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July 16, 2021

Office of the General Counsel

Department of Public Health

250 Washington Street

Boston, Massachusetts 02108

**Re: BORN: 244 CMR 4.00**

Dear Acting Commissioner Cooke:

We write as current and former Board Members of the Massachusetts Association of Nurse Anesthetists (MANA), representing more than 1,100 Certified Registered Nurse Anesthetists (CRNAs) in the Commonwealth. In this capacity, we respectfully ask you to amend proposed regulations currently under review by the Board of Registration in Nursing (BORN).

The following language better reflects a CRNA’s current practice settings and the development of anesthesia care plans for optimal patient care.

1. **CRNA Scope of Practice Definition**

First, MANA wishes to express support for the updated scope of practice language for CRNAs located in 244 CMR 4.06 (1). Every day, CRNAs throughout Massachusetts and across this country practice in every setting in which anesthesia is delivered: traditional hospital surgical suites and obstetrical delivery rooms; critical access hospitals; ambulatory surgical centers; the offices of dentists, podiatrists, ophthalmologists, plastic surgeons, women’s health centers, pain management specialists, and U.S. military, Public Health Services, Department of Veterans Affairs healthcare facilities. Regulatory language should not limit CRNA practice settings and should be broad enough to meet the demands of evidence-based healthcare innovation. We thank the BORN for this thoughtful language update.

1. **Implementation of Revised Prescriptive Practice Statute**

MANA supports all CRNAs obtaining their own independent practice authority, and we thank the BORN for making that a possibility with these regulations in 244 CMR 4.07. However, MANA urges the BORN to add clarifying language specifying that independent practice authority began on March 26, 2020 with the implementation of the “Order of the Commissioner of Public Health Authorizing Independent Practice of Advanced Practice Registered Nurses” for all CRNAs who had two years of supervised practice experience. That Order held the full force of law and there was no transition period between the Order’s revocation and the BORN Emergency Regulations effective date. CRNAs and other APRNs began utilizing independent practice authority on March 26, 2020, and others have gained that status throughout the past sixteen months. As a result, many Massachusetts APRNs are already eligible to supervise as Qualified Healthcare Professionals. Finally, MANA supports and echoes all efforts made by our APRN colleagues to minimize regulatory barriers so any APRN who wishes to achieve independent practice can easily do so.

1. **Elimination of Language Referencing Physicians and Anesthesia Protocols**

The language in 244 CMR 4.06(1)(c) related to protocols in anesthesia in no way reflects the current practice of both CRNAs and physicians in the Commonwealth. Anesthesia protocols simply do not and cannot exist as anesthetics that are patient specific and not a recipe. MANA requests the following amendment to the regulation.

*“A CRNA who does not register for prescriptive authority dispenses medications for immediate administration for anesthesia pursuant to the signed order of a registered prescriber. Such CRNA may select and administer anesthetic agents* ***in accordance with the anesthesia plan as appropriate for the patient and practice setting.”***

Every day, CRNAs in Massachusetts are independently creating individualized anesthesia plans for their patients. CRNAs are a first point of contact to assess a patient, review their personal medical history, and make the determination of anesthetic for that individual’s needs. No two anesthetics are alike. The selection and administration of medications is based on the CRNA’s extensive knowledge and expertise to match the unique profile of the patient and then modified based on the patient’s response to anesthetic and invasive procedure. No protocol is responsive to provide individualized anesthesia care for optimal patient outcomes.

In many cases when a CRNA is providing anesthesia, there is not a physician with anesthesia expertise present throughout the perioperative period. A CRNA develops and administers a responsive anesthesia care plan for a patient. The regular practice of using two anesthesia providers is not economically feasible or necessary in the majority of cases. Working in collaboration with the patient’s team, CRNAs hold the highest standards of anesthesia practice to determine the best anesthesia care plan. As healthcare providers gain independent practice in the Commonwealth to provide safe and affordable healthcare, the BORN has opportunity to remove regulatory barriers that would optimize CRNA practice as advanced practice registered nurses.

One important example of removal of scope of practice barriers in Massachusetts is the ROE Act, which became law in 2020 and allows Nurse Practitioners and Physician Assistants to perform abortions. If one of those providers is performing the procedure, 244 CMR 4.06(1)(c) as currently drafted would require that a physician who can administer anesthesia in a clinic provide anesthesia and not the CRNA who may be the only anesthesia provider in the facility. This is a costly and unnecessary impact of the regulation, and it contradicts the legislative intent of reducing and removing medically unnecessary barriers to care.

When billing for anesthesia, the Centers for Medicare & Medicaid Services (CMS) Hospital Conditions of Participation (CoPs) do not require that CRNAs select anesthetic agents pursuant to a protocol with a physician. (§482.52--Condition of Participation: Anesthesia Services). Additionally, Medicaid allows for direct billing for anesthesia services by CRNAs without reference to physician protocols, merely a requirement that “the operating physician or an anesthesiologist is immediately available if needed”. (130 CMR 433.454 (B) - Services Provided by a Certified Registered Nurse-anesthetist (CRNA)).

There are strong federal and state safeguards in place for the safety of practitioners and patients in the use of controlled substances. Federal and state laws and regulations tightly regulate the movement of controlled substances and narcotics through the hospital. These pertain to documentation, handling, and storage of controlled substances, including common anesthesia medications. All records regarding controlled substances must be retained and available for inspection for at least two years, and a complete record must be maintained. Regulations require that all hospitals provide effective controls and procedures to safeguard against theft and diversion of controlled substances. All scheduled substances must be housed in a securely locked, substantially constructed cabinet, with only authorized personnel having access to this area. (42 CFR 482.23(c)(6)(i)(D) and 42 CFR 482.25(b)(2)(i); MGL 94C and 105 CMR 700)

Finally, the American Association of Nurse Anesthetists (AANA) holds CRNAs to a high standard for care in their Code of Ethics for Certified Registered Nurse Anesthetists. The Code states: “As an independently licensed professional, the CRNA is responsible and accountable for judgments made and actions taken in his or her professional practice. Requests or orders by physicians, other healthcare professionals, or institutions do not relieve the CRNA of responsibility for judgments made or actions taken.” CRNAs, like physicians, have an ethical responsibility to manage “medications to prevent diversion of drugs and substances.” Pursuant to 244 CMR 4.09, all CRNAs in direct patient care obtain and maintain professional malpractice liability insurance.

Thank you for your consideration on these important matters to patient care and CRNA practice in the Commonwealth. Please, feel free to contact me with any questions related to MANA or a CRNA’s practice.

Sincerely,

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| Elaine Sullivan, CRNA, MHL, DNP  President  Director/Owner ICON Plastics, LLC | Susan Hall, DNP, CRNA  President Elect  Assistant Clinical Faculty, Northeastern University Bouve College of Nurse Anesthesia  Staff CRNA, Southcoast Hospitals  Per Diem CRNA, CAPanesthesia |
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