**Board of Registration in Medicine**

**Proposed Regulations 243 CMR 2.07**

**Patient Care Assessment Program**

 **May 19, 2017**

These comments are submitted on behalf of the Massachusetts Society of Anesthesiologists (MSA), which represents over 950 physician anesthesiologists practicing in the Commonwealth.

MSA’s comments are focused on the proposed regulations governing informed consent within 243 CMR 2.07 (26) governing the practice of medicine. These regulations are virtually identical to the proposed informed consent regulations in 243 CMR 3.10, Patient Care Assessment, which were the subject of a hearing on March 1, 2017.

During that comment period for the Patient Care Assessment regulations, MSA expressed its strong concerns about the required informed consent provision then proposed as overly broad and vague and deviate from accepted medical standards. This new proposed regulation 2.07 (26) now sweeps that language into the regulations governing the practice of medicine. We once again wish to express our strong concerns about the Board’s proposed amendments.

We understand that the proposed detailed provision for obtaining informed consent is in response to issues that have arisen around concurrent surgical procedures. However the sweeping nature of the proposed regulations appears to apply to all diagnostic, therapeutic or invasive procedures, medical intervention or treatment. This broad brush approach potentially subjects practically every medical procedure or treatment to the specific process of obtaining informed consent contained in the proposed regulations. To the extent regulation 243 CMR 2.07 (26) requires that a physician, as a condition of licensure, adhere to the proposed informed consent regulation, any deviation from the specific process of obtaining informed consent as proposed in the regulations potentially exposes a physician to disciplinary action even if the informed consent process meets current nationally accepted standard of care for informed consent. MSA believes the Board should approach the issue of imposing any new requirements regarding the process for obtaining informed consent with care and with such specificity that it not only addresses the issues of concern, but reflects commonly accepted medical standards and practice. We would like to note that in most current anesthesiology practices the consent for the anesthetic is a separate document from the surgical consent.

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Of particular concern to MSA are the following:

Section 2.07 (26) (d) and (e). Both of these sections require the attending physician/primary operator to be responsible for discussing the risks and benefits of the procedure, intervention or treatment and obtain the patient’s written informed consent. Residents and fellows are considered physician extenders under the proposed regulations, and cannot obtain a patient’s informed consent. We believe it is a crucial aspect of training for an anesthesiology resident or fellow to learn how to properly obtain an informed consent by meeting with the patient and obtaining the informed consent from the patient while under the supervision of the attending physician. Limiting the obligation to obtain informed consent to the attending physician anesthesiologist would undermine an important and required part of anesthesiology clinical training. Residents and fellows should be allowed to obtain informed consent for the administration of anesthesia, as the attending anesthesiologist will be available to respond to patient questions and co-sign the consent form if necessary. We hold the position that a physician anesthesiologist, which includes residents and fellows in training, is the only person who should be obtaining the patient’s consent.

Section 2.07 (26) (f) Patient’s Medical Record Must Reflect Who Will Participate in the Procedure. The proposed regulations states: “Prior to the procedure [emphasis added], the attending physician/primary operator must inform the patient of who will be participating in the procedure, intervention or treatment, including the names of all physician extenders who are under the direct supervision of the attending physician/primary operator. The attending physician/primary operator shall note the physician extenders on the written informed consent form.” The anesthesia consent is often obtained at the time of the preoperative clinic visit, days or even weeks before the surgery. This is beneficial to the patient to discuss the risks of anesthesia ahead of time instead of immediately prior to the procedure. In the days prior to the procedure, or the day of the procedure, patients often have follow up questions. Anesthesia schedules are not made until the day prior or the day of surgery, so the actual anesthesia providers who will be in the Operating Room (OR) would not be known at the time of the preoperative clinic visit. In addition, frequently there are changes in the location of the OR the patient will be assigned to in response to unavailability of the surgeon or the particular operating room. These delays can extend into after hours and an “on call” anesthesia team. The OR schedule may often change. Anesthesia care teams are usually assigned to a specific OR rather than a surgeon or patient. We emphasize that it is not always the best care of the patient to obtain informed consent at the last minute before an operation. In addition, for various reasons including the time of day, the attending anesthesiologist, resident or fellow, or CRNA in the OR may change while the patient is under anesthesia. OR cases sometimes take much longer than their assigned times. It is common for the anesthesia consent document to stipulate that the anesthesia care team may change while the patient is in the OR. MSA believes that accurate identification of the names of the attending anesthesiologist and physician extenders when the informed consent is obtained, is oftentimes not feasible or practical and we would request that consent for anesthesia be exempt from this provision.

Section 2.07 (26) (g) Patient’s Medical record Must Reflect any Absence of Attending Physician/Primary Operator. Anesthesia is typically administered as part of an Anesthesia Care Team in which the attending physician anesthesiologist may be supervising a resident, fellow or CRNA in more than one room, as allowed under national standards governing the administration of anesthesia. The attending anesthesiologist will be physically present during certain times while the patient is under anesthesia, but may move from room to room during the surgery while the patient is being monitored by a physician extender and is immediately available to return in case of an urgent problem. The attending anesthesiologist is still supervising the anesthesia as head of the Anesthesia Care Team. Documentation of

the attending anesthesiologist’s involvement in the patient’s care is contained in the anesthesia record which is part of the patient’s medical record. It may not be as specified by the proposed regulation but reflects nationally accepted practice standards. MSA would request that anesthesia be exempt from the specific provisions of this section.

As anesthesiologists, we recognize the great significance of the informed consent process and the need for the patient to have adequate medical information prior to making the decision to undergo anesthesia which can be frightening and risky. However, we note that the proposed informed consent regulations have been met with great concern by the greater medical and hospital community. The Massachusetts Hospital Association suggested at the March 1 hearing that the Board pull back the proposed regulations regarding informed consent and convene a group of stakeholders to work with the Board to identify issues of concern and how, and to what extent, should these concerns be addressed. MSA endorses that suggestion, and stands ready to work with the Board and other stakeholders on this issue.

Respectfully submitted,

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President