

January 23, 2023

Ms. Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services PO Box 8010 Baltimore, MD 21244-1850

RE: Request for Information; Essential Health Benefits (87 Fed.Reg. 74097, December 2, 2022)

Dear Ms. Brooks-LaSure:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on this Request for Information (RFI): Essential Health Benefits (EHBs). Our comments pertain to the areas of the RFI regarding Barriers of Accessing Services Due to Coverage or Cost and Addressing Gaps in Coverage and include:

- I. Promulgation of a Meaningful Regulation on the Issue of Provider Nondiscrimination to Ensure Patient Access to the Highest Quality Cost Effective Care
- II. Include the Role of Anesthesia in Enhanced Recovery after Surgery Protocol as an EHB

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 59,000 CRNAs and SRNAs, representing about 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 50 million anesthetics to patients each year in the United States. For further information, see: https://www.aana.com/about-us.

I. <u>AANA Recommendation: Promulgation of a Meaningful Regulation on the Issue of Provider Nondiscrimination to Ensure Patient Access to the Highest Quality Cost Effective Care</u>

As advanced practice registered nurses (APRNs), CRNAs bring unique and highly valuable skills and services to the healthcare system. Our members predominate in rural and underserved areas, allowing struggling facilities throughout the country to provide critical services, including obstetrics and surgery, to many patient populations who might overwise not have access to care. While all healthcare providers have a role in addressing gaps in coverage and disparities in the healthcare system, our members are uniquely

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positioned to help deal with these disparities by increasing access to critical services to the populations we serve, closing gaps in healthcare coverage and helping achieve greater access to care, which is a key goal of the Affordable Care Act (ACA). Because of this, we support the agency's efforts to review the EHB as part of the ACA to determine whether changes are needed to help access to care, account for changes in scientific advancement and address gaps in healthcare coverage. One solution to the issue of patient barriers of accessing services due to coverage or cost, would be promulgation of a regulation on provider nondiscrimination.

The federal provider nondiscrimination provision in the Patient Protection and Affordable Care Act (Sec. 1201, Subpart 1, creating a new Public Health Service Act Sec. 2706(a), "Non-Discrimination in Health Care, 42 USC §300gg-5), which took effect January 1, 2014, and prohibits health plans from discriminating against qualified licensed healthcare professionals, such as CRNAs, solely based on their licensure. However, no regulation has been issued since this law took effect and there is no real way to enforce it, allowing health plans to issue discriminatory policies against CRNAs and other APRNs. Ensuring that qualified health plans adhere to this nondiscrimination law would promote patient access to a range of beneficial, safe and cost-efficient healthcare professionals, consistent with public interests in quality, access and cost-effectiveness. Meaningful implementation of this provision is important to protect CRNAs and other APRNs from discriminatory practices in the private insurance market. In the absence of meaningful implementation of the statute, health plans and insurers have refused to allow our members in their networks or to contract with them, have reimbursed our members unequally for the same high-quality care as our physician colleagues, have imposed supervision requirements beyond what is required by state and federal laws, and have not allowed them to participate in value-based care programs solely based on licensure. They also have refused to cover procedures for services provided by CRNAs that are clearly included in their state scope of practice. Such discrimination impairs access to needed healthcare services, consumer choice and competition, and impairs efforts to control healthcare cost growth. Further, this discrimination violates the federal provider nondiscrimination provision.

In 2010, Congress passed the *Patient Protection and Affordable Care Act* (ACA), which included amendments to the Public Health Services Act (PHS Act). Section 2706 of the PHS Act prohibits private health plans from discriminating against qualified licensed healthcare professionals based on their licensure. However, this provision was not implemented through the rulemaking process and guidance and enforcement of this provision have been wholly inadequate. The latest action taken on this issue was subregulatory guidance in the form of a 2015 Frequently Asked Questions (FAQ) document. The FAQ stated, "Until further guidance is issued, the Departments will not take any enforcement action against a group health plan, or health insurance issuer offering group or individual coverage, with respect to implementing the requirements of PHS Act section 2706(a) as long as the plan or issuer is using a good faith, reasonable interpretation of the statutory provision."

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¹ Patient Protection and Affordable Care Act, Sec. 1201, Subpart 1, creating a new Public Health Service Act Sec. 2706(a), Non-Discrimination in Healthcare (42 U.S.C. §.300gg-5). The statutory provision reads as follows: "(a) Providers.--A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any healthcare provider who is acting within the scope of that provider's license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any healthcare provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures."

Congress has made clear that federal implementation to date has not been sufficient. In December 2020, the *Consolidated Appropriations Act of 2021*, (Public Law 116–260) was signed into law, which included the *No Surprises Act*. Section 108 of the *No Surprises Act* required the Secretaries of the Departments of Health and Human Services, Labor and Treasury to issue a proposed rule no later than January 1, 2022 to implement the provider non-discrimination protections under Section 2706 of the ACA, with a final rule issued no later than six months after the conclusion of the 60-day comment period on the proposed rule². Based on the regulatory timeline required under Section 108, a final rule should have already been promulgated to permanently implement these protections again provider discrimination. We are very concerned that numerous deadlines have passed to promulgate this rule, and we encourage the agencies to release this rule in the very near future.

Nurse anesthetists are experienced and highly trained anesthesia professionals who provide high-quality patient care, demonstrated through evidence in decades of scientific research and practice to the full extent of their education, training, and certification. A May/June 2010 study from the journal *Nursing Economic\$*, stated that 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.³ An August 2010 study published in *Health Affairs* showed no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.⁴ Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration, the internationally recognized authority on evidence-based practice in healthcare.⁵ In addition, a study published in *Medical Care* found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.⁶

Health plans must all avoid discrimination against qualified, licensed healthcare professionals based on licensure. To help promote access to healthcare, consumer choice of safe and high-quality healthcare professionals, reduce healthcare costs through competition, and allow providers to practice to the full extent of their education, training, and certification we urge promulgation of an enforceable regulation that will end this problematic practice.

II. AANA Request: Include the Role of Anesthesia in Enhanced Recovery after Surgery Protocol as an EHB

The AANA supports the agency's objective through this RFI to study how EHBs can be modified to address

² Public Law 116–260, https://www.congress.gov/bill/116th-congress/house-bill/133/text/enr

³ Paul F. Hogan et al., "Cost Effectiveness Analysis of Anesthesia Providers." *Nursing Economic\$*. 2010; 28:159-169. http://www.aana.com/resources2/research/Documents/nec_mj_10_hogan.pdf

⁴ B. Dulisse and J. Cromwell, "No Harm Found When Nurse Anesthetists Work Without Physician Supervision." *Health Affairs*. 2010; 29: 1469-1475. http://content.healthaffairs.org/content/29/8/1469.full.pdf

⁵ 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. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010357.pub2/abstract

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, http://journals.lww.com/lww-medicalcare/Abstract/publishahead/Scope of Practice Laws and Anesthesia.98905.aspx.

gaps in healthcare coverage or scope of benefits, especially with patients who have coverage or access gaps in the area of chronic and lifelong conditions. A recommended method on how EHBs can better address gaps in coverage, and improve the care of people at risk for or living with chronic or lifelong conditions, is to include the role of anesthesia in Enhanced Recovery after Surgery (ERAS®) programs as an EHB.

CRNAs have an abundance of experience and training in the pain realm, including providing anesthesia and acute, chronic and interventional pain management services. As CRNAs personally administer more than 50 million anesthetics to patients each year in the United States, CRNA services are crucial to the successful development and implementation of the use of techniques such as ERAS® programs. An increasing number of procedures are utilizing non-operating room anesthesia (NORA) and protocols that allow for the use of techniques that help patients recover more quickly and eliminate the use of opioids and the complications they bring. A clinician's judgement, experience and knowledge are important aspects of providing patient care safely and goes towards the quality of care patients receive.

ERAS® is a patient-centered, evidence-based, pain management strategy employed by CRNAs to reduce the need for opioids, improve patient outcomes and reduce costs. Using specific protocol-driven enhanced recovery after surgery pathways improves patient outcomes by reducing the patient's stress response to surgery, shortening the overall hospital length of stay, and accelerating the return to normal daily function. For example, the enhanced recovery pathway for total hip arthroplasty engages the entire perioperative team with the patient to limit care variation that improves outcomes and patient satisfaction. A total hip arthroplasty that includes minimally invasive surgical techniques and multimodal pain management with motor sparing regional anesthesia allow the patient to eat, drink and walk/exercise soon after recovery from anesthesia. The patient's pain management plan of care begins pre-procedure and continues through post-discharge using techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures.

As ERAS® protocols have been implemented, patient engagement in their own plan of care has improved return to pre-procedure health on the day of surgery. CRNAs play an integral role in these episodes of care, in both inpatient and outpatient settings, as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and ultimately in cost savings. 10 Conversely, research shows that suboptimal care in the preoperative, intraoperative, or postoperative phases of surgery may compromise care, resulting in poor patient outcomes and unnecessarily higher healthcare costs. 11 Facility and population specific ERAS® protocols engages the patient and the multidisciplinary team in the plan of care and continued assessment of patient status to optimize care, decrease complications, decrease time to discharge, improve outcomes and lower cost of care by limiting variation in care. CRNAs provide many ERAS® elements of care to optimize the patient to return to normal activity and diet, including

⁷ Non-operating room anesthesia: Is it worth the risk? Bruce J. Leone Current Anesthesiology Reports volume 10, pages449–455 (2020). Available at https://link.springer.com/article/10.1007/s40140-020-00423-4.

⁸ Non-Operating Room Anesthesia: Patient Selection and Special Considerations. Local Reg Anesth. 2020; 13: 1–9. Published online 2020 Jan 8. doi: 10.2147/LRA.S181458. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6956865/.

⁹ AANA Enhanced Recovery After Surgery, https://www.future-of-anesthesia-care-today.com/pdfs/eras-info.pdf.

¹⁰ See for example Rice AN, Muckler VC, Miller WR, Vacchiano CA. Fast-tracking ambulatory surgery patients following anesthesia. J Perianesth Nurs. Apr 2015;30(2):124-133. Also see Kimbrough CW et al. Improved Operating Room Efficiency via Constraint Management: Experience of a Tertiary-Care Academic Medical Center. *Journal of the American College of Surgeons* 2015; 221: 154-162.

¹¹ Miller TE, Roche AM, Mythen M. Fluid Management and Goal-Directed Therapy as an Adjunct to Enhanced Recovery After Surgery (ERAS). *Canadian Journal of Anesthesia* 2015; 62 (2)" 158-168.

minimally invasive surgical techniques, giving the patient a carbohydrate beverage at least two hours before surgery, maintaining patient warmth during the procedure and also providing multimodal pain management services to minimize or eliminate use of opioids. We urge that the agency emphasize the strategic consideration of the role of anesthesia delivery that is safe and cost-efficient and include the use of techniques such as ERAS® programs, which help reduce costs and improve patient outcomes.¹²

As ERAS® protocols have been implemented, patient engagement in their own plan of care has improved return to pre-procedure health on the day of surgery. CRNAs play an integral role in these episodes of care, in both inpatient and outpatient settings, as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and ultimately in cost savings. Conversely, research shows that suboptimal care in the preoperative, intraoperative, or postoperative phases of surgery may compromise care, resulting in poor patient outcomes and unnecessarily higher healthcare costs. Facility and population specific ERAS® protocols engages the patient and the multidisciplinary team in the plan of care and continued assessment of patient status to optimize care, decrease complications, decrease time to discharge, improve outcomes and lower cost of care by limiting variation in care. CRNAs provide many ERAS® elements of care to optimize the patient to return to normal activity and diet, including minimally invasive surgical techniques, giving the patient a carbohydrate beverage at least two hours before surgery, maintaining patient warmth during the procedure and also providing multimodal pain management services to minimize or eliminate use of opioids.

ERAS[®] protocols are also used in prevention and treatment services for substance use disorders, mental health services, crisis intervention and pain care; and further enable care that is well-coordinated and effectively integrated. CRNAs have an abundance of experience and training in the pain realm, including providing anesthesia and acute, chronic and interventional pain management services. As CRNAs personally administer more than 50 million anesthetics to patients each year in the United States, CRNA services are crucial to the successful development and implementation of the use of techniques such as anesthesia enhanced recovery after surgery (ERAS[®]) programs. An increasing number of procedures are utilizing non-operating room anesthesia (NORA) and protocols that allow for the use of techniques that help patients recover more quickly and eliminate the use of opioids and the complications they bring.¹⁵ A clinician's judgement, experience and knowledge are important aspects of providing patient care safely and goes towards the quality of care patients receive.¹⁶ We urge that the agency emphasize the strategic

¹² See for example Boulind CE, Yeo M, Burkill C, et al. Factors predicting deviation from an enhanced recovery programme and delayed discharge after laparoscopic colorectal surgery Colorectal Dis. 2011;14:103-110; Miller TE, Thacker JK, White WD, et al. Reduced length of hospital stay in colorectal surgery after implementation of an enhanced recovery protocol. Anesth Analg. May 2014;118(5):1052-1061; and Enhanced recovery care pathway. A better journey for patients seven days a week and better deal for the NHS. National Health Service 2012-2013. http://www.nhsiq.nhs.uk/resource-search/publications/enhanced-recovery-care-pathway-review.aspx. Accessed February 25, 2015.

¹³ See for example Rice AN, Muckler VC, Miller WR, Vacchiano CA. Fast-tracking ambulatory surgery patients following anesthesia. J Perianesth Nurs. Apr 2015;30(2):124-133. Also see Kimbrough CW et al. Improved Operating Room Efficiency via Constraint Management: Experience of a Tertiary-Care Academic Medical Center. *Journal of the American College of Surgeons* 2015; 221: 154-162.

¹⁴ Miller TE, Roche AM, Mythen M. Fluid Management and Goal-Directed Therapy as an Adjunct to Enhanced Recovery After Surgery (ERAS). *Canadian Journal of Anesthesia* 2015; 62 (2)" 158-168.

¹⁵ Non-operating room anesthesia: Is it worth the risk? Bruce J. Leone Current Anesthesiology Reports volume 10, pages449–455 (2020). Available at https://link.springer.com/article/10.1007/s40140-020-00423-4.

¹⁶ Non-Operating Room Anesthesia: Patient Selection and Special Considerations. Local Reg Anesth. 2020; 13: 1–9. Published online 2020 Jan 8. doi: 10.2147/LRA.S181458. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6956865/.

consideration of the role of anesthesia delivery that is safe and cost-efficient and include the use of techniques such as ERAS® programs, which help reduce costs and improve patient outcomes.¹⁷

The AANA appreciates the opportunity to comment on this EHB RFI. Should you have any questions regarding our comments, please feel free to contact AANA Senior Associate Director, Federal Regulatory and Payment Policy, Randi Gold at rgold@aana.com.

Sincerely,

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AANA President

cc: William Bruce, MBA, CAE, AANA Chief Executive Officer

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¹⁷ See for example Boulind CE, Yeo M, Burkill C, et al. Factors predicting deviation from an enhanced recovery programme and delayed discharge after laparoscopic colorectal surgery Colorectal Dis. 2011;14:103-110; Miller TE, Thacker JK, White WD, et al. Reduced length of hospital stay in colorectal surgery after implementation of an enhanced recovery protocol. Anesth Analg. May 2014;118(5):1052-1061; and Enhanced recovery care pathway. A better journey for patients seven days a week and better deal for the NHS. National Health Service 2012-2013. http://www.nhsiq.nhs.uk/resource-search/publications/enhanced-recovery-care-pathway-review.aspx. Accessed February 25, 2015.