

January 8, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4812-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-4812-P - Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (82 Fed. Reg. 56336, November 28, 2017)

Dear Ms. Verma:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to submit comments to the proposed rule CMS-4812-P - Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. We are firmly committed to working with the agency and other healthcare stakeholders to help achieve our common goals of increasing access to healthcare, reducing regulatory burdens on stakeholders, empowering consumers and making healthcare more affordable for all Americans. The AANA makes the following comments and recommendations:

- I. CRNAs Provide Safe, High Quality and Cost Effective Healthcare**
- 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. Our Proposals for Promoting Healthcare Marketplace Innovation and Reducing Regulatory Burdens

- A. The Costly and Unnecessary Requirements Relating to Physician Supervision of CRNA Anesthesia Services should be Removed
- B. Cost-Effective Models in Healthcare Delivery such as Non-medically Directed Anesthesia Services Performed by CRNAs Should be Included as Part of Healthcare Reform
- C. Implementing CRNA Full Practice Authority Increases Veterans Access to Care and Promotes Safe, Efficient Healthcare Delivery
- D. Prohibit the Use of Wasteful Tele-Supervision of CRNA Services
- E. Reducing Regulatory Barriers for CRNAs Increases Access to Anesthesia Care in Rural Communities

I. 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

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. 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

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.

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.⁵ Regarding the treatment of acute and chronic pain, the AANA believes it's 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 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 settings (e.g., hospitals, ambulatory surgical centers, offices, and pain management clinics).⁶

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 titled, *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.”⁷

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

⁵ The Centers for Disease Control and Prevention, “Annual Surveillance Report of Drug Related Risks and Outcomes” (2017), <https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf>

⁶ See AANA Chronic Pain Management Guidelines, September 2014, [https://www.aana.com/docs/default-source/practice-aana-com-web-documents-\(all\)/chronic-pain-management-guidelines.pdf?sfvrsn=d40049b1](https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/chronic-pain-management-guidelines.pdf?sfvrsn=d40049b1)

⁷ See AANA Position Statement, “A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment”, July 2016, [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_2](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_2)

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 are uniquely qualified to help eradicate the opioid epidemic that is tearing at the fabric of our nation. CRNAs work in hospitals, ASCs, and physicians' offices providing every type of anesthetic drug for every type of procedure that requires anesthesia services, including surgery, obstetrics, trauma stabilization, and acute and chronic pain management. CRNAs are involved in every aspect of a patient's anesthesia and analgesia care including the pre-anesthesia patient assessment, obtaining informed consent for anesthesia, developing the anesthesia and acute pain plan of care, administering the anesthetic, monitoring and addressing the patient's response to anesthesia, providing emergency services as needed, and managing the patient's anesthesia and pain related needs following the procedure. In some states CRNAs are the sole anesthesia providers in nearly 100 percent of rural hospitals. They are also the primary hands-on providers of anesthesia care in Veterans Hospitals and the U.S. Armed Services.

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.⁸ 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 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 recently endorsed the Emergency Nurses Association and the International Nurses Society on Addiction 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

⁸ See: <http://www.nbcna.com/NSPM/Pages/Non-Surgical-Pain-Management.aspx>.

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. Our Proposals for Reducing Regulatory Burden on Providers and Promoting Healthcare Marketplace Innovation

The AANA supports the agency's request to seek comment on stakeholder input to help reduce regulatory burden and increase efficiencies in the healthcare marketplace ways to help provide consumers with quality, person centered coverage. We recommend removing administrative and regulatory barriers to the use of CRNA services, which will help promote competition and choice while reducing costs in the healthcare system. Before outlining these proposals, we wanted to provide an overview of the professional regulation of CRNAs. The scope of practice for CRNAs is first determined by the profession⁹, and is subject to state legislation and regulation through nurse practice acts and regulations, and through state healthcare facility licensing statutes and regulations. At the federal level, CRNA practice is circumscribed by federal regulations governing Medicare healthcare facilities, chiefly hospital conditions of participation (CoPs) and ambulatory surgery center conditions for coverage (CfCs).¹⁰ At both the state and federal levels, however, recognition of CRNA services to the full extent of the profession's practice authority is commonly constrained through the highly organized and well-funded policy advocacy efforts of marketplace competitors from the community of organized medicine.^{9,10,11}

A. The Costly and Unnecessary Requirements Relating to Physician Supervision of CRNA Anesthesia Services Should be Removed

⁹ American Association of Nurse Anesthetists. "Scope of nurse anesthesia practice." AANA, Park Ridge, IL, 2013. <http://www.aana.com/resources2/professionalpractice/Pages/Scope-of-Nurse-Anesthesia-Practice.aspx>.

¹⁰ For example, Medicare hospital conditions of participation require CRNA anesthesia services to be subject to supervision by the operating practitioner or by an anesthesiologist who is immediately available, unless the state in which the service is provided has opted-out from this supervision requirement. See 42 CFR §482.52 at <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec482-52.pdf> and Medicare hospital interpretive guidelines at the Medicare state operations manual Appendix A, tag #A-1000, at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

CRNAs' ability to practice to their full scope is affected by Medicare regulations associated with Medicare Part A Conditions of Participation and Conditions for Coverage (CoPs and CfCs). The Medicare CoPs and CfCs are federal regulations with which particular healthcare facilities must comply in order to participate in the Medicare program. While these regulations directly apply to facilities, they affect CRNA practice and impair competition and choice. Regulatory reforms that reduce barriers to CRNA practice can help improve healthcare quality, reduce healthcare expenditures and increase access for patients. Among these reforms is a recommendation to eliminate the Medicare requirement for physician supervision of CRNA anesthesia services.¹¹

The requirement for physician supervision of CRNA anesthesia services is costly and unnecessary, driving healthcare expenditures higher without improving patient safety. Eliminating the requirement supports delivery of healthcare in a manner allowing states and healthcare facilities to make their own decisions based on state laws and patient needs, thus controlling cost, providing access and delivering quality care. There is strong and compelling evidence showing that physician supervision does not have any impact on quality, and may restrict access and increase cost. Studies have repeatedly demonstrated the high quality of nurse anesthesia care, and a 2010 study published in *Health Affairs*¹² led researchers to recommend that costly and duplicative supervision requirements for CRNAs be eliminated. Examining Medicare records from 1999-2005, the study compared anesthesia outcomes in 14 states that opted out of the Medicare physician supervision requirement for CRNAs with those that did not opt out. (To date, 17 states have opted out.) The researchers found that anesthesia has continued to become safer in opt-out and non opt-out states alike. In reviewing the study, the *New York Times* stated, "In the long run, there could also be savings to the healthcare system if nurses delivered more of the care."¹³ Most recently, a peer-reviewed study published in *Medical Care* (June 2016) found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.¹⁴

¹¹ See 42 CFR §§ 482.52, <http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767cbd4a62741e97f60fae03464e62&node=42:5.0.1.1.1&rgn=div5#42:5.0.1.1.4.4.2> , 482.639 <http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767cbd4a62741e97f60fae03464e62&node=42:5.0.1.1.4&rgn=div5#42:5.0.1.1.4.4.7.16> , and 416.42, <http://www.ecfr.gov/cgi-bin/text-idx?SID=fc767cbd4a62741e97f60fae03464e62&node=42:3.0.1.1.3&rgn=div5#42:3.0.1.1.3.3.1.3>.

¹² Dulisse, op cit.

¹³ Who should provide anesthesia care? (Editorial) *New York Times*, Sept. 6, 2010, http://www.nytimes.com/2010/09/07/opinion/07tue3.html?_r=0 .

¹⁴ Negusa, op cit.

CRNA safety in anesthesia is further evidenced by the significant decrease in liability premiums witnessed in recent decades. In 2015, self-employed CRNAs paid 33 percent less for malpractice premiums nationwide when compared to the average cost in 1988. When adjusted for inflation through 2015, the reduction in CRNA liability premiums is an astounding 65 percent less than approximately 25 years ago according to Anesthesia Insurance Services, Inc. According to a May/June 2010 study published in the journal of *Nursing Economic*®, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery without any measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.¹⁵

The evidence also demonstrates that the supervision requirement is costly. Though Medicare requires supervision of CRNAs (except in opt-out states) by a physician, hospitals and healthcare facilities often misinterpret this requirement to be a quality standard rather than a condition of participation.

The AANA receives reports from the field that anesthesiologists suggest erroneously that supervision is some type of quality standard, an assertion bearing potential financial benefit for anesthesiologists marketing their medical direction services as a way to comply with the supervision condition of participation. When this ideology is established, anesthesiologist supervision adds substantial costs to healthcare by requiring duplication of services where none is necessary. Further, the Medicare agency has clearly stated that medical direction is a condition for payment of anesthesiologist services and not a quality standard.¹⁶ But there are even bigger costs involved if the hospital administrator believes that CRNAs are required to have anesthesiologist supervision (which they are not).

According to a nationwide survey of anesthesiology group subsidies,¹⁷ hospitals pay an average of \$160,096 per anesthetizing location to anesthesiology groups, an increase of 13 percent since the previous survey in 2008. An astounding 98.8 percent of responding hospitals in this national survey reported that they paid an anesthesiology group subsidy. Translated into concrete terms, a hospital with 20 operating rooms pays on average a \$3.2 million anesthesiology subsidy. Anesthesiology groups receive this payment from hospitals in addition to their direct professional billing.

¹⁵ Hogan, op cit.

¹⁶ 63 FR 58813, November 2, 1998.

¹⁷ Healthcare Performance Strategies. Anesthesia Subsidy Survey 2012

There is also strong evidence in the literature that anesthesiologist supervision fails to comply with federal requirements, either the Part A conditions of participation or Part B conditions for coverage. Lapses in anesthesiologist supervision are common even when an anesthesiologist is medically directing as few as two CRNAs, according to a 2012 study published in the journal *Anesthesiology*,¹⁸ the professional journal of the American Society of Anesthesiologists. The authors reviewed over 15,000 anesthesia records in one leading U.S. hospital, and found supervision lapses in 50 percent of the cases involving anesthesiologist supervision of two concurrent CRNA cases, and in more than 90 percent of cases involving anesthesiologist supervision of three concurrent CRNA cases. This is consistent with more than 10 years of AANA membership survey data.

Since this regulatory requirement is meaningless in practice, contributes to greater healthcare costs, and is contrary to existing evidence regarding patient safety and access to care, we recommend CMS eliminate the regulatory barrier of physician supervision of CRNAs in the Medicare program. Removing this barrier is also consistent with the findings and recommendations of the National Academy of Medicine, whose landmark publication titled *The Future of Nursing: Leading Change, Advancing Health* calls for removing barriers so that APRNs, including CRNAs, can practice to the full extent of their education and training, indicating that APRNs play a critical role in the future of healthcare.¹⁹

B. Cost-Effective Models in Healthcare Delivery such as Non-Medically Directed Anesthesia Services Performed by CRNAs should be Included as Part of Healthcare Reform

The AANA supports efforts to better understand the potential benefits of new healthcare delivery models that have emerged in recent years which can offer significant cost savings while maintaining, or even improving, quality of care. These models may also increase the supply of healthcare services, which can expand consumer access to care. We recommend that innovative, cost-effective models in anesthesia delivery such as *non-medically directed* anesthesia services performed by a CRNA be included in the agency's strategic plan to help reform, strengthen and modernize our nation's healthcare system.

¹⁸ Epstein R, Dexter F. Influence of Supervision Ratios by Anesthesiologists on First-case Starts and Critical Portions of Anesthetics. *Anesth.* 2012;116(3): 683-691.

¹⁹ IOM (Institute of Medicine). *The Future of Nursing: Leading Change, Advancing Health* (Washington, DC: The National Academies Press, 2011).

In most respects, Medicare reimburses CRNAs and anesthesiologists at the same rate for the same high-quality service -- 100 percent of a fee for providing non-medically directed (CRNA) or personally performed (anesthesiologist) services. However, Medicare Part B also authorizes payment for “anesthesiologist medical direction”²⁰ that provides a financial incentive for anesthesiologists to “medically direct” CRNAs who are capable of and often provide patient access to highquality anesthesia care unassisted. An anesthesiologist claiming medical direction services may be reimbursed 50 percent of a fee in each of up to four concurrent cases, a total of 200 percent over a given period of time, and twice what the anesthesiologist may claim when personally performing anesthesia services in one case. Under medical direction, the CRNA may claim the remaining 50 percent of a fee for his or her case. Peer-reviewed evidence demonstrates anesthesiologist medical direction increases healthcare costs without improving Safety.²¹ The CMS has also stated that medical direction is a condition of payment of anesthesiologist services and not a quality standard.²²

In demonstrating the increased costs associated with anesthesiologist medical direction, suppose there are four identical cases: (a) anesthesia delivered by a non-medically directed CRNA; (b) anesthesia delivered by a CRNA medically directed at a 4:1 ratio by a physician overseeing four simultaneous cases and attesting fulfillment of the seven conditions of medical direction in each; (c) anesthesia delivered by a CRNA medically directed at a 2:1 ratio; and (d) anesthesia delivered by a physician personally performing the anesthesia service. (There are instances where more than one anesthesia professional is warranted; however, neither patient acuity nor case complexity is a part of the regulatory determination for medically directed services. The literature demonstrates that the quality of medically directed vs. non-medically directed CRNA services is indistinguishable in terms of patient outcomes, quality and safety.) Further suppose that the annual pay of the anesthesia professionals approximate national market conditions, \$170,000 for the CRNA²³ and \$540,314 for the anesthesiologist²⁴. Under the Medicare program and most private payment systems, practice modalities (a), (b), (c) and (d) are reimbursed the same. Moreover, the literature indicates the quality of medically directed vs. non-medically directed CRNA services is indistinguishable. However, the annualized labor costs (excluding benefits) for each modality vary widely. The annualized cost of practice modality (a) equals \$170,000 per year. For case (b), it is \$305,079 per year ($\$170,000 + (0.25$

²⁰ 42 CFR §415.110. <http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol2/pdf/CFR-2003-title42-vol2-sec415-130.pdf>

²¹ Hogan, op cit.

²² 63 FR 58813, November 2, 1998, <http://www.gpo.gov/fdsys/pkg/FR-1998-11-02/pdf/98-29181.pdf>.

²³ AANA member survey, 2014

²⁴ MGMA Physician Compensation and Production Survey, 2014. www.mgma.com

x \$540,314). For case (c) it is \$440,157 per year ($\$170,000 + (0.50 \times \$540,314)$). Finally, for case (d), the annualized cost equals \$540,314 per year.

Anesthesia Payment Model	FTEs / Case	Clinician costs per year / FTE
(a) CRNA Non-medically Directed	1.00	\$170,000
(b) Medical Direction 1:4	1.25	\$305,079
(c) Medical Direction 1:2	1.50	\$440,157
(d) Anesthesiologist Only	1.00	\$540,314
<i>Anesthesiologist mean annual pay</i>	<i>\$540,314</i>	<i>MGMA, 2014</i>
<i>CRNA mean annual pay</i>	<i>\$170,000</i>	<i>AANA, 2014</i>

If Medicare, Medicaid, and private plans pay the same rate whether the care is delivered according to modalities (a), (b), (c) or (d), someone in the health system is bearing the additional cost of the medical direction service authorized under the Medicare regulations at 42 CFR §415.110. This additional cost is shifted onto hospitals and other healthcare facilities, and ultimately to patients, premium payers and taxpayers. With CRNAs providing over 43 million anesthetics each year in the United States, and a considerable fraction of them being “medically directed,” the additional healthcare costs driven by this medical direction service are substantial.

In addition, the most recent peer-reviewed literature makes clear that the requirements of anesthesiologist medical direction are often not met in practice and if anesthesiologists submit claims to Medicaid for medical direction but did not perform all of the required services in each instance, then the likelihood of widespread fraud in this area is high. Lapses in anesthesiologist supervision are common even when an anesthesiologist is medically directing as few as two CRNAs, according to a 2012 study published in the journal *Anesthesiology*,²⁵ the professional journal of the American Society of Anesthesiologists. The authors reviewed over 15,000 anesthesia records in one leading U.S. hospital, and found supervision lapses in 50 percent of the cases involving anesthesiologist supervision of two concurrent CRNA cases, and in more than 90 percent of cases involving anesthesiologist supervision of three concurrent CRNA cases. This study raises critical issues about Medicare claims compliance in a common and costly model of anesthesia delivery at a time when quality, cost-effectiveness, and best use of Medicare resources are the focus of healthcare reform. In the interest of patient safety and access to care, these additional costs imposed by medical direction modalities more than justify the public interest in recognizing and reimbursing fully for non-medically directed CRNA

²⁵ Epstein R, Dexter F. Influence of Supervision Ratios by Anesthesiologists on First-case Starts and Critical Portions of Anesthetics. *Anesth.* 2012;116(3): 683-691.

services within Medicare, Medicaid and private plans in the same manner that physician services are reimbursed.

In conclusion, anesthesiologist medical direction reimbursement models contribute to increased healthcare system costs without improving access or quality, and also present fraud risk when medical direction requirements are not met by the anesthesiologist submitting a claim for such services. Therefore, such costs should be considered when developing and carrying out new systems for anesthesia reimbursement in healthcare delivery models, and to favor reimbursement systems that support the most cost-effective and safe anesthesia delivery models such as for non-medically directed CRNA services.

C. Implementing CRNA Full Practice Authority Increases Veterans Access to Care and Promotes Safe, Efficient Healthcare Delivery

The AANA advocates on numerous issues to help improve healthcare, patient safety and practice excellence by working to increase access to healthcare, make healthcare more affordable, and improve the quality of the care available to all patients, including our nation's veterans. On December 14, 2016, the Department of Veterans Affairs (VA) published its final rule granting full practice authority to three of the four APRN specialties, illogically excluding CRNAs from the rule "due to VA's lack of access problems in the area of anesthesiology."²⁶ This is a dangerously inaccurate statement that is clearly refuted by evidence. The most recent evidence was shown in a news story from Denver highlighting the lack of access to anesthesia services at Veterans Health Administration (VHA) facilities and the ensuing delays for critical surgeries for our veterans.²⁷ Due to anesthesia delays, veterans are indeed waiting for care they deserve and have earned. The decision to exclude CRNAs will cause veterans to continue to endure dangerously long wait times for anesthesia and other healthcare services due to the ongoing underutilization of CRNAs currently working in VHA facilities.

In the interest of expanding Veterans' access to quality healthcare, we express strong support for the VHA recognizing all APRNs, including CRNAs, to practice to the full extent of their education, training, and certification without the clinical supervision of physicians. Nurse anesthetists are experienced, highly educated anesthesia professionals who provide quality patient care confirmed by decades of scientific research. Peer-reviewed research and authoritative policy documents have illustrated how CRNAs consistently deliver safe, high-quality, cost-effective anesthesia care in today's

²⁶ 81 Fed. Reg. 90198. <https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-29950.pdf>

²⁷ Rob Low, "VA Surgeries postponed because there aren't enough anesthesiologists" Fox31 Denver. October 11, 2017. <http://kdvr.com/2017/10/11/va-surgeries-postponed-because-there-arent-enough-anesthesiologists/>

ever-changing healthcare environment and this has long been recognized by the VHA. By standardizing care delivery models across the country via full practice authority for APRNs, including CRNAs, Veterans can be assured consistently safe and high quality care delivery in any VHA healthcare facility. More than 900 CRNAs provide every type of anesthesia care, as well as chronic pain management services, for our Veterans in the VHA.

Permitting full practice authority for CRNAs will ensure veterans receive the full scope of high-quality anesthesia and pain management care they so rightfully deserve. An Independent Assessment of the VA's healthcare delivery system and management processes as required by the Veterans Choice Access and Accountability Act of 2014, recommended formalizing Full Nursing Practice Authority for all APRNs, including CRNAs, throughout the VHA.²⁸ In addition, in June 2016 following an exhaustive 10-month assessment of the VHA, the independent federal Commission on Care reported that 23 percent of healthcare professionals in the VHA are not working to the top of their licensure, identifying this underuse of available resources as a major barrier to effective healthcare provision.²⁹ One solution recommended by the Commission is implementation of policy that allows full practice authority for APRNs, which adds further data to the increasing amount of evidence in support of allowing CRNAs and other APRNs to practice to the full scope of their education, training, and abilities in the VHA, without physician supervision.³⁰ This policy would not only help address the increasing healthcare demands of our nation's veterans, but would also improve healthcare efficiency in the VHA system by reducing wait times and increasing cost-effective care. The common sense solution to avoid further interruption in veterans' care is to immediately implement full practice authority for all CRNAs and APRNs working in the VHA system.

The landmark National Academy of Medicine report *To Err is Human* found in 2000 that anesthesia was 50 times safer than in the 1980s. Though many studies have demonstrated the high quality of nurse anesthesia care, the results of a 2010 study published in *Health Affairs* led researchers to recommend that costly and duplicative supervision requirements for CRNAs be eliminated. Examining Medicare records from 1999-2005, the study compared anesthesia outcomes in 14 states that opted-out of the Medicare physician supervision requirement for CRNAs with those that did not

²⁸ U.S. Department of Veterans Affairs Assessment B - Health Care Capabilities (September 1, 2015), http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities.pdf

²⁹ The Commission on Care, Final Report on the Commission on Care (June 30, 2016), https://commissiononcare.sites.usa.gov/files/2016/07/Commission-on-Care_Final-Report_063016_FOR-WEB.pdf

³⁰ The Commission on Care, op cit.

opt out. (To date, 17 states have opted-out). The researchers found that anesthesia has continued to grow more safe in opt-out and non-opt-out states alike. A June 2016 study published in the independent scientific journal *Medical Care* found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.³¹ The study, which is the first to focus on the effects of state scope of practice laws and anesthesia delivery models on patient safety, also concluded that limitations on CRNA practice such as state scope of practice restrictions and physician supervision reduce patient access to quality care and increase costs of healthcare services.³² Furthermore, a 2014 Cochrane Collaboration publication found no differences in care between nurse anesthetists and physician anesthesiologists.

In the interest of improving veterans' access to quality healthcare, we express strong support for the VA recognizing CRNAs to practice to the full extent of their education, training, and licensure without the clinical supervision of physicians. Permitting full practice authority for CRNAs will ensure Veterans receive the full scope of high-quality anesthesia and pain management care they so rightfully deserve. The Independent Assessment of the healthcare delivery system and management processes of the VA recommended formalizing full practice authority for all APRNs, including CRNAs, throughout the VHA.³³ In addition, in June 2016, following an exhaustive 10-month assessment of the VHA, the independent federal Commission on Care reported that 23 percent of healthcare professionals in the VHA are not working to the top of their licensure, identifying this underuse of available resources as a major barrier to effective healthcare provision.³⁴ One solution recommended by the Commission is implementation of policy that allows full practice authority for APRNs, which adds further data to the increasing amount of evidence in support of allowing CRNAs to practice to the full scope of their education, training, and licensure in the VHA, without physician supervision.³⁵ This policy would not only help address the increasing healthcare demands of our nation's Veterans, but would also improve healthcare efficiency in the VHA system by reducing wait times and thereby increasing cost-effective

³¹ Negrusa B, Hogan PF, Warner JT, Schroeder CH, Pang B. Scope of Practice Laws and Anesthesia Complications: No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications. *Med Care*. (May 20, 2016). http://journals.lww.com/lww-medicalcare/Abstract/publishahead/Scope_of_Practice_Laws_and_Anesthesia.98905.aspx

³² Negrusa op cit.

³³ U.S. Department of Veterans Affairs Assessment B - Health Care Capabilities (September 1, 2015), http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities.pdf

³⁴ The Commission on Care, Final Report on the Commission on Care (June 30, 2016), https://commissiononcare.sites.usa.gov/files/2016/07/Commission-on-Care_Final-Report_063016_FOR-WEB.pdf

³⁵ The Commission on Care, op cit.

care. Moreover, granting full practice authority to CRNAs would allow CRNAs to fully utilize their education and training to enhance the patient care team model and work collaboratively with anesthesiologists as equal partners in anesthesia delivery for surgery, labor and delivery, trauma stabilization, and chronic pain management.

Recognizing CRNAs to their full practice authority corresponds with the first policy recommendation from the National Academy of Medicine report titled *The Future of Nursing: Leading Change, Advancing Health*. This report outlines several paths by which patient access to care may be expanded, quality preserved or improved, and costs controlled through greater use of APRNs.³⁶ The National Academy of Medicine report specifically recommends that, “advanced practice registered nurses should be able to practice to the full extent of their education and training.”³⁷

Access to care should be measured by whether veterans are getting the services they need. Notwithstanding the VA’s efforts to reform access issues, veterans are still experiencing long wait times for care, which has been identified in numerous instances by published government reports, the VHA Independent Assessment, and observations within the VHA. Such delays justify prompt implementation of full practice authority for VHA CRNAs. Thus, we urge the VA to allow full practice authority for CRNAs to continue improving healthcare for our veterans throughout the country.

D. Prohibit the Use of Wasteful Tele-Supervision of CRNA Services

The AANA is supportive of telehealth and remote monitoring technology that improves the quality of care provided for all patients. We caution the agency against the use of wasteful telehealth services that increase costs without improving healthcare access or quality as part of the Strategic Plan for 2018-2022. Specifically, we oppose policies that allow anesthesiologists to be reimbursed without providing actual anesthesia care, through billing for remote supervision services. This type of remote supervision would not improve access to healthcare for patients with chronic conditions and would instead reward providers not actually furnishing healthcare services. Furthermore, there is no evidence of a benefit for the use of supervision of anesthesia via telehealth.³⁸ Therefore, we ask that the use

³⁶ National Academy of Medicine (formerly Institute of Medicine). (2011). *The Future of Nursing: Leading Change, Advancing Health*. Washington, DC: The National Academies Press. <http://www.iom.edu/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx>

³⁷ National Academy of Medicine op cit., p. 9.

³⁸ See: Applegate RL, 2nd, Gildea B, Patchin R, et al. Telemedicine pre-anesthesia evaluation: a randomized pilot trial. *Telemed J E H ealth*. 2013;19:211-6; Cone SW, Gehr L, Hummel R, Merrell RC. Remote anesthetic monitoring using

wasteful anesthesiologist tele-supervision of CRNA services is prohibited in the future strategies the agency plans to help reform, strengthen, and modernize the Nation's health care system.

E. Reducing 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. 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.

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.³⁹ 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.⁴⁰ CRNAs play an essential role in assuring that rural America has access to critical anesthesia services and by removing regulatory barriers to CRNA practice and allowing CRNAs to practice to the full

satellite telecommunications and the Internet. *Anesthesia and analgesia*. 2006;102(5):1463-1467; Dilisio RP, Dilisio AJ, Weiner MM. Preoperative virtual screening examination of the airway. *J Clin Anesth*. 2014;26:315-7; and Galvez JA, Rehman MA. Telemedicine in anesthesia: an update. *Curr Opin Anaesthesiol*. 2011;24:459-62.

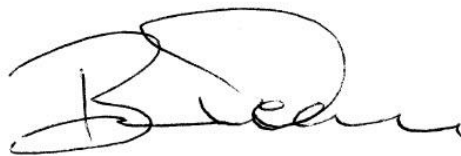
39 Liao CJ, Quraishi JA, Jordan, LM. Geographical Imbalance of Anesthesia Providers and its Impact on the Uninsured and Vulnerable Populations. *Nurs Econ*. 2015;33(5):263-270. <http://www.aana.com/resources2/research/Pages/NursingEconomics2015.aspx>

40 Liao, op cit.

extent of their scope, licensure and training, patients in rural areas will receive consistently safe and high quality care delivery.

The AANA appreciates this opportunity to comment on this proposed rule. CRNAs are vital to resolving the challenges facing our nation's healthcare system and we look forward to partnering with the agency to show the important role CRNAs can have in achieving the main goals of meaningful reform, reducing health care costs, 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,

A handwritten signature in black ink, appearing to read 'B. Weiner', with a large, stylized initial 'B'.

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

Cc: Randall Moore II, DNP, MBA, CRNA, AANA CEO
Ralph Kohl, AANA Senior Director of Federal Government Affairs
Randi Gold, MPP, AANA Associate Director Federal Regulatory and Payment Policy