AANA
American Association of
NURSE ANESTHESIOLOGY

August 5, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3419-P
P.O. Box 8016
7500 Security Blvd.
Baltimore, MD 21244

RE: CMS-3419-P – Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates Proposed Rule (87 Fed.Reg. 40350, July 6, 2022)

Dear Administrator Brooks-LaSure:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on this proposed rule; Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates (87 Fed.Reg. 40350, July 6, 2022). The AANA makes the following comments and requests of CMS:

- Remove Physician Supervision Requirement for CRNAs from § 485.524(d)(3)(ii)
- Ensure that Telemedicine Credentialing and Privileging Process Requirements Do Not Provide a Pathway to Reimbursement for Anesthesiologist TeleSupervision of Anesthesia Services
- Allow for Flexibility in the Professional Healthcare Staff that May Provide Advice on Written Policies for the Provision of Services (Proposed § 485.514(b))

Background of the AANA and CRNAs

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

CRNAs are involved in every aspect of anesthesia services including a pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery and recovery. CRNAs also provide acute, chronic, and interventional pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Services. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

Numerous peer reviewed studies have shown that CRNAs are safe, high quality and cost effective anesthesia professionals who should practice to the full extent of their education and

[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.

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

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

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

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

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

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

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

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

AANA Request: Remove Physician Supervision Requirement for CRNAs from § 485.524(d)(3)(ii)

The AANA supports the creation of the new Rural Emergency Hospital (REH) designation and the opportunity for CRNAs to participate in these facilities especially as they often serve as the sole anesthesia provider in rural hospitals. While the AANA supports the Centers for Medicare & Medicaid Services' (CMS) approach to model the REH Conditions of Participation (CoPs) based on those used for the Critical Access Hospitals (CAH), we strongly oppose imposition of physician supervision requirements of CRNAs in the REH CoPs as proposed in § 485.524(d)(3)(ii). We request removal of the sentence from § 485.524(d)(3)(ii), "In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section."

This requirement is not explicitly mentioned in the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), and, as the peer-reviewed literature demonstrates, does nothing to advance the safety of patients. More importantly, it will drive up costs for REHs at a time when such facilities are operating on razor thin margins and are vulnerable to closure. 140 rural hospitals have closed since 2010, with more than 183 hospitals having closed since 2005.[8] Currently, 673 additional facilities are vulnerable and could close, representing more than one-third of rural hospitals in the U.S. Increasing the cost of anesthesia services to these facilities without evidence of increasing quality or advancing health equity will have an impact on the access to affordable safe care.

[7] Liao, op cit.

[8] See: UNC Shep Center on Rural Hospital Closures, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

In addition, this requirement could further exacerbate the impact on access to care given the labor shortage and the demand for CRNA anesthesia services. A Health Affairs article entitled *A Worrisome Drop in the Number of Young Nurses* highlights the issues we are facing with the nursing workforce. According to the article, "Now, two years into the COVID-19 pandemic, the supply of RNs is under threat again. Using monthly data from the Current Population Survey, our recently published analyses in Health Affairs showed that growth in the RN workforce plateaued during the first 15 months of the pandemic. Although it is difficult to disentangle the contributing factors, these likely include early retirements, pandemic burnout and frustration, interrupted work patterns from family needs such as childcare and elder care, COVID-19 infection and related staffing shortages, and other disruptions throughout healthcare delivery organizations. Extending that analysis through the end of 2021 furthers our concern. New data here, covering the entirety of 2021, show the total supply of RNs decreased by more than 100,000 in one year—a far greater drop than ever observed over the past four decades."[9] Furthermore, the demand for CRNAs are great as evidenced by CMS's own data. Initial data from CMS also showed that during the first three months of the pandemic, CRNAs were among the top 20 most utilized specialty providers. Finally, this requirement is moving in a different direction than the current CMS blanket waiver on physician supervision for CRNAs in facilities such as rural and Critical Access Hospitals.[10]

The importance of CRNA services in rural areas was highlighted in a recent study which examined the relationship between socioeconomic factors related to geography, insurance type, and the distribution of anesthesia provider type.[11] 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 showed that compared with anesthesiologists, CRNAs are more likely to work in areas with

[9] Auerbach, D. et al, A Worrisome Drop in the Number of Young Nurses," HEALTH AFFAIRS FOREFRONT, April 13, 2022, available at: https://www.healthaffairs.org/do/10.1377/forefront.20220412.311784/.

[10] See: https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf, CMS is waiving requirements under 42 CFR §482.52(a)(5), §485.639(c) (2), and §416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs §482.52(a)(5) and §485.639(c)(2).

[11] 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

lower median incomes and larger populations of citizens who are unemployed, uninsured, and/or Medicaid beneficiaries.

Our request also corresponds with a recommendation from the National Academy of Medicine's (NAM) 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.[12] The NAM report specifically recommends that, "advanced practice registered nurses should be able to practice to the full extent of their education and training."[13]

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 cost. Studies have repeatedly demonstrated the high quality of nurse anesthesia care, and a 2010 study published in *Health Affairs*[14] 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, 22 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."[15] Previously stated, a study published in *Medical Care* June 2016 found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.[16]

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[12] National Academy of Medicine. The Future of Nursing: Leading Change, Advancing Health (Washington, DC: The National Academies Press, 2011); p. 69.

[13] NAM op. cit. p. 7-8.

[14] Dulisse, op. cit.

[15] Who should provide anesthesia care? (Editorial) *New York Times*, Sept. 6, 2010.

[16] Negrusa B et al. op. cit.

CRNA safety in anesthesia is further evidenced by the significant decrease in liability premiums witnessed in recent decades. In 2022, self-employed CRNAs paid 36.17 percent less for malpractice premiums nationwide when compared to the average cost in 1988. When adjusted for inflation through 2022, the reduction in CRNA liability premiums is an astounding 74.5 percent less than approximately 34 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.[17]

The evidence also demonstrates that the supervision requirement is costly. Though Medicare requires supervision of CRNAs (except in opt-out states) by an operating practitioner or by an anesthesiologist who is immediately available if needed, hospitals and healthcare facilities often misinterpret this requirement to be a quality standard rather than a CoP. 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 CoP. 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.[18] But there are even bigger costs involved if the hospital administrator believes that CRNAs are required to have anesthesiologist supervision.

According to a nationwide survey of anesthesiology group subsidies,[19] 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,

[17] Paul F. Hogan et. al, "Cost Effectiveness Analysis of Anesthesia Providers." *Nursing Economic$.* 2010; 28:159-169.

[18] 63 FR 58813, November 2, 1998.

[19] Healthcare Performance Strategies. Anesthesia Subsidy Survey 2012.

a hospital with 20 operating rooms hospital pays an average of $3.2 million in anesthesiology subsidy. Anesthesiology groups receive this payment from hospitals in addition to their direct professional billing.

As independently licensed professionals, CRNAs are responsible and accountable for judgments made and actions taken in his or her professional practice.[20] The scope of practice of the CRNA addresses the responsibilities associated with anesthesia practice and pain management that are performed by the nurse anesthetist as a member of inter-professional teams. The same principles are used to determine liability for surgeons for negligence of anesthesiologists or nurse anesthetists. The laws' tradition of basing surgeon liability on control predates the discovery of anesthesia and continues today regardless of whether the surgeon is working with an anesthesiologist or a nurse anesthetist. [21]

There is 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*,[22] 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 over ten years of AANA membership survey data. Moreover, the American Society of Anesthesiologists *ASA Relative Value Guide 2013* suggests loosening further the requirements that anesthesiologists must meet to be "immediately available," stating that it is "impossible to define a specific time or distance

[20] American Association of Nurse Anesthetists. Code of Ethics for the Certified Registered Nurse Anesthetist. Adopted 1986, Revised 2018. See: https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/code-of-ethics-for-the-crna.pdf?sfvrsn=d70049b1_2

[21] Blumenreich, G. Another article on the surgeon's liability for anesthesia negligence. *AANA Journal*. April 2007.

[22] 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.

for physical proximity." This *ASA Relative Value Guide* definition marginalizes any relationship that the "supervisor" has with the patient and is inconsistent with the Medicare CoPs and CfCs, and with the Medicare interpretive guidelines for those conditions, which require anesthesiologists claiming to fulfill the role of "supervising" CRNA services be physically present in the operating room or suite.

If a 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 that CMS remove unnecessary supervision requirements in this proposed rule. Implementation of our request would also require the technical correction of deleting § 485.524(d)(5) *Standard: State exemption*.

AANA Request: Ensure that Telemedicine Credentialing and Privileging Process Requirements Do Not Provide a Pathway to Reimbursement for Anesthesiologist TeleSupervision of Anesthesia Services

As CMS is proposing telemedicine credentialing and privileging process requirements in this proposed rule, the AANA cautions against any requirements that would promote the use of wasteful services in the name of telehealth that would increase costs without improving healthcare access or quality. We caution CMS against requirements or policies that could serve as a pathway to reimbursing anesthesiologists for anesthesia care for remote "supervision" services. This type of remote supervision would not improve access to healthcare for patients and would instead reward providers not actually furnishing healthcare services. CMS states in the preamble in the Medicare Physician Fee Schedule CY 2020 rule that they are concerned that virtual presence would not be sufficient "…in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures…such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation."[23] Furthermore, as there is no evidence of the efficacy and cost-effectiveness of in-person physician

[23] 85 FR 84539, December 28, 2020.

supervision requirements,[24] there also is no evidence regarding the benefit for the use of supervision of anesthesia via telehealth.[25] As evidence shows that in-person supervision by physicians does not improve anesthesia outcomes, while it does significantly increase costs; thus it stands to reason that remote supervision would not improve outcomes, while also substantially increasing costs. In these instances, anesthesiologist telesupervision of anesthesia provider services would not meet CMS's current Category 2 criteria for Medicare telehealth services of providing a clinical benefit to the patient. As CMS has noted that Medicare Part B anesthesiologist medical direction is a condition for payment of anesthesiologist services[26] and not quality standards,[27] we also would urge the agency against using interactive telecommunications technology as a way to fulfill any of the seven required steps for payment. We stress that the use of telehealth for these purposes would be wasteful and would constitute inappropriate use.

AANA Request: Allow for Flexibility in the Professional Healthcare Staff that May Provide Advice on Written Policies for the Provision of Services (Proposed § 485.514(b))

We request flexibility in the REH professional healthcare staff that may be allowed to provide advice on written policies for the provision of services as proposed at 485.514 (b). As CMS is proposing REH staff members "including physician assistants, nurse practitioners, or clinical nurse specialists" who may provide advice written policies, it is not clear from this language whether other APRNs, such as CRNAs, would be excluded. We are pleased that nothing in these proposed rules would automatically preclude a CRNA to be part of a REH's medical staff. We would also ask that CMS also provide clarity and flexibility in this language at 485.514 (b) so that other APRNs, such as CRNAs, may be included. CRNAs play an essential role in ensuring

[24] See B. Dulisse and J. Cromwell op cit. and Paul F. Hogan et. al, op cit.

[25] 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 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.

[26] 42 CFR §415.110 Conditions for payment: Medically directed anesthesia services.

[27] 63 FR 58813, November 2, 1998.

that rural America has access to critical anesthesia services, including critical obstetrical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many necessary procedures. As CRNAs have expertise in anesthesia and pain management services that may be provided in a REH, CRNAs should be allowed to provide advice on written policies affecting the provision of these and related services.

We thank you for the opportunity to comment on this proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Ralph Kohl, at 202.484.8400, rkohl@aanadc.com.

Sincerely,

Dina Velocci, DNP, CRNA, APRN
AANA President

cc: William Bruce, MBA, CAE, AANA Chief Executive Officer
Ralph Kohl, AANA Senior Director of Federal Government Affairs
Romy Gelb-Zimmer, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy