American Association of
NURSE ANESTHESIOLOGY

June 27, 2025

Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: AHRQ–2025–0001–Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again (90 Fed.Reg. 20478, May 14, 2025)

Dear Secretary Kennedy:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on this Request for Information. The AANA makes the following comments and requests:

- Rescind physician supervision requirements for CRNAs as part of the Hospital, Critical Access Hospital, and Rural Emergency Hospital Conditions of Participation (CoPs) and the Ambulatory Surgical Center Conditions for Coverage (CfCs) per 42 CFR §482.52(a)(4) and (c), §485.639(c) (2) and (e), §416.42 (b)(2) and (c), and § 485.524 (d)(3)(ii) and (d)(5).
- Modify 42 CFR§ 482.52 So That Anesthesia Services (42 CFR§ 482.52) Can Be Under the Direction of a CRNA.

AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 65,000 CRNAs and SRNAs, representing about 88 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 58 million anesthetics to patients each year in the United States.[1]

What HHS regulations and/or guidance meet one or more of the following seven criteria identified in E.O. 14219? Should they be modified or repealed? What would be the impact of this change, especially the costs and savings?

[1] For further information see: https://www.aana.com/about-us.

AANA urges the Department of Health and Human Services (HHS) to remove physician supervision requirements for CRNAs as part of the Hospital, Critical Access Hospital, and Rural Emergency Hospital Conditions of Participation (CoPs) and the Ambulatory Surgical Center Conditions for Coverage (CfCs) per 42 CFR §482.52(a)(4) and (c), §485.639(c)(2) and (e), §416.42 (b)(2) and (c), and § 485.524 (d)(3)(ii) and (d)(5) as these requirements meet several of the seven criteria for removal identified in E.O.14219. There is no evidence to support the continued use of these requirements. These requirements were originally rescinded in a final rule on January 18, 2001,[2] but this final rule was withdrawn and replaced with a bureaucratic opt-out process for states to individually remove the requirements.[3] These requirements are regulatory overreach as there exists no enabling statute mandating CMS to implement physician supervision requirements of CRNAs or for the state supervision opt out.[4] Furthermore, no other health care provider is required to lobby their state governors to opt out of federal regulations for the purposes of meeting CoP or CfC requirements.

CRNAs must be board certified and must participate in continuing education and recertification every 4 years to practice. As independently licensed professionals, CRNAs are responsible and accountable for making judgments and taking actions in their professional healthcare practice.[5] CRNAs provide expert anesthesia and pain management care across diverse clinical settings and are trained and licensed to care for all patients, including those with complex medical conditions. In some states, CRNAs are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

There exists clear evidence demonstrating the safety of CRNAs autonomously delivering anesthesia care. A peer-reviewed study published in the Journal of Medicare Care in 2016 looked at anesthesia-related complications for CRNA-only care, physician anesthesiologist-only care, and a team-based approach to care, and found there were no differences in complication rates based on delivery model.[6] This corroborates an earlier peer-reviewed study published in Health Affairs in 2010 that looked at the differences in outcomes in states that had opted out of Medicare's supervision requirement for CRNAs and found no difference in outcomes compared to states that maintained supervision requirements.[7] A comprehensive literature review on anesthesia staffing models completed by the Cochrane Library in 2014 further reinforced these

---

[2] 66 Fed. Reg.4674, January 18, 2001

[3] 66 Fed. Reg. 56762, November 13, 2001

[4] See 66 Fed. Reg. 4674, 4685 et seq., January 18, 2001 and 66 Fed. Reg. 56762, 56768 et seq.,November 13, 2001.

[5] AANA Code of Ethics for the Certified Registered Nurse Anesthetists, July 18, available at: https://issuu.com/aanapublishing/docs/code_of_ethics_for_the_certified_registered_nurse_?fr=sZGY1YTU2NDAxMjU.

[6] Negrusa B., et al., Scope of practice laws and anesthesia complications: No measurable impact of certified registered nurse anesthetist expanded scope of practice on anesthesia-related complications, Medical Care (June 2016),

[7] B. Dulisse and J. Cromwell, No Harm Found When Nurse Anesthetists Work Without Physician Supervision, Health Affairs, 29: 1469-1475 (2010).

findings and found that there could be no definitive statement made about the superiority of any one anesthesia delivery model with respect to safety or adverse outcomes.[8]
Physician supervision requirements contribute to cost inefficiencies and waste in the Medicare program, and drive up costs particularly for rural facilities that rely upon CRNAs for their care. Physician supervision requirements under the CoPs and CfCs, which are not required as a Condition of Payment for CRNAs under Medicare Part B,[9] incentivize the use of Medicare Part B anesthesiologist medical direction payment models. These payment models used by physician anesthesiologists allow them to spuriously collect 50% of the fee per case for up to four concurrent cases performed by CRNAs, while consistently failing to meet Medicare regulatory requirements, resulting in significant lapses as made evident by a 2012 study in Anesthesiology, the official journal of the American Society of Anesthesiologists.[10] The study found that at even a 1:2 anesthesiologist to CRNA ratio, lapses occurred on 35 percent of days.

These supervision requirements are more stringent than most state laws. While the Medicare regulation allows states to opt out of this requirement for CRNAs, the bureaucratic process to do so is onerous. Additionally, CRNAs are the only provider type required to go through this hurdle. To date, half of all states have opted out of the CMS requirement for physician supervision of CRNAs. Furthermore, 44 states do not have any requirements for physician supervision of CRNAs in their nursing/medicine laws or rules. If these requirements were necessary to protect patients, CMS would not allow states to opt out. Physician supervision of CRNAs under the Medicare program remains in place only due to political pressure from a small number of providers who have successfully lobbied for wasteful spending that benefits their own special interests and robs taxpayers of their hard-earned money. Rescinding these requirements would align Medicare policy with clinical evidence and would allow facilities the flexibility to choose the anesthesia delivery model that meets their needs, thus reducing operating costs.

We therefore request that HHS rescind these requirements by modifying the existing language as follows (relative to the existing rule, additional language is <u>underlined</u> 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);

---

[8] Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anesthetists versus non-physician providers of anesthesia for surgical patients, Cochrane Database of Systematic Reviews, Issue 7. Art. No.: CD010357. DOI: 10.1002/14651858.CD010357.pub2, (2014).

[9] 42 CFR § 414.60 Payment for the services of CRNAs. "Condition for payment. Payment for the services of a CRNA may be made only on an assignment related basis, and any assignment accepted by a CRNA is binding on any other person presenting a claim or request for payment for the service."

[10] Epstein RH, Dexter F. Influence of supervision ratios by anesthesiologists on first-case starts and critical portionsof anesthetics. Anesthesiology. 2012 Mar;116(3):683-91. doi: 10.1097/ALN.0b013e318246ec24. PMID: 22297567.

(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.

* * * * *

(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 <u>an anesthesiologist's assistant</u> ~~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~~,~~ <u>must be</u> 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.~~

§ 485.524 Condition of participation: Additional outpatient medical and health services.

(d) **Standard: Surgical services**. If the REH provides outpatient surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the REH in accordance with the designation requirements under paragraph (a) of this section.

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

(i) Anesthesia must be administered by only—

(A) A qualified anesthesiologist;

(B) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(C) A doctor of dental surgery or dental medicine;

(D) A doctor of podiatric medicine;

(E) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(F) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(G) A supervised trainee in an approved educational program, as described in § 413.85 or §§ 413.76 through 413.83 of this chapter.

(ii) ~~In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section.~~ An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

* * * * *

~~(5) ***Standard: State exemption.***~~

~~(i) An REH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (d)(3) of this section, if the state in which the REH 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 they have 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.~~

~~(ii) 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.~~

For more general deregulatory consideration under E.O. 14219 are there additional HHS regulation and/or guidance that impose requirements on the wrong individual or group?

Under current regulations at 42 CFR§ 482.52, CRNAs are precluded from directing the provision of anesthesia services in hospitals as these regulations only allow a doctor of medicine or osteopathy to do so. We urge HHS to modify this requirement so that CRNAs are allowed to direct anesthesia services as there is no evidence supporting their exclusion. 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 they are a doctor of medicine or of osteopathy. In other cases, the hospital may have to contract with and pay a stipend to an anesthesiologist for department administration only in order to meet the requirement. 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.

Modifying this requirement 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. This proposal would 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. This would also reduce 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.

HHS has authority to include CRNAs among the healthcare professionals who may direct the provision of anesthesia services in hospitals under the Social Security Act. When anesthesia services are under the direction of a CRNA, each Medicare beneficiary 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.

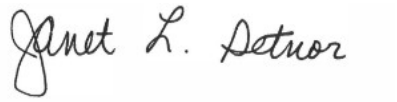
We recommend the introductory language be modified to read (relative to the existing rule, additional language is <u>underlined</u>):

§ 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).

Thank you for the opportunity to comment on this request for information. Should you have any questions regarding these matters and to schedule a meeting, please contact AANA Director of Regulatory Affairs, Romy Gelb-Zimmer at 202-484-8400, rgelb-zimmer@aana.com.

Sincerely,



Janet Setnor, MSN, CRNA, Col. (Ret), USAFR, NC
AANA President

cc: William Bruce, MBA, CAE, AANA Chief Executive Officer
Ingrid Lusis, AANA Chief Advocacy Officer
Romy Gelb-Zimmer, MPP, AANA Director of Regulatory Affairs