



October 14, 2026

The Digital Health Center of Excellence (DHCoE)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration
Submitted via: <https://www.regulations.gov/docket/FDA-2026-N-7874>

**RE: Considerations for the Regulation of Generative AI-Enabled Medical Devices:
Discussion Paper and Request for Feedback [FDA-2026-N-7874-000]**

On behalf of more than 71,000 members, the American Association of Nurse Anesthesiology (AANA) submits these comments to the FDA's request for feedback on CDRH's discussion paper regarding regulation of generative-AI (GenAI) enabled medical devices.

AANA is the professional association representing Certified Registered Nurse Anesthetists (CRNAs) and Student Registered Nurse Anesthetists (SRNAs) nationwide. CRNAs are Advanced Practice Registered Nurses (APRNs) who are doctorally prepared autonomous anesthesia providers through their training and preparation. CRNAs provide the full spectrum of 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.

AI tools, assistance, and enabled devices have the potential to increase efficiency, advance research, and improve patient safety in anesthesia care delivery. However, any policymaking in this field must incorporate the expertise of CRNAs and support their clinical decision-making, not supersede it. CRNAs' direct experience and input is critical as those who use these tools in direct patient care, especially in rural and underserved communities, where CRNAs are the predominant provider of anesthesia care.¹ In rural counties, for instance, CRNAs represent over 80 percent of all anesthesia providers.² Facilities in these areas struggle with anesthesia provider shortages and thin margins, causing access gaps that require efficient solutions that maintain the highest levels of patient safety. Reliance on the leadership of CRNAs is necessary for AI healthcare policy that expands access to high-quality safe patient care where it is needed most.

¹ Liao, C.J., Quraishi, J.A., & Jordan, L.M. (2015). Geographical Imbalance of Anesthesia Providers and its Impact On the Uninsured and Vulnerable Populations. *Nursing economic\$,* 33 5, 263-70.

² Martsolf GR, Baird M, Cohen CC, Koirala N. Relationship Between State Policy and Anesthesia Provider Supply in Rural Communities. *Med Care.* 2019;57(5):341-347. doi:10.1097/MLR.0000000000001106.

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Therefore, AANA asserts several guiding policy positions to lead AI regulatory frameworks to utilize CRNA expertise and advance CRNA practice. These include:

1. Any AI tools, decision-support systems, or AI technology cannot replace CRNA skills, knowledge, and expertise as critical members of the healthcare workforce. CRNAs retain independent professional judgment when using AI and decision-support tools.³
2. Any development of AI-related regulations or guidance must include direct CRNA involvement to ensure that the perspective and clinical practice of nursing and nurse anesthesia are accurately represented.
3. CRNAs are prepared, educated and licensed as independent practitioners; therefore, AI technology and decision-support tools must not be used within any practice models to facilitate or expand supervision, beyond what is required by federal or state law.

Additionally, AANA has established eight foundational principles to guide the development and implementation of AI in anesthesia care in response to the National Science Foundation's RFI to develop an AI Action Plan.⁴ These principles are recommendations from ensuring AI is a tool and not a replacement, to the necessity of interdisciplinary collaboration to ensure technology aligns with clinical realities.

AANA urges the FDA to incorporate these policy positions and foundational principles as part of its considerations for the regulation of GenAI-enabled devices. Specifically, AANA is responding to the following questions in the discussion paper:

Question 4: Who qualifies as a specialist when evaluating risk?

AANA recommends that FDA use the term "qualified clinicians with relevant clinical expertise" to include and recognize the knowledge, skills, and expertise of all qualified clinicians involved in patient care rather than limiting this assessment to a distinction between generalist and specialist physicians.

The appropriate level of clinical expertise should be determined by the intended use of the GenAI-enabled medical device, the clinical functions it performs or supports, the patient

³ American Association of Nurse Anesthesiology. Code of Ethics for the Certified Registered Nurse Anesthetist. April 2026. Available at:

https://issuu.com/aanapublishing/docs/code_of_ethics_for_the_certified_registered_nurse_?fr=sZGY1YTU2NDAXMjU.

⁴ American Association of Nurse Anesthesiology. Request for Information on the Development of an AI Action Plan. February 27, 2025. Available at: <https://www.aana.com/wp-content/uploads/2025/03/AANA-comments-on-RFI-Development-of-an-AI-Action-Plan.pdf>.

population, and the environment in which it will be used. Healthcare professionals other than physicians may possess specialized education, training, certification, and clinical expertise relevant to evaluating the risks associated with a particular device or clinical function.

Specifically, CRNAs provide the full spectrum of anesthesia, pain management, and related care across diverse healthcare settings, including hospitals, non-operating room anesthetizing locations, ambulatory surgical centers, office-based practices, and community health facilities. CRNAs deliver anesthesia services for surgical, diagnostic, therapeutic, and interventional procedures. Their practice encompasses, but is not limited to, the entire perioperative continuum, including preoperative assessment and optimization, development of individualized anesthetic plans, administration and management of anesthesia, physiologic monitoring and stabilization, acute and chronic pain management, and post-anesthesia recovery care.⁵ CRNAs exercise independent professional judgment and adhere to strict practice standards, prioritizing patient safety.⁶ When a GenAI-enabled medical device is intended to perform or support functions related to anesthesia care, CRNAs should be included among the qualified clinicians involved in evaluating the device's potential risks.

AANA therefore recommends that FDA use "qualified clinicians with relevant clinical expertise" and determine the appropriate expertise based on the device's intended use and clinical function rather than professional title alone.

Question 14: Who should serve as the clinical comparator when evaluating AI performance?

AANA recommends that the appropriate clinical comparator reflect the qualified healthcare professional or interdisciplinary clinical team with the education, training, experience, and clinical expertise necessary to perform the activity represented by the device's intended use.

Clinical performance standards should not be limited to comparisons with generalist or specialist physicians when other qualified healthcare professionals, including CRNAs, routinely perform the clinical function being evaluated. Selecting comparators based on relevant knowledge, skills, and clinical expertise would provide a more accurate

⁵ American Association of Nurse Anesthesiology. Scope of Nurse Anesthesia Practice. April 2026. Available at: https://issuu.com/aanapublishing/docs/scope_of_nurse_anesthesia_practice_2.23?fr=sNDg2MDU2NDAxMjU.

⁶ American Association of Nurse Anesthesiology. Standards for Nurse Anesthesia Practice. August 2026. Available at: https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU.

assessment of how a GenAI-enabled medical device performs within its intended clinical environment.

For GenAI-enabled medical devices intended to perform or support functions related to perioperative care, anesthesia care, and pain management, CRNAs should be represented in the development of performance standards and participate as clinical comparators, expert adjudicators, or members of clinical evaluation panels.

AANA encourages FDA to adopt an inclusive, function-based approach in which the appropriate comparator is determined by the device's intended use, clinical function, patient population, and practice environment, rather than by professional title alone. When a device supports care delivered by an interdisciplinary team, evaluation should also consider whether comparison with the relevant clinical team better reflects real-world practice.

Question 21: What role should professional societies and clinicians play in ongoing AI safety monitoring?

Professional societies, such as the AANA, and clinicians, such as CRNAs, can provide valuable specialty-specific expertise in post-market monitoring of GenAI-enabled medical devices. CRNAs who provide direct patient care are positioned to observe how these technologies perform within real-world clinical environments and may identify safety or performance concerns that are not apparent during premarket evaluation. AANA should be involved in the development of any specialty-specific AI guidelines, resources, and education.

Through the information provided by CRNAs, AANA can support post-market monitoring by helping identify and communicate:

- emerging patient safety concerns and potential safety signals
- unintended clinical consequences
- workflow and implementation challenges
- specialty-specific performance issues
- clinician education and competency needs
- patterns or concerns reported by clinicians
- use of GenAI-enabled medical devices in ways that extend beyond or differ from their intended use

Professional societies serve as an important two-way communication channel among clinicians, healthcare organizations, manufacturers, regulators, and other stakeholders by

helping aggregate specialty-specific observations and identify trends that warrant further evaluation as well as communicate important information to the society's membership in a direct, timely fashion.

AANA supports the development of mechanisms that allow clinicians and professional societies to communicate emerging patient safety signals and real-world performance concerns to the FDA and manufacturers. Such mechanisms should be clearly defined, accessible, and designed to facilitate meaningful feedback from clinicians using these technologies in practice.

Participation by clinicians, healthcare institutions, and professional societies in post-market safety monitoring should not transfer or dilute manufacturer responsibility for the safety, effectiveness, quality, and ongoing performance of their devices. Manufacturers should retain primary responsibility for appropriate post-market surveillance, evaluation of safety signals, and corrective action when warranted.

We appreciate CDRH's careful approach to collecting the necessary information on regulating GenAI-enabled devices. CRNA expertise will be critical in the policymaking process for this technology. AANA welcomes additional stakeholder feedback opportunities and looks forward to discussing with your agency the forthcoming AANA Position Statement, "Artificial Intelligence in Nurse Anesthesia Practice." Should you have any questions please contact Ewa Greenier, Senior Director of Practice and Patient Safety at egreenier@aana.com and Romy Gelb-Zimmer, Director of Regulatory Affairs at rgelbzimmer@aana.com.

Sincerely,

A handwritten signature in cursive script that reads "Tracy P. Young".

Tracy P. Young, MSNA, MBA, CRNA
AANA President