American Association of
NURSE ANESTHESIOLOGY

September 6, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1809–P
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1809-P –Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities (89 Fed. Reg. 59186, July 22, 2024)

Dear Ms. Brooks-LaSure:

The American Association of Nurse Anesthesiology (AANA) welcomes the opportunity to comment on this Proposed Rule: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities (89 Fed. Reg. 59186, July 22, 2024). AANA makes the following comment and request:

- Ensure that Any Final Rule and Corresponding Subregulatory Guidance Regarding the Conditions of Participation (CoPs) for Obstetrical Services Should Recognize Healthcare Providers Operating at the Top of their Scope and Should be Evidence-Based

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 88 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.

AANA Request: Ensure that Any Final Rule and Corresponding Subregulatory Guidance Regarding the Conditions of Participation (CoPs) for Obstetrical Services Should Recognize Healthcare Providers Operating at the Top of their Scope and Should be Evidence-Based

AANA appreciates the Centers for Medicare & Medicaid Services' (CMS) efforts to improve maternal healthcare and the agency's commitment to protecting the health and safety of pregnant, birthing, and post-partum patients. In pursuance of the efforts CMS is currently undertaking to improve maternal health outcomes, AANA applauds CMS's recognition of the critical roles that advanced practice providers, including CRNAs, play in obstetric care. We strongly urge that any final rule and corresponding subregulatory guidance regarding the Condition of Participations (CoPs) for obstetrical services for hospitals and critical access hospitals recognize healthcare professionals operating at the top of their scope with respect to the delivery of obstetrical anesthesia and not create any additional barriers to care by imposing standards that are not based in evidence. As many rural counties across the country remain maternal healthcare deserts, it is of the utmost importance that CMS promulgates rules and subregulatory guidance that ensures access to the health and safety of pregnant, birthing, and post-partum patients.

In the area of obstetrics, CRNAs provide pain control via neuraxial techniques, such as epidurals and spinals, to help facilitate labor and delivery. The neuraxial technique is utilized to provide adequate pain relief and/or sensory blockade while preserving motor function, typically achieved by administering a combination of local anesthetics and opioids, which allows for lower doses of each agent and mitigates adverse side effects and shortens latency. In addition, CRNAs play a critical role in the prevention of non-anesthesia-related maternal deaths, such as those caused by hemorrhage, hemodynamic instability, critical illness, and sepsis. AANA was involved in the American College of Obstetricians and Gynecologists (ACOG) Council on Patient Safety in Women's Healthcare and helped in the development of evidence-based safety bundles for maternal care. These bundles included the topics of obstetric hemorrhage, hypertension in pregnancy, perinatal depressional and anxiety, reduction of primary cesarean birth, support after a severe maternal event, and venous thromboembolism.[1] In addition, AANA developed guidelines for the management of the obstetrical patient, which were recently updated *Analgesia and Anesthesia for the Obstetric Patient Practice Guidelines*.[2]

[1] See: www.safehealthcareforeverywoman.org

[2] See: https://issuu.com/aanapublishing/docs/analgesia_and_anesthesia_for_the_obstetric_patient?fr=sN2ZlNTU2NDAxMjU.

We remain concerned that the preamble of the proposed rule references the 2019 Levels of Maternal Care (LoMC) published by the ACOG for the purpose of OB staffing and organization within a hospital care setting, and we ask that the final regulation and subregulatory guidance not explicitly reference it with respect to obstetrical anesthesia. We recognize that the proposed regulatory text for the CoP does not explicitly mention the LoMC; however, the regulatory text at §482.59, §485.649 creates a standard for the delivery of service that states:

> "There must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program."

As CMS develops subregulatory guidance, including the interpretive guidelines associated with the requirement, the LoMC may have serious repercussions for maternal patients across the country. This is especially true in rural and other medically underserved areas, for the ob-gyns and CRNAs who provide maternal patient care, and for the facilities that serve this patient population.

The revised consensus statement for Level II requirements in the LoMC Consensus Statement state that an anesthesiologist be "readily available 24 hours a day, 7 days a week, for consultation and assistance, and able to be physically present onsite within a time frame that incorporates maternal and fetal/neonatal risks and benefits with the provision of care. Further defining this time frame should be individualized by facilities and regions, with input from their obstetric care providers."

AANA is unaware of any evidence that supports the requirement for an anesthesiologist to be "available 24 hours a day, 7 days a week" or that shows this requirement will improve maternal and child outcomes. AANA supports the adoption of evidence interventions that improve access to care and the quality of care given to patients. The adoption of this statement achieves neither.

AANA believes that including an anesthesiologist preference in any consensus statement has the potential of negative consequences associated with adoption, especially in light of critical workforce shortages. We are concerned that anesthesiologists will in turn market their skills as superior to CRNAs, pointing to support and confirmation from ACOG's LoMCs. ACOG indicates the extensive benefits of complying with the LoMCs. If facilities cannot meet these requirements, they, like CRNAs, may risk loss of advantages in marketing, contracting, and reimbursement, may violate state law that incorporates these requirements, and may suffer other unnecessary harms. CRNAs will suffer additional negative effects as small facilities that cannot afford extra staff and the cost of an anesthesiologist in addition to the CRNA are incentivized to replace CRNAs with anesthesiologists to meet the anesthesiologist readily available requirements.

Contrary to the ACOG consensus statement is the successful track record of CRNAs, who have been extensively studied and found to have excellent quality of care outcomes that are equivalent to anesthesiologists. Gold-standard studies show that CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery and there are no differences in

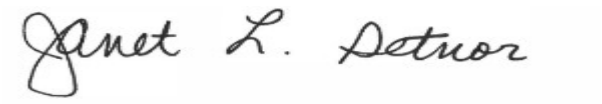
patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.

Any regulation and subregulatory guidance with respect to obstetrical anesthesia should be provider-neutral. An example of evidence-based obstetrical standards as a model for the CoPs would be The Joint Commission's (TJC) Advanced Perinatal Care Certification as an example of standards with anesthesia provider neutral language that recognizes providers at the top of their scope.[3] The standards in part state that the Advanced Perinatal Care Certification exceeds TJC's current Care Certification to apply to all pregnancies at all risk levels and address maternal morbidity, perinatal and mortality high risk factors, such as mental health disorders, including substance use; social needs; and health care disparities. This new program targets integrated, coordinated, patient-centered care throughout the perinatal period from prenatal to postpartum care. Important for CRNAs, this program takes an interdisciplinary approach that includes anesthesia and CRNAs and emphasizes evidence-based care. The program also has standards to address unanticipated obstetric, fetal and newborn complications that occur during labor and delivery.

As CMS develops subregulatory guidance, we also ask that AANA be included in its development particularly as it relates to obstetrical anesthesia. The inclusion of all impacted providers is the only way to ensure that requirements adequately address all variables involved in delivering high-quality maternal healthcare. CRNAs have a robust record of providing excellent anesthesia care in obstetric settings. Their expertise and experience would make for valuable input and their participation would only benefit CMS and pregnant, birthing, and post-partum patients at facilities. We stand ready to work with the agency.

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

Sincerely,



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

cc: William Bruce, MBA, CAE, AANA Chief Executive Officer
Ingrida Lusis, AANA Chief Advocacy Officer

[3] See: https://www.jointcommission.org/what-we-offer/certification/certifications-by-setting/hospital-certifications/certifications-for-perinatal-care/advanced-certification-in-perinatal-care/

Romy Gelb-Zimmer, MPP, AANA Director of Regulatory Affairs