, holistic manner, using a variety of therapeutic, physiological, pharmacological, and interventional modalities. The purpose behind this approach is to reduce the reliance on opioids as a primary pain management modality, thus aiding in the reduction of potential adverse drug events related to opioids, including addiction. In developing a plan of care for the patient, CRNAs, evaluate the patient, obtain a complete patient history, order and review necessary diagnostic testing, and assess the patient’s psychological and emotional state. Non-pharmacologic pain mitigation techniques are often employed in the treatment of chronic pain and considered as part of the care plan. These techniques may include patient education regarding behavioral changes that can decrease pain, such as weight loss, smoking cessation, daily exercise, stretching, and physical or chiropractic therapy. Such techniques may not be sufficient when used alone but have significant benefit when they are used in a complementary manner with other therapies.

III. Acute and Chronic Pain Management Education 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 Abuse Disorder for Anesthesia Professionals and Chronic Pain Management Guidelines.

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, the CDC, the Food and Drug Administration, the American Nurses Association, the 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.

IV. Invite the AANA to Collaborate in the Development of Education Recommendations for Pain Management and Safe Use of Opioid Analgesics

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. Prescriber education is also essential to curbing the opioid epidemic, and
CRNAs are also well-positioned to educate clinicians and patients alike on the minimization or elimination of prescribed opioids for both acute and chronic pain management. The National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA) offers a voluntary nonsurgical pain management (NSPM) subspecialty certification for CRNAs. The Council on Accreditation of Nurse Anesthesia Educational Programs (COA) requires acute and chronic pain management content in the curriculum of the 120-accredited nurse anesthesia educational programs, and for continued learning, the AANA offers CRNAs a continuum of educational resources for pain management practice. These resources include advanced acute and chronic pain management workshops for CRNAs to enhance their skills to improve quality of life and to mitigate complications associated with opioid use and misuse. 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. In addition, Texas Christian University, the University of South Florida, and Middle Tennessee School of Anesthesia offer fellowships to CRNAs seeking to further specialize in this growing field. The AANA also offers an Online Continuing Education pain management educational series that includes a lecture on non-opioid anesthesia for substance use disorder (SUD) patients, to increase understanding of the acute and recovery phases of SUD with knowledge of how to create an anesthesia care plan that supports the patient’s recovery efforts. The AANA also offers an online continuing education lecture on Opioid Prescribing Guidelines: A Virtual Environment Gaming Scenario, which teaches how technique and selection of specific corticosteroids used for epidural injection can manage chronic back pain and radicular pain effectively while minimizing risk that leads to unnecessary harm.

In addition to the education efforts by the AANA, the agency 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, the AANA has endorsed the

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Emergency Nurses Association and the International Nurses Society on Addition joint position statement, Substance Use Among Nurses and Nursing Students.

V. **Patient Education for Engagement in their Plan of Care should be a Central Component of Acute and Chronic Pain Management**

Patient-centered care offers the patient greater transparency, understanding, and engagement in their care for desired outcome. 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.

VI. **Ensure That Educational Efforts Are Harmonized Across all Specialty and Care Settings to Minimize Variation in Care Across the Patient’s Healthcare Experience**

As HHS develops and implements programs for prescriber education and training, the AANA recommends that such efforts be inclusive of all specialties across all types of healthcare settings to optimize safe and appropriate use of opioids for chronic pain. As there is no bright line between acute and chronic pain, opioid use disorder may originate or become evident in many care settings. We believe that being prescriber-inclusive will minimize variation in care across the patient’s healthcare experience.

The AANA stands ready to work with the agency to support its efforts. Please consider the valuable contribution that APRNs and specifically CRNAs will offer the interprofessional teams who create policy and resources necessary to make this guideline the standard for pain management. As APRNs, CRNAs are uniquely skilled to deliver pain treatment in a compassionate and holistic manner. By virtue of education and individual clinical experience and competency, a CRNA may practice chronic pain management utilizing a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of pain. The AANA has many evidence

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based resources related to acute and chronic pain management considerations and guidelines which can guide patient care settings, such as *Chronic Pain Management Guidelines* and *Regional Anesthesia for Surgical Procedures and Acute Pain Management, Practice Considerations*. CRNA knowledge and practice experience will prove invaluable as the agency works to develop and implement provider education and training programs.

**VII. Ensure that Prescriber Education and Training Efforts Extend to All Members of the Multidisciplinary Team**

The AANA recognizes that acute and chronic pain management involves a multidisciplinary approach, and we believe that HHS’s efforts should extend to all members of the multidisciplinary team and be aligned with national guidelines. Because patients see many qualified healthcare professionals, all healthcare education programs for professional disciplines of nursing, medicine, and other healthcare professions are needed to prepare pain management experts and leaders. Therefore, we ask that HHS ensure that efforts do not preclude clinicians, such as CRNAs, from educational opportunities. One potential issue that could arise without proper provider education would be clinicians who are not appropriately educated or have misinterpreted chronic pain guidelines. For example, if they have taken the guidelines “too far”, are not appropriately tapering medications or managing patients, or are not prescribing opioids when it is clinically appropriate to do so.

We also ask that prescribing education be comprehensive and provider neutral. As is recognized in the National Academies of Medicine’s report entitled *The Future of Nursing: Leading Change, Advancing Health*, APRNs, including CRNAs, should practice to the full extent of their education and training. However, leading physician subspecialty organizations in pain management research, practice guideline development, and education have used economic and advocacy measures to exclude other clinical providers from contributing to the pain management team. Patient access to care, diagnosis, treatment, and quality of life may be impacted when CRNA scope of practice is limited by physician societies through constrained scope of practice statute, facility privileges, or educational and training opportunities.

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11 National Academies of Medicine, op cit. p. 9
In many rural and frontier areas, CRNAs often are the only health care professionals trained in pain management in these communities. Without CRNAs to provide chronic pain management services, patients in vast rural and frontier areas would lose access to vital treatment, which could result in poor healthcare outcomes, lower quality of life, and unnecessary costs to patients and the healthcare system. According to a 2012 analysis by the Lewin Group of four case studies based on the real life situations of four individuals living in rural communities representing different geographic locations throughout the U.S., the direct medical costs of alternatives such as surgery or nursing home care range between 2.3 times to more than 150 times the cost of a CRNA providing these services in the community.\(^\text{12}\)

Furthermore, a report issued in April 2015 by the Federal Trade Commission (FTC), *Competition and the Regulation of Advanced Practice Registered Nurses*, underscores the point that for CRNAs and other APRNs, “even well intentioned laws and regulations may impose unnecessary, unintended, or overbroad restrictions on competition, thereby depriving health care consumers of the benefits of vigorous competition.”\(^\text{13}\) Therefore, we recommend that the HHS ensure that educational and training opportunities are inclusive of all clinicians. We request that the agency engage with the FTC to prevent efforts to block access to prescriber education. In the interest of patients and the public, the education, regulation, and reimbursement of each member of the pain management team should allow the team to practice to the full extent of their education and training.

**VIII. Support Increased Patient Access to Safe, Responsible use of Medication Assisted Treatment (MAT) for the Comprehensive Treatment of Substance and Opioid Use Disorder**

The AANA supports increased patient access to safe, responsible use of MAT for the comprehensive treatment of substance and opioid use disorder. The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act was enacted into law on October 24, 2018.\(^\text{14}\) This new law represents a major bipartisan victory and the strongest response yet to the opioid crisis. One of the major provisions of the bill is a section that would allow CRNAs

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and other advanced practice registered nurses (APRNs) to obtain a waiver from the Drug Enforcement Agency (DEA) to prescribe medication-assisted treatments (MATs), such as buprenorphine, to individuals suffering from opioid addiction. The law allows for a five-year pilot program for most APRNs, including CRNAs, and is an acknowledgment of the CRNA’s clinical expertise in pain management. This continues to allow CRNAs to be uniquely qualified to help eradicate the opioid epidemic that is tearing at the fabric of our nation.

The AANA recognizes that CRNAs have an ethical obligation and professional responsibility for self-assessment of their knowledge and skills related to the comprehensive treatment of substance use disorders (SUD) and related somatic and/or mental health conditions; developing and maintaining clinical competencies related to the care of individuals receiving MAT; and obtaining any necessary continuing education beyond the required 24 hours of training necessary in order to provide safe behavioral healthcare involving MAT. CRNAs provide MAT in accordance with their professional state specific scope of practice, state and federal laws and regulations, and their respective facility’s institutional policies. CRNAs may prescribe MAT in states where they have prescriptive authority, consistent with state law.

Anesthesia professionals may encounter more patients with substance use disorder, on medication-assisted treatment or in abstinent recovery who require surgery and procedures that involve analgesia and anesthesia. Considerations include preanesthesia assessment and evaluation, developing a plan of care in collaboration with the patient and the interdisciplinary healthcare team, deploying an opioid-sparing multimodal approach to managing pain, and responsible oversight that includes safe prescribing practices and discharge planning to provide a patient-centered approach to care.

X. Our Recommendations for Creating a Substance Use and Drug Diversion Policy

We recommend that facilities address an important element of patient and provider safety through a comprehensive program and non-discriminatory policy that includes education to identify signs and

behaviors and strategies to minimize drug diversion and substance use disorder. Substance use disorder should not be ignored, for patient and provider safety. The policy should apply to and communicated to employed staff, contracted providers and students training at clinical sites.

A substance use and drug diversion policy that includes the following elements may discourage diversion and substance use, identify possible substance use to intervene to prevent death, and promote the well-being of employees and patients:

- Promote healthy behaviors to support professional responsibility to be fit for duty.
- Build awareness of individual risk factors.
- Identify behaviors and symptoms of substance use disorder and drug diversion.
- Acknowledge harmful consequences of substance use disorder, drug diversion and impairment in the workplace.
- Utilize drug diversion prevention strategies.
- Optimize drug testing modalities (e.g., pre-employment, random, for-cause) to include testing for anesthesia drugs.
- Outline safe reporting processes of impaired individuals through the appropriate chain of command.
- Facilitate a safe intervention for appropriate treatment evaluation.
- Address specific treatment considerations for anesthesia professionals.
- Clarify reporting obligations to authorities and/or licensing boards.
- Require specific criteria before consideration for reentry into practice.
- Assist with safe transition back to anesthesia practice that includes a return to work contract and monitoring plan.
- Maintain a safe, stigma-free workplace environment18.

The AANA appreciates this opportunity to comment on this RFI. CRNAs are vital to resolving the challenges facing our nation’s healthcare system and we look forward to a continued partnership with the agency to show the important role CRNAs can have in achieving the main goals of meaningful reform, reducing health care costs, increasing health care competition and improving access to the highest quality healthcare. Should you have any questions, please feel free to contact the AANA Senior Director of Federal Government Affairs, Ralph Kohl, at 202-741-9080 or rkohl@aanadc.com.

Sincerely,

[Signature]

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18 AANA Position Statement, “Addressing Substance Use Disorder for Anesthesia Professionals”
https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/addressing-substance-use-disorder-for-anesthesia-professionals.pdf?sfvrsn=ff0049b1_4
Garry, Brydges, PhD, DNP, MBA, CRNA, ACNP-BC, FAAN
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Cc: Randall Moore II, DNP, MBA, CRNA, AANA CEO
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