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February 12, 2018

The Honorable Orrin Hatch
Chairman
US Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
US Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

RE: Request for Information – Senate Finance Committee Request for Information on Policy Recommendations for the Medicare and Medicaid Programs Regarding the Opioid Crisis

Dear Chairman Hatch and Ranking Member Wyden:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments on your request for information regarding barriers to opioid treatment in the federal health programs and opportunities to prevent opioid abuse among their beneficiaries. The AANA shares the committee'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. The AANA makes the following comments and recommendations:

I. Multi-Modal Pain Management CRNA Services Can Help Diminish the Opioid Epidemic

- **CRNAs Provide Safe, High Quality and Cost-Effective Healthcare**
- **CRNAs are an Underutilized Resource in Combating the Opioid Epidemic**
- **Should the Committee and CMS Address the Opioid Epidemic through Prescriber Education, Invite the AANA to Collaborate in the Development of Educational Recommendations for Pain Management and Safe Use of Opioid Analgesics**

II. Our Recommendations to Remove Barriers CRNAs Face in Helping to Solve the Opioid Crisis

- **Remove Barriers to the Use of Medically Necessary CRNA Pain Management Services**
- **Reduce Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities**

- **Remove from Subregulatory Guidance the Exclusion of Practitioners Who are Not Physicians from Serving on Medicare Carrier Advisory Committees**

I. Multi-Modal Pain Management CRNA Services Can Help Diminish the Opioid Epidemic

A. CRNAs Provide Safe, High Quality and Cost-Effective Healthcare

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 52,000 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 approximately 43 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]

B. CRNAs are an Underutilized Resource in Combating the Opioid Epidemic

The AANA shares the Committee'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, with CRNAs playing a key role in the process. Suffering from chronic and acute pain is a personal experience that, if left undertreated or mismanaged, can radically change an individual's quality of life and impact important relationships. The AANA believes that one method to help treat chronic and acute pain, while providing the maximum benefit to the patient that will help prevent reliance on opioids, is to utilize a patient-centered, multidisciplinary, multimodal treatment approach to pain management as a primary pain management modality. Acute and chronic pain is best treated and managed by an interdisciplinary team that actively engages with the patient to diagnose and manage their pain for improved well-being, functionality, and quality of life. As members of the interdisciplinary team, CRNAs are well positioned to provide holistic, patient-centered, multimodal pain treatment and management across the continuum of pain and in all clinical

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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

[2] 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

[3] 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

[4] 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.

settings (e.g., hospitals, ambulatory surgical centers, offices, and pain management clinics). [5]

As a main provider of pain management services, CRNAs are uniquely skilled to provide both acute and chronic pain management in a patient centered, compassionate and holistic manner. As anesthesia professionals, CRNAs are qualified pain practitioners who work in many practice settings to treat patients suffering from a wide range of acute and chronic pain conditions. Many patients rely on CRNAs as their primary pain specialist. CRNA chronic pain management practitioners are able to minimize the use of opioids to address chronic pain through the use of a multimodal approach that includes pharmacologic and non-pharmacologic pain mitigation strategies. 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. This is shown in a recent study which calls for an increased number of nursing pain specialists "to not only implement aggressive acute pain care to prevent chronic pain but also to effectively treat chronic pain with evidence-based integrative therapies that include multimodal analgesia, interventional techniques, and complementary and alternative approaches to pain management."[6]

In developing the plan of care for the patient, CRNAs obtain patient history, evaluate the patient, 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 therapies may not be sufficient when used alone, but they have significant benefit when they are used in a complementary manner with other therapies.

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, or ERAS[7]. Because CRNAs personally administer more than 43 million anesthetics to patients each year in the United States, their services are crucial to the successful

5 AANA Chronic Pain Management Guidelines, September 2014, available at: http://www.aana.com/resources2/professionalpractice/Pages/Chronic-Pain-Management-Guidelines.aspx.

[6] Schoneboom B et al. Answering the call to address chronic pain in military service members and veterans: Progress in improving pain care and restoring health. *Nursing Outlook* June 2016.

[7] AANA. Enhanced Recovery. www.aana.com/enhancedrecovery.

development and implementation of techniques such as anesthesia ERAS programs. CRNAs and other anesthesia professionals play an integral role in these episodes of care as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings.[8] Conversely, research shows that suboptimal care in the preoperative, intraoperative, or postoperative phases of surgery may compromise care, resulting in poor patient outcomes and unnecessarily higher healthcare costs.[9][10]

For surgical pain, using 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 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. Though individual elements of an ERAS pathway are beneficial, implementation and compliance with patient appropriate elements of a comprehensive pathway across the entire perioperative continuum have been shown to improve outcomes.[11]

By virtue of education and individual clinical experience and competency, a CRNA may also practice chronic pain management utilizing a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of pain. From entry into practice education and certification through ongoing education and skills acquisition throughout their

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[8] See for example Rice AN, Muckler VC, Miller WR, Vacchiano CA. Fast-tracking ambulatory surgery patients following anesthesia. J Perianesth Nurs. Apr 2015;30(2):124-133. Also see Kimbrough CW et al. Improved Operating Room Efficiency via Constraint Management: Experience of a Tertiary-Care Academic Medical Center. *Journal of the American College of Surgeons* 2015; 221: 154-162.

[9] Miller TE, Roche AM, Mythen M. Fluid Management and Goal-Directed Therapy as an Adjunct to Enhanced Recovery After Surgery (ERAS). *Canadian Journal of Anesthesia* 2015; 62 (2)" 158-168.

[10] See for example Boulind CE, Yeo M, Burkill C, et al. Factors predicting deviation from an enhanced recovery programme and delayed discharge after laparoscopic colorectal surgery Colorectal Dis. 2011;14:103-110; Miller TE, Thacker JK, White WD, et al. Reduced length of hospital stay in colorectal surgery after implementation of an enhanced recovery protocol. Anesth Analg. May 2014;118(5):1052-1061; and Enhanced recovery care pathway. A better journey for patients seven days a week and better deal for the NHS. National Health Service 2012-2013. http://www.nhsiq.nhs.uk/resource-search/publications/enhanced-recovery-care-pathway-review.aspx. Accessed February 25, 2015.

[11] American Association of Nurse Anesthetists Enhanced Recovery After Surgery, https://www.aana.com/practice/clinical-practice-resources/enhanced-recovery-after-surgery

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.[12] 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. Additionally, 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.

In addition to the education efforts by the AANA, the AANA along with the American Association of Colleges of Nursing and other APRN organizations are developing a joint online educational series that will serve as a resource for practicing nurses, faculty, and students on opioid topics. As part of this initiative, these organizations presented four webinars in the Fall of 2016 to provide an overview of the current need to address opioid use disorder and overdose; integration of timely content into education program curricula; and the Centers for Disease Control and Prevention's (CDC) new prescribing guideline.

C. **Should the Committee and CMS Address the Opioid Epidemic through Prescriber Education, Invite the AANA to Collaborate in the Development of Educational Recommendations for Pain Management and Safe Use of Opioid Analgesics**

[12] See: http://www.nbcrna.com/NSPM/Pages/Non-Surgical-Pain-Management.aspx.

CRNAs have for many decades and continue to provide access to acute and chronic pain management services in their community. 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.

Should the Committee and the Centers for Medicare & Medicaid Services (CMS) address the opioid epidemic through prescriber education, any national education framework should be in the form of recommendations that are adaptable to profession- and practice-specific requirements. Interprofessional education should 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 any multidisciplinary collaborative.

II. Our Recommendations to Remove Barriers CRNAs Face in Helping to Solve the Opioid Crisis

A. Remove Barriers to the Use of Medically Necessary CRNA Pain Management Services

There are barriers that limit the use of medically necessary CRNA pain management services. For instance, private health plans, Medicare administrative contractors and Medicaid plans, have developed policies that limit CRNAs from providing and being reimbursed for medically necessary chronic pain management services, absent any evidence to support such policies. Furthermore, leading physician subspecialty organizations in pain management research, practice guideline development, and education are known to use economic and advocacy means to exclude other members of the pain management team, such as CRNAs, from educational and practice opportunities, thereby limiting patient access to care, diagnosis, treatment, and ultimately improved patient quality of life. 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."[13] Therefore, we recommend that the Committee be cognizant of these barriers and ensure that the Medicare and Medicaid programs do not impose barriers that limit a CRNA's ability to provide comprehensive pain management care. 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. These programs should not contain barriers that limit the use of these medically necessary CRNA pain management services.

B. Reduce Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities

As 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, it vital that the agency should promote access to the use of CRNA anesthesia services in rural America. Furthermore, the agency should ensure that future policy does not create unintended barriers to the use of CRNA services and that CRNA are practicing at their full professional education, skills, and scope of practice.

[13] Federal Trade Commission. Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses, March 2014, p. 1.

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.[14]

Nurse anesthetists are experienced and highly trained anesthesia professionals who provide high-quality patient care, which has been proven through decades of scientific research. 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, affording these facilities the capability to provide many necessary procedures. Our policy recommendation corresponds with a recommendation from the National Academy of Medicine's report titled *The Future of Nursing: Leading Change, Advancing Health*, which outlines several paths by which patient access to care may be expanded, quality preserved or improved, and costs controlled through greater use of APRNs, including CRNAs.[15]

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.[16] 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 unemployed, uninsured, and/or Medicaid beneficiaries.[17] CRNAs play an essential role in assuring that rural America has access to critical anesthesia services

[14] The Lewin Group, Cases: Costs of Alternative Pain Management Paths, August 14, 2012, available at: http://www.lewin.com/publications/publication/201208140454.html.

[15] National Academy of Medicine (2011), *The Future of Nursing: Leading Change, Advancing Health* https://www.nap.edu/download/12956#

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

17 Liao, op cit.

and by removing regulatory barriers to CRNA practice and allowing CRNAs to practice to the full extent of their scope, licensure and training, patients in rural areas will receive consistently safe and high quality care delivery.

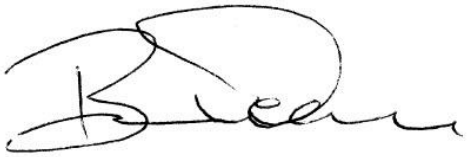
C. Remove from Subregulatory Guidance the Exclusion of Practitioners Who are Not Physicians from Serving on Medicare Carrier Advisory Committees

We urge the Committee to direct CMS to remove from subregulatory guidance that excludes practitioners who are not physicians from serving on Medicare Administrative Contractors' (MACs) Carrier Advisory Committees (CAC). Specifically, we note that Exhibit 3 of the Section 13.8.1 of the Medicare Program Integrity Manual specifically states, "Do not include other practitioners on this committee," which ultimately precludes APRNs, including CRNAs, from participation. [1] We urge removal of this clause from the manual. We are troubled by multiple instances where MACs have exceeded their authority by issuing local coverage determinations (LCD) that contradict existing CMS regulation and policy and scope of practice under state law that harm patient access to vital and medically necessary services. As CACs are crucial in the development and review of LCDs, it is imperative that practitioners such as APRNs and CRNAs are represented on CACs so as to ensure that the LCD process reflect evidence-based policies, the perspective of practitioners who are not physicians, and protect robust patient access to medically necessary APRN services under Medicare.

The AANA appreciates this opportunity to comment on this important issue. CRNAs are vital to helping resolve the widespread opioid drug crisis, a huge challenge facing our nation's healthcare system, with services that eliminate or decrease the use of opioids to address pain through multimodal pain management techniques. Using a patient-centered, multidisciplinary, multimodal treatment approach including interventional pain management can help reduce the reliance on opioids as a primary pain management modality, thus helping curb the prescribed opioid epidemic.
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,

[1] Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, Rev. 608, August 4, 2015, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf and http://www.cms.gov/manuals/downloads/pim83exhibits.pdf.



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