November 18, 2019

Alec Alexander
Deputy Administrator and Director
Center for Program Integrity
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Via ProgramIntegrityRFI@cms.hhs.gov

RE: Center for Program Integrity’s Request for Information on the Future of Program Integrity

Dear Mr. Alexander:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the Request for Information on the Future of Program Integrity. The AANA is firmly committed to working with the agency and other healthcare stakeholders to help achieve our common goals of increasing access to the highest quality healthcare, reducing regulatory burdens on providers, promoting healthcare innovation and reducing healthcare costs. The issues addressed in our comment are outlined as follows:

I. CRNAs Provide Safe, High Quality and Cost-Effective Care

II. Align Medicare Policy with State Scope of Practice Consistent with the Recommendations of the National Academy of Medicine, and Remove Costly and Unnecessary Supervision Requirements

III. Amend Medicare Guidance to Clarify that CRNAs Can Order and Refer Medicare Services if Allowed Under State Law

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes nearly 54,000 CRNAs and SRNAs, representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 49
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.

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

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
on evidence-based practice in healthcare. 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.

CRNAs play an essential role in ensuring 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.

### II. AANA Request: Align Medicare Policy with State Scope of Practice Consistent with the Recommendations of the National Academy of Medicine, and Remove Costly and Unnecessary Supervision Requirements

The AANA believes that fraud is a serious matter that can have negative implications for federal programs such as Medicare, Medicaid, and CHIP by increasing costs at the expense of patient care. We commend the Centers for Medicare and Medicaid Services (CMS) for continuing work on this issue while also requesting comment from stakeholders on approaches to strengthen program integrity in this request for information. The current Medicare regulations as they pertain to CRNA practice, in some cases encourage wasteful and ineffective care. As payment moves to rewarding

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6 Liao, op cit.
desired care outcomes and providing the best care at lower cost, adoption of outcome and evidenced-based regulations that reward and support high-quality, team-based care will focus attention on population and community needs at the local level. We have attempted to think out of the box in presenting recommendations to improve performance of the health care system as a whole. We have suggested regulatory reform related to the delivery of anesthesia services that will promote competitiveness and economic growth through reduction of waste and innovation at the local level. As part of this effort, the AANA recommends that CMS remove costly and unnecessary requirements relating to physician supervision of CRNA anesthesia services. These requirements are more restrictive than the majority of states and impede local communities from implementing the most innovative and competitive model of providing quality care. Reforming the Conditions of Coverage (CfCs) and the Conditions of Participation (CoPs) to eliminate the costly and unnecessary requirement for physician supervision of CRNA anesthesia services supports delivery of population and community health care in a manner allowing states and healthcare facilities nationwide to make their own decisions based on state laws and patient needs, controlling cost, providing access and delivering quality care.

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 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 health care system if nurses delivered more of the care.”

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7 See 42 CFR §§ 482.52, 485.639, 416.42.
8 Dulisse, 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.10

Letting states decide this issue according to their own laws is consistent with Medicare policy reimbursing CRNA services in alignment with their state scope of practice,11 and with the National Academy of Medicine’s recommendation, “Advanced practice registered nurses should be able to practice to the full extent of their education and training.”12 The opt-out process introduces unique, political barriers to the optimal utilization of CRNAs to ensure access to high quality cost-effective care. With the evidence for CRNA patient safety so clear, the Agency should eliminate the requirement for governors to request additional permission to implement their own statutes and policies in this area. 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.

Evidence 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 condition of participation. The AANA receives reports from the field that anesthesiologists erroneously suggest 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

10 Paul F. Hogan et. al, “Cost Effectiveness Analysis of Anesthesia Providers.” Nursing Economic$. 2010; 28:159-169
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.\(^{13}\) But there are even bigger costs involved if the hospital administrator believes that CRNAs are required to have anesthesiologist supervision.

According a nationwide survey of anesthesiology group subsidies,\(^{14}\) 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 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.\(^{15}\) 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.\(^{16}\)

There is strong evidence in the literature that anesthesiologist supervision fails to comply with federal requirements, either the Part A CoP or Part B CfC. Lapses in anesthesiologist supervision are common even when an anesthesiologist is medically directing as few as two CRNAs, according

\(^{13}\) 63 FR 58813, November 2, 1998.


to a 2012 study published in the journal Anesthesiology,\textsuperscript{17} 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 Newly 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 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, it is obsolete and unnecessary and should be eliminated. In 2001, the Medicare agency\textsuperscript{18} sought to eliminate this counterproductive regulation and maximize flexibility when it repealed the Medicare requirement for physician supervision of nurse anesthetists in a final rule. That final rule was subsequently suspended with the change in administrations, and replaced with a final rule\textsuperscript{19} establishing the process by which Medicare requires governors to ask the agency’s permission to “opt out” of the Medicare supervision requirement.

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. With over 35 states not requiring physician supervision, the 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 be reversed by the sole decision of the governor without public comment or legislative oversight. There is no precedent at CMS for this whip-saw approach to healthcare policy.

We propose that CMS streamline this regulation to be more effective and efficient by deferring to state scope of practice for healthcare professionals practicing in hospitals, CAHs and ASCs, and removing the federal supervision requirement in the CoPs and in the CfCs that goes beyond what is required in the majority of states. In doing so, the opt-out process is superseded.

III. **AANA Request: Amend Medicare Guidance to Clarify That CRNAs Can Order and Refer Services if Allowed Under State Law**

The AANA fully supports combatting fraud, fraud, and abuse, and securing program integrity in the Medicare program; however, we have believe the current policy prohibiting CRNAs from ordering and referring services is having unintended consequences for access to care, especially for Medicare beneficiaries living in rural and underserved areas. The AANA requests that CMS clarify in its educational materials that CRNAs can order and refer medically necessary Medicare services and also include CRNAs among the order and referring data file as long as CRNAs are legally authorized to perform these services in the state in which the services are furnished. CRNAs are not expressly prohibited from ordering and referring Medicare services by legislation or by regulation. In fact, Medicare in November 2012 published a rule indicating Medicare coverage of all Medicare CRNA services within their state scope of practice. However, our membership has informed us that the services that CRNAs order and specialists they refer to are not being

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20 See [https://data.coms.gov/](https://data.coms.gov/)

reimbursed because CRNAs are not included among the type or specialty to be on the CMS ordering and referring file. Furthermore, a Medicare Learning Network article revised in October 2015 does not list CRNAs among the specialists that can order and refer. These denials are affecting patient access to needed services as laboratory services and physical therapy related to chronic pain management services, especially in rural areas. We stand ready to work with CMS on this issue and would be happy to discuss this matter in further detail.

We thank you for the opportunity to comment on this request for information. 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, rko.hl@aanadc.com.

Sincerely,

Kathryn Jansky, MHS, CRNA, APRN, USA LTC (ret)
AANA President

cc: Randall D. Moore, DNP, MBA, CRNA, AANA Chief Executive Officer
Ralph Kohl, AANA Senior Director of Federal Government Affairs
Randi Gold, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy