

AANA RECOMMENDATIONS

AANA Request: Encourage Flexibility and Efficiency by Removing 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.¹ These requirements are more restrictive than the majority of state requirements and also impede local communities from implementing the most innovative and competitive model of providing quality care. Reforming the Conditions for 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*

¹ See 42 CFR §§ 482.52, 485.639, 416.42.

*Affairs*² 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.”³

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.⁴

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,⁵ 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.”⁶ 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

² Dulisse, op. cit.

³ Who should provide anesthesia care? (Editorial) *New York Times*, Sept. 6, 2010.

⁴ Paul F. Hogan et. al, “Cost Effectiveness Analysis of Anesthesia Providers.” *Nursing Economic*®, 2010; 28:159-169.

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

⁶ 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.

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.⁷ 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,⁸ 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.

⁷ 63 FR 58813, November 2, 1998.

⁸ Healthcare Performance Strategies. Anesthesia Subsidy Survey 2012.

As independently licensed professionals, CRNAs are responsible and accountable for judgments made and actions taken in his or her professional practice.⁹ 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.¹⁰

There is strong evidence in the literature that anesthesiologist supervision fails to comply with federal requirements, either the Part A CoP or Part B condition for payment. 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*,¹¹ 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.

⁹ American Association of Nurse Anesthetists. Code of Ethics for the Certified Registered Nurse Anesthetist. Adopted 1986, Revised 2005.

¹⁰ Blumenreich, G. Another article on the surgeon's liability for anesthesia negligence. *AANA Journal*. April 2007.

¹¹ 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.

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 agency¹² 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 rule¹³ 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,

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

¹³ 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.

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~~(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.

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(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: 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

CMS can also promote flexibility in deferring to facility policies by allowing 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 inexperienced 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, CRNAs 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.¹⁴ In fact, CMS stated that it agreed that an anesthesiologist who is concurrently teaching two SRNAs to be able to bill for 100 percent of the anesthesia fee schedule for each case involving a SRNA “would establish parity of payment...” for anesthesia services.¹⁵ 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.”¹⁶

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

¹⁴ P.L.110-275, MIPPA, Sec. 139.

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

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

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 among the order and referring data file¹⁷ 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.¹⁸ 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.¹⁹ These denials are affecting patient access to needed services, such 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.²⁰ 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

¹⁷ See <https://data.cms.gov/>

¹⁸ 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>.

¹⁹ 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>.

²⁰ 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>.

Schedule final rule²¹ 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 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.

²¹ 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>.