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Safe and effective
anesthesia



September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1976-P
P.O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1976-P – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule (82 Fed.Reg. 33950, July 21, 2017)

Dear Ms. Verma:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on this proposed rule; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (82 Fed.Reg. 33950, July 21, 2017). The AANA makes the following comments and requests of the Centers for Medicare & Medicaid Services (CMS):

- Support CRNA Crosswalk to Anesthesiology for Malpractice Expense Update
- Do Not Devalue Anesthesia Codes Associated with Colorectal Cancer Screening Tests
- Prohibit Wasteful Tele-Supervision of CRNA Services From Being Included among the List of Telehealth Services for Remote Patient Monitoring
- Work with the AANA to Establish Predetermined Criteria for E&M for Pain Management Procedures
- Use the Same Definitions that are Used under the MIPS Program to Identify Providers that Fall under Special Status Scoring For the AUC Program
- Maintain Neutral Payment Adjustment for 2018 PQRS Program for Satisfactorily Reporting One Measure for at Least 50 Percent of Medicare Patients

- Support Proposal to Modify Value Modifier's Negative Payment Adjustment Levels and Support Proposal to Change PQRS Reporting Criteria
- Support Proposal to Incorporate Patient Relationship Codes into the CPT Code Set

REQUEST FOR INFORMATION

- 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
- Promote Efficiency by Amending the Ambulatory Surgical Center Conditions of Coverage (CfCs) by Recognizing CRNAs to Evaluate the Risk of Anesthesia Immediately Before Surgery
- Encourage Flexibility by Amending the Hospital Conditions of Participation so that Anesthesia Services (42 CFR§ 482.52) Can be Under the Direction of Either a CRNA or a Physician
- Promote Parity in Anesthesia Education by Amending Anesthesia Payment Rules to Allow 100 Percent Payment for One Anesthesiologist Teaching Two SRNAs
- Amend Medicare Guidance to Clarify that CRNAs Can Order and Refer Medicare Services if Allowed Under State Law
- Update Medicare Policy to Include CRNAs Among the List of Providers that Can Provide E&M Services
- Remove From Subregulatory Guidance the Exclusion of Practitioners Who are Not Physicians From Serving on Medicare Carrier Advisory Committees

Background of the AANA and CRNAs

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists, and AANA membership includes more than 50,000 CRNAs and student nurse anesthetists (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 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 continue to be 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 provide every aspect of the delivery of anesthesia services including 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 and chronic 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. 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, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.¹ Furthermore, an August 2010 study published in *Health Affairs* shows 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.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

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

¹ Paul F. Hogan et. al, "Cost Effectiveness Analysis of Anesthesia Providers." *Nursing Economic*. 2010; 28:159-169.

² B. Dulisse and J. Cromwell, "No Harm Found When Nurse Anesthetists Work Without Physician Supervision." *Health Affairs*. 2010; 29: 1469-1475.

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.

⁴ Negusa 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.

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.⁵ 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.⁶

AANA Request: Support CRNA Crosswalk to Anesthesiology for Malpractice Expense Update

We support the agency's proposal to crosswalk the specialty code of 43 (CRNAs) to the specialty code of 05 (anesthesiology) for the anesthesia malpractice (MP) relative value unit (RVU). We also would like to highlight that devaluing anesthesia services could put anesthesia delivery at risk. A 2007 GAO study found that Medicare paid 67 percent of what private insurers paid for anesthesia services.⁷ In response to this report, CMS's November 2007 Medicare Physician Fee Schedule CY 2008 final rule (72 FR 66221 November 27, 2007) recognized that anesthesia payment was substantially undervalued; the agency therefore increased the value of anesthesia work by 34 percent, yielding a 20 percent increase in the anesthesia conversion factor in 2008 relative to what the anesthesia conversion factor would have otherwise been. We do have concerns about including specialty code of 32 (anesthesiologist assistants) in this crosswalk, and whether inclusion of this specialty code distorts the anesthesia MP RVU. We note that anesthesiologist assistants typically do not carry their own malpractice insurance and their services are not covered by Medicare unless they are medically directed by an anesthesiologist.

⁵ 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>

⁶ Liao, op cit.

⁷ U.S. Government Accountability Office (GAO) op cit.

AANA Request: Do Not Devalue Anesthesia Codes Associated with Colorectal Cancer Screening Tests

We applaud CMS for acknowledging that anesthesia furnished as part of screening colonoscopies is the standard of care, and for finalizing the proposal to include anesthesia as part of colorectal cancer screening tests in the 2015 final rule. However, the AANA has concerns about the agency's proposal and alternative proposal to devalue anesthesia procedure CPT codes 008X1 and 008X2. We note that the AANA is excluded from the AMA Relative Value Update Committee (AMA-RUC) process, and did not have the opportunity to provide initial input on these codes. The AANA has an interest in improving patient outcomes by delivering colonoscopies safely, comfortably and efficiently, and we caution the agency not to devalue these codes. Patients recover more quickly from Monitored Anesthesia Care than from other sedation, enabling GI endoscopy proceduralists to provide a dramatically greater number of higher quality procedures than those using alternative forms of sedation. This point emphasizes the importance and value of these procedures. We stand ready to work with the agency and would be happy to answer any questions to help with this process.

AANA Request: Prohibit Wasteful Tele-Supervision of CRNA Services From Being Included among the List of Telehealth Services for Remote Patient Monitoring

The AANA is supportive of telehealth and remote monitoring technology that improves the quality of care provided for all patients and especially those with chronic conditions, but cautions against the use of wasteful services in the name of telehealth that would increase costs without improving healthcare access or quality. As CMS is considering making separate payment for CPT codes that describe remote patient monitoring (P. 33975), we stress that one wasteful policy would be to cover anesthesiologists without providing actual anesthesia care, through billing for remote so-called "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 regarding the benefit for the use of supervision of anesthesia via telehealth.⁸ In these instances, anesthesiologist tele-

⁸ 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;

supervision of CRNA services would not meet CMS's criteria for Medicare telehealth services of providing a clinical benefit to the patient. Therefore, we ask in this and future rules that CMS prohibit wasteful anesthesiologist tele-supervision of CRNA services from being included among the list of telehealth services as a part of separate payment for remote patient monitoring.

AANA Request: Work with the AANA to Establish Predetermined Criteria for E&M for Pain Management Procedures

We appreciate that the agency is taking the initiative to make the guidelines for evaluation and management (E&M) less burdensome and ambiguous (p. 34079). E&M is integral for the practice of pain management. Prior to performing a pain management technique, CRNAs conduct a comprehensive patient evaluation to confirm the necessity of the planned technique. These E&M services may include conducting a history and physical examination, ordering and reviewing diagnostic tests including imaging studies, and performing the indicated diagnostic and therapeutic pain management techniques. Conducting a history and physical examination and reviewing diagnostic studies is a well-established and essential component of patient evaluation.

We recommend that CMS work with the AANA to develop specific predetermined criteria or benchmarks for E&M associated with spinal interventional codes, such as 62321, 62323, 64483, 64484, 64520, 64490, 64493, 64633, and 64635. Furthermore, we also request that consult and follow-up for these procedures also have specific criteria as well. These criteria could resemble the preoperative assessment currently done by all CRNAs prior to the administration of an anesthetic. These predetermined criteria would make coding and billing more straight forward by allowing CRNAs to meet criteria without fear of under or over-coding patient visits. We are happy to work with the agency in developing this process.

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.

AANA Request: Use the Same Definitions that are Used under the MIPS Program to Identify Providers that Fall under Special Status Scoring For the AUC Program

We recommend that CMS use the same definitions used under the Merit-Based Incentive Payment System (MIPS) program to identify providers that fall under special status scoring, such as non-patient facing clinicians for the Medicare Appropriate Use Criteria (AUC) program. Given that CRNAs were originally excluded from the Medicare Electronic Health Record (EHR) Incentive Program and are optional providers under the advancing care information performance category under MIPS, CRNAs should be excluded from the AUC program as an ordering or consulting provider.

CRNAs are predominantly classified as non-patient facing clinicians; therefore if the AUC program is implemented, CMS should use caution when identifying a CRNA who has submitted performance data via the group reporting option under MIPS. While CRNAs may be involved in ordering imaging services, in many cases, the CRNA may not have any control or access to clinical decision support mechanisms (CDSM) technology, as is the case with EHR technology, to meet the requirements of the AUC program even if the plurality of the group, such as face-to-face clinicians, satisfactorily met the advancing care information performance category. Furthermore, we ask for clarification as to how the 21st Century Cures Act will affect the AUC program by the noting the provisions made to ambulatory surgical centers (ASCs) with regards to the Medicare EHR Incentive Program and subsequent advancing care information performance category under the Quality Payment Program (QPP). We believe that the AUC consultation requirements to be burdensome and challenging for ordering clinicians in the outpatient and ASCs settings noting the lack of EHR and CDSM technology. We also request further clarification about documentation and claims information required to meet the qualifications. As such, we do agree with the agency's proposal to make the AUC an improvement activity.

AANA Request: Maintain Neutral Payment Adjustment for 2018 PQRS Program for Satisfactorily Reporting One Measure for at Least 50 Percent of Medicare Patients

We support and appreciate that CMS is adjusting the data submission requirements for the CY2018 payment adjustment to be in line with the reporting criteria for the quality performance category under the MIPS program. In addition, we recommend that CRNAs who submit measures for individual reporting maintain a neutral 2018 payment adjustment if they had satisfactorily reported one measure for at least 50 percent of the eligible participant's Medicare Part B fee-for-service patients seen during the reporting period to which the measure applies for in claims and registry reporting mechanisms. In previous PQRS performance periods, CRNAs had few applicable anesthesia measures to choose from. Even though CMS had an anesthesia measure-applicability validation (MAV) cluster consisting of 4 anesthesia measures (424,426,427,430) in the 2016 PQRS performance period, we note that many CRNAs only had one applicable measure to choose from within the cluster. While many of the measures maintain face validity, often the measures have construct issues. For example, many anesthesia measures are not written to take into account for non-inhalational anesthesia, non-operating room anesthesia or other anesthetizing locations outside of a traditional inpatient setting operating room, such as the outpatient or ASC settings. Furthermore, these measures generally do not apply to interventional pain management, many gastrointestinal procedures, and cataract procedures. Even with the proposition of lowering the data submission requirement, CRNAs still face significant challenges under MAV as non-patient facing clinicians and should not be penalized under PQRS.

AANA Request: Support Proposal to Modify Value Modifier's Negative Payment Adjustment Levels and Support Proposal to Change PQRS Reporting Criteria

The AANA acknowledges and supports CMS's proposal to modify the Value Modifier's negative payment adjustment levels as CRNAs and other eligible clinicians transition into MIPS under the QPP. In addition, we support CMS's proposal to change the PQRS reporting criteria that affect CRNAs and other eligible clinicians, and note that this has implications for meeting the Value Modifier reporting requirements. The proposed changes to the PQRS reporting criteria include reducing the number of measures that eligible clinicians must report and eliminating the need for clinicians to report measures across multiple domains.

AANA Request: Support Proposal to Incorporate Patient Relationship Codes into the CPT Code Set

The AANA supports CMS' effort to incorporate the CY 2018 Patient Relationship Codes incorporated into the CPT code set. Given that CRNAs and their billers are already familiar with the CPT code set, this would be a relatively simple transition for our membership to incorporate the new Patient Relationship Codes in their Medicare claims.

REQUEST FOR INFORMATION

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

We appreciate the agency's commitment towards reducing regulatory burden in the Medicare program. The current regulations in some cases encourage wasteful and ineffective care. As payment moves to rewarding 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.⁹ 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.

⁹ See 42 CFR §§ 482.52, 485.639, 416.42.

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*¹⁰ 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.”¹¹

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.¹²

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,¹³ and with the National Academy of Medicine’s recommendation, “Advanced practice registered nurses should

¹⁰ Dulisse, op. cit.

¹¹ Who should provide anesthesia care? (Editorial) *New York Times*, Sept. 6, 2010.

¹² Paul F. Hogan et. al, “Cost Effectiveness Analysis of Anesthesia Providers.” *Nursing Economic*®. 2010; 28:159-169.

¹³ 42 CFR §410.69(b), 77 Fed. Reg. 68892, November 16, 2012.

be able to practice to the full extent of their education and training.”¹⁴ 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 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.¹⁵ 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,¹⁶ 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

¹⁴ National Academy of Medicine. *The future of nursing: leading change, advancing health*. Washington, DC: The National Academies Press, p. 3-13 (pdf p. 108) 2011.

¹⁵ 63 FR 58813, November 2, 1998.

¹⁶ Healthcare Performance Strategies. Anesthesia Subsidy Survey 2012.

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.¹⁷ 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.¹⁸

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 to a 2012 study published in the journal *Anesthesiology*,¹⁹ 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

¹⁷ American Association of Nurse Anesthetists. Code of Ethics for the Certified Registered Nurse Anesthetist. Adopted 1986, Revised 2005.

¹⁸ Blumenreich, G. Another article on the surgeon's liability for anesthesia negligence. *AANA Journal*. April 2007.

¹⁹ 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.

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 agency²⁰ 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 rule²¹ 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,

²⁰ 66 Fed. Reg.4674, January 18, 2001.

²¹ 66 Fed. Reg. 56762, November 13, 2001.

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.

We request that CMS consider replacing the existing language with the following proposed language (relative to the existing rule, additional language is underlined and language is stricken):

§ 482.52 Condition of participation: Anesthesia services.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, ~~who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or~~

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

* * * * *

~~(c) Standard: State exemption. (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt out of the current physician supervision requirement, and that the opt-out is consistent with State law.~~

~~(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.~~

§ 485.639 Condition of participation: Surgical services.

* * * * *

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

- (1) Anesthesia must be administered by only—
- (i) A qualified anesthesiologist;
 - (ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
 - (iii) A doctor of dental surgery or dental medicine;
 - (iv) A doctor of podiatric medicine;
 - (v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;
 - (vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or
 - (vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

~~(2) 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. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.~~

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

~~(e) *Standard: State exemption.* (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.~~

~~(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.~~

§ 416.42 Condition for coverage—Surgical services.

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(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which an anesthesiologist's assistant a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an the anesthesiologist's assistant, must be under the supervision of an anesthesiologist.

~~(c) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with~~

~~State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.~~

~~(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.~~

AANA Request: Promote Efficiency by Amending the Ambulatory Surgical Center Conditions for Coverage (CfCs) by Recognizing CRNAs to Evaluate the Risk of Anesthesia Immediately Before Surgery

Performing the comprehensive preanesthetic assessment and evaluation of the risk of anesthesia is within the scope of practice of a CRNA. We ask that Medicare recognize CRNAs as authorized to evaluate the risk of anesthesia immediately before a surgical procedure performed in an ASC in the same manner that the agency recognizes both CRNAs and physicians conducting the final pre-anesthetic assessment of risk for a patient in the hospital. Accordingly, the AANA requests revision of 42 CFR § 416.42 (a) (1).

We recommend amending the ambulatory surgical center CfCs so that CRNAs are authorized to evaluate the risk of anesthesia immediately before surgery. The AANA continues to receive examples of inefficiency and operational waste due to this regulation. In actual practice, CRNAs evaluate patients preoperatively for anesthesia risk in the ASC environment. The CRNA has a duty to do so, consistent with Standard 1 of the Standards for Nurse Anesthesia Practice.²² The current ASC rule on preanesthesia examination is inconsistent with ASC rules regarding patient discharge, and with Medicare hospital CoPs in this same area. Under the hospital CoPs for anesthesia services (42 CFR§ 482.52 (b) (1)), CRNAs are recognized to perform the pre-anesthesia evaluation for hospital patients presenting with a greater range of complexity and multiple chronic conditions than ASC patients.

The problem appears to be that the current language combines the assessment of surgical risk with the assessment of anesthetic risk in one sentence, when in reality these activities are most frequently performed by two different members of the team, the surgeon and the anesthesia

²² American Association of Nurse Anesthetists. Standards for Nurse Anesthesia Practice. Adopted 1974, Revised 2013.

professional. The CfCs for ASC surgical services at 42 CFR§ 416.42 (a) (1) state that a “physician must examine the patient immediately before surgery to *evaluate the risk of anesthesia and of the procedure to be performed.*” (Italics added.) By combining the two functions into a single sentence, in an ASC, a physician must evaluate the risk of anesthesia, precluding a CRNA from being recognized for performing an essential function within the CRNA’s scope of practice and may place the surgeon in the position of evaluating an aspect of care outside his field of expertise. Yet, under 42 CFR § 416.42 (a) (2), a CRNA is recognized to evaluate the patient prior to discharge. CRNAs perform anesthesia risk assessment routinely in hospitals across America. Modification of this regulation to promote efficiency will reduce administrative burden associated with unnecessary delays.

In order to streamline and provide clarity to this regulation, we recommend that ASC CfCs separate the language referring to the assessment for anesthesia risk from that describing the surgeon’s immediate assessment of the risk of the procedure. Our recommendation limits the direction under “Standard: Anesthetic risk and evaluation” solely to those matters relating to anesthesia, and places language related to the surgical risk evaluation within the “Standard: Admission and pre-surgical assessment.” The AANA recommends the language at 42 CFR§ 416.42 (a) (1) be revised to read (relative to the existing rule, additional language is underlined and language is stricken):

- (a) *Standard: Anesthetic risk and evaluation.* (1) A physician or certified registered nurse anesthetist, as defined in 42 C.F.R. § 410.69(b) must examine the patient immediately before surgery the procedure to evaluate the risk of anesthesia ~~and of the procedure to be performed.~~

Further, the AANA recommends the language at 42 CFR§ 416.52(a) (2) be revised to read (relative to the existing rule, additional language is underlined):

§ 416.52 Conditions for coverage—Patient admission, assessment and discharge.

* * * * *

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination immediately prior to surgery for any changes in the patient’s condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.

AANA Request: Encourage Flexibility By Amending the Hospital Conditions of Participation so That Anesthesia Services (42 CFR§ 482.52) Can Be Under the Direction of Either a CRNA or a Physician

To promote cost effective and innovative approaches to the delivery of quality anesthesia services, CMS should allow hospitals to determine the administrative structure that best meets the needs of their patients and surgeons by revising 42 CFR§ 482.52 to include CRNAs among the healthcare professionals who may direct the provision of anesthesia services in hospitals.

The agency has authority to make this change under the Social Security Act. When anesthesia services are under the direction of a CRNA, each Medicare beneficiary patient remains under the overall care of a physician, consistent with the statutes and regulations governing the Medicare program in general and the hospital CoPs in particular. The change we recommend would relieve hospital regulatory burden associated with operating the Medicare program, reduce healthcare costs, and enable the organization of anesthesia services tailor-made to ensure patient safety and meet community needs.

We recommend the introductory language be revised to read (relative to the existing rule, additional language is underlined):

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy, or a certified registered nurse anesthetist, as defined in 42 C.F.R. § 410.69(b).

The proposed change reduces regulatory burdens on hospitals by eliminating the need to pay a stipend for a physician “in name only” to serve as director of the anesthesia department while the hospital would have the flexibility to retain those services if they so desired. In some cases, the existing regulation leads to confusion by placing into the hands of persons inexpert in anesthesia care a federal regulatory responsibility for directing the unified anesthesia service of a hospital solely because he or she is a doctor of medicine or of osteopathy. In other cases, the hospital

may contract with and pay a stipend to an anesthesiologist for department administration only, solely because there is a federal regulation. There is no evidence supporting the requirement for a physician or osteopathic doctor to direct anesthesia services.

CRNAs are highly educated anesthesia experts and are fully qualified to serve in this role. In many hospitals the CRNA may be the only health care professional possessing expertise and training in the anesthesia specialty. The scope of nurse anesthesia practice includes responsibilities for administration and management, quality assessment, interdepartmental liaison and clinical/administrative oversight of other departments.

Because CRNAs possess a strong foundation in nursing, critical care and anesthesia and pain management, CRNAs are frequently called upon to assume administrative and executive positions. With their specialty background as well as the CRNA educational preparation at the master's and doctoral level, CRNA are being selected to function as anesthesia and surgery department administrators, chief nurse executives, chief operating officers and chief executive officers of hospitals. To achieve a more effective regulatory framework, we propose maximizing flexibility and innovation at the local level by encouraging facilities to structure their anesthesia departments efficiently and effectively. Hospitals should be able to select the very best anesthesia leader for the job at a cost they can afford.

AANA Request: Promote Parity in Anesthesia Education By Amending Anesthesia Payment Rules to Allow 100 Percent Payment for One Anesthesiologist Teaching Two SRNA

In order to make health care more accessible and reduce barriers to educational opportunities for anesthesia professionals, the AANA requests equitable reimbursement in anesthesia educational settings. For an anesthesiologist to be reimbursed only 50 percent for each of two cases involving SRNAs is not consistent with Medicare's equitable payment policies for CRNAs and anesthesiologists, nor does it comply with the intent of Congress that directed the teaching rules for CRNAs be "consistent" with the rules for anesthesiologists.²³ In fact, CMS stated that it agreed that an anesthesiologist who is concurrently teaching two SRNAs to be able to bill for

²³ P.L.110-275, MIPPA, Sec. 139.

100 percent of the anesthesia fee schedule for each case involving a SRNA “would establish parity of payment...” for anesthesia services.²⁴ CMS also stated in the proposed rule and in the final rule that, “There currently are no substantive differences in payment between teaching anesthesiologists and teaching CRNAs, and there would continue to be no such differences under our proposed policies.”²⁵

We appreciate that CMS recognizes there are no substantive differences in payment between CRNAs and anesthesiologists. However, by allowing an anesthesiologist to bill for only 50 percent of the fee for each of two cases involving SRNAs, when an anesthesiologist can bill for 100 percent for the fee for each of two cases involving residents and CRNAs can bill for 100 percent of the fee for each of two cases involving SRNA, this creates a substantive difference between its payments for teaching anesthesiologists and teaching CRNAs. Regardless of whether a teaching CRNA or teaching anesthesiologist is involved in the cases with SRNAs, the teacher is providing 100 percent of an anesthesia service to each patient and should be able to bill for 100 percent of the fee for each case.

In addition, to reimburse an anesthesiologist only 50 percent when teaching SRNAs erroneously implies that services provided by a teaching anesthesiologist and SRNA are less valuable than anesthesia service provided by a teaching CRNA and SRNA or a teaching anesthesiologist and anesthesiology resident. This lower reimbursement is discriminatory by devaluing the anesthesia services provided by a teaching anesthesiologist and SRNA.

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

In the interest of improving 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

²⁴ 74 Fed. Reg. 61872, November 25, 2009.

²⁵ 74 Fed. Reg. 33606, July 13, 2009 and 74 Fed. Reg. 61871, November 25, 2009.

among the order and referring data file²⁶ 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.²⁷ However, our membership has informed us that the services that CRNAs order and specialists they refer to are not being 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.²⁸ 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.

AANA Request: Change Medicare Policy Manual to Clarify That E&M Services are Allowed

In the interest of improving access to care, the AANA requests that CMS include CRNAs among the list of providers that can provide Evaluation and Management Services (E&M) in the Medicare Claims Processing Manual.²⁹ This section of the manual has not been updated since January 2010, and does not take into account the language from the CY 2013 Physician Fee Schedule final rule³⁰ and from Section 140.4.3 of the Medicare Claims Processing Manual, clarifying that Medicare covers all medically necessary Medicare services provided by CRNAs within their state scope of practice. Prior to performing a pain management technique, CRNAs

²⁶ See <https://data.cms.gov/>

²⁷ 77 Fed. Reg. 68892, 69005 et seq., Nov. 16, 2012, amending 42 CFR §410.69(b). Certified Registered Nurse Anesthetists scope of benefit. <http://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf>.

²⁸ Medicare Learning Network MLN Matters Article, SE1305 Revised, Full Implementation of Edits on the Ordering/Referring Providers in Medicare Part B, DME, and Part A Home Health Agency (HHA) Claims (Change Requests 6417, 6421, 6696, and 6856): Revised Oct. 21, 2015, available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1305.pdf>.

²⁹ Internet Only Manual Publication #100-04, Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners, Section 30.6.1, available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>.

³⁰ 77 Fed. Reg. 68892, 69005 et seq., Nov. 16, 2012, amending 42 CFR §410.69(b). Certified Registered Nurse Anesthetists scope of benefit. <http://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf>.

conduct a comprehensive patient evaluation to confirm the necessity of the planned technique. These E&M services may include conducting a history and physical examination, ordering and reviewing diagnostic tests including imaging studies, and performing the indicated diagnostic and therapeutic pain management techniques. Conducting a history and physical examination and reviewing diagnostic studies is a well established and essential component of patient evaluation. In some cases, the referring physician conducts the comprehensive patient evaluation and in other practices, the CRNA may be responsible to obtaining the patient history, physical examination, psychosocial evaluation, and numerous studies associated with the pain condition.

AANA Request: Remove from Subregulatory Guidance the Exclusion of Practitioners Who are Not Physicians From Serving on Medicare Carrier Advisory Committees

We urge CMS to remove from subregulatory guidance the exclusion of practitioners who are not physicians from serving on Medicare Administrative Contractors’ (MACs) Carrier Advisory Committees (CAC). Specifically, we note that Exhibit 3 of the Section 13.8.1 of the Medicare Program Integrity Manual specifically states, “Do not include other practitioners on this committee,” which ultimately precludes APRNs, including CRNAs, from participation.³¹ We urge removal of this clause from the manual. We are troubled by multiple instances where MACs have exceed their authority by issuing local coverage determinations (LCD) that contradict existing CMS regulation and policy and scope of practice under state law that harm patient access to vital and medically necessary services. As CACs are crucial in the development and review of LCDs, it is imperative that practitioners such as CRNAs are represented on CACs so as to ensure that the LCD process reflect evidence-based policies, the perspective of practitioners who are not physicians, and protect robust patient access to medically necessary APRN services under Medicare.

³¹ Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, Rev. 608, August 4, 2015, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf> and <http://www.cms.gov/manuals/downloads/pim83exhibits.pdf>.

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,



Cheryl L. Nimmo, DNP, MSHSA, CRNA
AANA President

cc: Wanda O. Wilson, PhD, MSN, CRNA, AANA Executive Director
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