

July 25, 2022

Via OASHPrimaryHealthCare@hhs.gov

Dear Ms. Steinberg:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on the Request for Information (RFI): HHS Initiative to Strengthen Primary Health Care. We have appreciated our long and fruitful relationship with the agency, and we appreciate and support efforts to remove barriers that limit healthcare professionals, such as CRNAs, from practicing at the top of their license and scope of practice and ensuring patients have access to timely, cost effective and high-quality care.

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 59,000 CRNAs and SRNAs, representing about 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 50 million anesthetics to patients each year in the United States and are among the nation's most trusted professions according to Gallup¹. 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, in all types of settings where anesthesia is delivered and also provide acute, chronic, and interventional pain management services. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Services. Numerous peer reviewed studies have shown that CRNAs are safe, high quality and cost effective anesthesia professionals who should practice to the full extent of their education and abilities. According to a May/June 2010 study published in the journal *Nursing Economic*\$, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.² An August 2010 study published in *Health Affairs* showed no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.³ Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane

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

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

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

Collaboration, the internationally recognized authority on evidence-based practice in healthcare.⁴ In addition, a study published in *Medical Care* found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.⁵

I. <u>Permanently Remove Unnecessary Regulatory Burdens That Limit Medicare Beneficiaries' Access</u> to Care

The AANA was encouraged to see the Centers for Medicare and Medicaid Services (CMS) temporarily waive Medicare's physician supervision requirement for CRNA anesthesia services as part of the Conditions of Participation and Conditions for Coverage during the Public Health Emergency (PHE). The PHE has shown the important need for health care professionals to work to the top of their scope to care for patients and highlights the important role that CRNAs play in our healthcare system, especially when workforce barriers to practice are eliminated.

In their roles as Advanced Practice Registered Nurses (APRNs), many CRNAs have assisted on the frontlines of the pandemic to provide expert care to the sickest patients. We have seen barriers to CRNA practice removed at both the state and federal levels, allowing CRNAs to provide critical, lifesaving care to patients. CRNAs are practicing independently, providing invaluable support by using their expertise in rapid systems assessment, airway management, managing ventilators, vascular volume resuscitation, placing of invasive lines and monitors, overseeing complex hemodynamic monitoring, emergency preparedness, and resource management. Data from CMS showed that CRNAs are one of the top specialties serving the most Medicare beneficiaries during the first three months of the pandemic (March – June) in 2020.⁶ Removing this requirement permanently will benefit patients and the larger healthcare system. Given the important role that CRNAs are playing in providing care during the pandemic through the removal of unnecessary rules, the AANA supports a thorough and evidence-based approach to ensure that any rules that have been suspended during the PHE are only re-enacted if they serve a meaningful purpose in healthcare delivery.

Medicare's physician supervision requirement for CRNAs is an unnecessary requirement that does not improve safety and only serves to increase costs and decrease access to care. This outdated and superfluous regulation adds an extra burden on states by overriding state laws to add unnecessary supervision requirements. Currently, only seven states require supervision of CRNA services according to state nursing laws. There is no evidence that physician supervision of CRNAs improves patient safety or quality of care. In fact, there is strong and compelling data showing that physician supervision does not have any impact on quality and may restrict access and increase healthcare costs. Studies have repeatedly demonstrated the high quality of nurse anesthesia care, and a gold standard study published in Health Affairs⁷ 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, 19

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

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

⁶ CMS Report January 2021 "Putting Patients First: The Center for Medicare and Medicaid Services Record of Accomplishment from 2017-2020."

⁷ Dulisse, op. cit

states have opted-out.) The researchers found that anesthesia has continued to become safer in opt-out and non-opt-out states alike.

The unique "opt-out process" has proven to be an unacceptable alternative to the simple deferral to state law. On one hand, it has proven to be a useful experiment in comparing healthcare in opt-out vs. non-opt-out states, with the result being the findings of Dulisse and colleagues in Health Affairs noted above, that "(no) harm (is) found when nurse anesthetists work without physician supervision." The results of that experiment are clearly in favor of letting states decide the issue by their statutes. Further, we have also found that the opt-out is burdensome and counterproductive at the state level resulting in wasted time and money spent on lobbying, public relations campaigns and lawsuits.

Currently, 43 states that have no supervision in their nursing/medicine laws or rules. This federal supervision requirement is impeding local communities from planning effective and efficient state regulatory frameworks that support innovation. The evidence for CRNA patient safety is clear, and the Medicare agency should eliminate the requirement for governors to request additional permission to implement their own statutes and policies. Nor should a state's statutes in this area be reversed by the sole decision of the governor in reversing an opt-out resulting in potential confusion regarding federal supervision and without public comment or legislative oversight. There is no precedent at CMS for this back-and-forth approach to healthcare policy.

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

Rural hospitals are vital to providing health care to their communities and the increasing closure of rural hospitals limits access to care, produces long trips for emergency care and causes an increase in negative health outcomes for patients living in rural areas. Over 130 rural hospitals have closed in the U.S. since 2010. CRNAs also play an essential role in assuring that rural America has access to critical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many necessary procedures.

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

Research evaluating type of facility, size, and anesthesia staffing by rural location shows that 55.5% of small rural hospitals and 61.2% of rural ambulatory surgery centers were predominately staffed by

Liao, op ci

⁸ "The Health 202: Congress is throwing a lifeline to struggling rural hospitals." The Washington Post, June 29, 2021.

⁹ Liao CJ, Qurashi JA, Jordan LM. Geographical Imbalance of Anesthesia Providers and its Impact on the Uninsured and Vulnerable Populations. Nurs Econ. 2015;33(5):263-270. http://www.aana.com/resources2/research/Pages/NursingEconomics2015.aspx

¹⁰ Liao, op cit.

CRNAs.¹¹ Further research has shown that there is significant geographic variation in anesthesia provider supply and lower supply in rural communities raises concerns about access to procedures that require anesthesia in rural areas.¹² The study found that enforcing state policies related to CRNA practice, such as less restrictive scope of practice regulations, were consistently correlated with a greater supply of CRNAs, especially in rural counties.¹³

III. <u>Use of Non-Opioid Alternatives, Do Lead to a Decrease in Prescription Opioid Use and Addiction</u> <u>And Include Strategic Consideration of the Role of Anesthesia in Enhanced Recovery after Surgery</u> <u>Protocol as an Innovative Healthcare Delivery Model</u>

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, especially in rural areas where there are shortages of healthcare providers to address it. CRNAs have been on the front lines of developing novel non-opioid based treatments for both chronic and acute pain and we support maximum flexibility in allowing pain treatment plans that rely on the clinical judgment of the practitioner directing care. As a main provider of pain management services in all types of settings, CRNAs are uniquely skilled to provide both acute and chronic pain management in a patient centered, compassionate and holistic manner across the pain continuum in all clinical settings. Furthermore, the approach that CRNA pain management practitioners employ when treating their chronic pain patients may reduce the reliance on opioids as a primary pain management modality, thus aiding in the reduction of potential adverse drug events related to opioids. CRNAs do address psychological and associated substance abuse potential of patients experiencing chronic pain disorders. CRNAs also act as educators who help other practitioners and patients effectively manage pain using opioid sparing techniques to decrease the risk of opioid misuse and addiction. CRNAs also employ medication-assisted therapies, such as Buprenorphine and naloxone, for opiate addiction.

CRNA services are crucial to the successful development and implementation of the use of innovative techniques such as anesthesia enhanced recovery after surgery (ERAS®) programs. An increasing number of procedures are utilizing non-operating room anesthesia (NORA) and ERAS® protocols that allow for the use of techniques that help patients recover more quickly and eliminate the use of opioids to treat pain and the complications they bring. A clinician's judgement, experience and knowledge are important aspects of providing patient care safely and goes towards the quality of care patients receive. ERAS® is a patient-centered, evidence-based, pain management strategy employed by CRNAs to reduce the need for opioids,

14 AANA Chronic Pain Management Guidelines, September 2014, available at: http://www.aana.com/resources2/professionalpractice/Pages/Chronic-Pain-Management-Guidelines.aspx, AANA Regional Anesthesia and Analgesia Techniques - An Element of Multimodal Pain Management Guidelines, https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6">https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6">https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6">https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6">https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6">https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6">https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/regional-anesthesia-and-analgesia-techniques-an-element-of-multimodal-pain-management.pdf?sfvrsn=8aac5eb1 6"

A Holistic Approach to Pain Management: Integrated, Multimodal, and Interdisciplinary Treatment https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/a-holistic-approach-to-pain-management-integrated-multimodal-and-interdisciplinary-treatment.pdf?sfvrsn=f40049b1.4

Coomer N. et al. (2019). Anesthesia staffing models and geographic prevalence post-Medicare CRNA/physician exemption policy. *Nursing Economic*\$, 37(2), 86-91. https://search.proquest.com/openview/3f55b0d94533f910b7c0c1dc5d7202bc/1?pq-origsite=gscholar&cbl=30765
 Martsolf, G et. Al. (2019) Relationship Between State Policy and Anesthesia Provider Supply in Rural Communities. *Medical Care*, 57(5):341:347. https://www.ncbi.nlm.nih.gov/pubmed/30870391

¹³ Martsolf, op cit.

treatment.pdf?sfvrsn=f40049b1_4

15 Non-operating room anesthesia: Is it worth the risk? Bruce J. Leone Current Anesthesiology Reports volume 10, pages449–455 (2020). Available at https://link.springer.com/article/10.1007/s40140-020-00423-4.

¹⁶ Non-Operating Room Anesthesia: Patient Selection and Special Considerations. Local Reg Anesth. 2020; 13: 1–9. Published online 2020 Jan 8. doi: 10.2147/LRA.S181458. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6956865/.

improve patient outcomes and reduce costs.¹⁷ 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 techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures. CRNAs play an integral role in these episodes of care, in both inpatient and outpatient settings, as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and ultimately in cost savings. We urge that the agency emphasize the strategic consideration of the role of anesthesia delivery that is safe and cost-efficient and include the use of techniques such as ERAS[®] programs as an innovative model.

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

Sincerely,

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AANA President

Cc: Willian Bruce, MBA, CAE, AANA Chief Executive Officer Ralph Kohl, BA, AANA Senior Director of Federal Government Affairs

Randi Gold, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy

¹⁷ AANA Enhanced Recovery After Surgery, http://www.future-of-anesthesia-care-today.com/pdfs/eras-info.pdf.