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November 6, 2020

Office of the General Counsel

Department of Public Health

250 Washington Street

Boston, Massachusetts 02108

**Re: BORN: 244 CMR 4.00**

Dear Commissioner Bharel:

I write as current President of the Massachusetts Association of Nurse Anesthetists (MANA), representing more than 1100 Certified Registered Nurse Anesthetists (CRNAs) in the Commonwealth. MANA seeks to amend proposed regulations currently under review by the Board of Registration in Nursing with language to better reflect a CRNA’s current practice settings and the development of anesthesia care plans.

1. **CRNA Practice Setting Language**

While the traditional views of a CRNA’s work is limited to the delivery of anesthesia connected to an in-patient surgery, there are CRNAs throughout Massachusetts currently working in a variety of out-patient settings completing patient centered work. For that reason, MANA believes that the language in 244 CMR 4.06(1)(b) referencing “offices of dentists, podiatrists, and physicians” is limiting, not a reflection of current and evolving practice settings, and inconsistent with the language for practice settings of our other APRN colleagues. MANA requests the following amendment to the regulation.

“A CRNA provides care in diverse settings, including, but not limited to, hospital surgical suites and obstetrical delivery rooms; critical access hospitals; acute care; ***and a variety of ambulatory care settings including private offices, community and public health clinics.”***

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 those settings and should be broad enough to allow for flexibility in the face of evolving healthcare settings.

CRNAs in Massachusetts are performing anesthesia-related care for patients that is extensive. Nurse anesthesia practice may include, but is not limited to, these elements:

a comprehensive history and physical; conducting a pre-anesthesia evaluation; obtaining informed consent for anesthesia; developing and initiating a patient-specific plan of care; selecting, ordering, prescribing and administering drugs and controlled substances; and selecting and inserting invasive and noninvasive monitoring modalities. CRNAs provide acute, chronic and interventional pain management services, as well as critical care and resuscitation services; order and evaluate diagnostic tests; request consultations; and perform point-of-care testing. CRNAs plan and initiate anesthetic or infusion techniques, including general, regional, local, and sedation. Anesthetic techniques may include the use of ultrasound, fluoroscopy and other technologies for diagnosis and care delivery, and to improve patient safety and comfort. Nurse anesthetists respond to emergency situations using airway management and other techniques; facilitate emergence and recovery from anesthesia; and provide post-anesthesia care, including medication management, conducting a post-anesthesia evaluation, and discharge from the post-anesthesia care area or facility.

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

The regulatory 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 for anesthetics that are managed by CRNAs. MANA requests the following amendment to the regulation.

“A CRNA who does not register for prescriptive authorityadministers anesthesia pursuant to the signed order of a registered prescriber. Such CRNA may select 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 the first point of contact to assess a patient, learn about their full medical status and history, and determine the unique type of anesthetic that will be best for that patient. No two anesthetics are alike. The use of medications is based on the unique needs of each patient, with appropriate doses determined for that patient. A CRNA makes that ongoing determination, and a protocol cannot evolve in a way that is required for best patient outcomes. An anesthetic can be dynamic. While a patient is anesthetized, it is the CRNA that manages medications to keep a patient alive.

In many cases, there is no physician present who would have any expertise in developing an anesthesia care plan for a patient. This is especially true in outpatient settings, but it is also true in many hospital care teams. CRNAs are the experts in education, training, and practice for keeping patients safe when determining the best course for an anesthesia care plan.

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” for the anesthetic. (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. A complete and accurate record of all controlled substances available 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.”

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

Sincerely,

Melissa Croad, MSNA, CRNA, APRN

President

Massachusetts Association of Nurse Anesthetists