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May 17, 2017

George Zachos, Executive Director
Board of Registration in Medicine
200 Harvard Mills Square, Suite 330
Wakefield, MA 01880

Re: Proposed Amendments to the BORIM Regulations 243 CMR 2.00

Dear Mr. Zachos:

On behalf of the Conference of Boston Teaching Hospitals (COBTH), I am pleased to offer comments for the Board's consideration related to the proposed amendments to CMR 243 CMR 2.00. The comments below reference the section numbers in the proposed regulations. For some sections, we request clarification from the Board, while in others, we suggest language for the Board's consideration or respectfully request that the Board give further consideration to the concerns raised by the proposed revision.

We hope that the following comments and recommendations are useful to the Board as it considers final action on the proposed regulations.

243 CMR 2.01, 2.02(1)(p), 2.02(2)(k), 2.06(2)(f) - Participation in MassHealth Program

We appreciate that the Board wants to ensure that all licensed physicians in the Commonwealth participate in the state's Medicaid program, MassHealth. However, this requirement raises a number of questions that require clarification before implementation. For instance, when in the licensure process will the application and approval take place, how will limited licenses who are not able to separately bill be handled, how will licensees with no affiliation with any health insurer be treated, who will apply, the candidate directly or a designated contact at their institution. Given the significant workload and resource constraints of both the Board and MassHealth, our fear is that this requirement will result in unnecessary delays in licensure and operational issues that could have the opposite result of the Board's intent and limit access. In addition, the proposed requirement that an applicant for licensure be enrolled in MassHealth is inconsistent with the MassHealth requirement that an applicant be a MA licensed physician.

Recommendation: We recommend that the Board delay action on this provision until both agencies are able to address these questions and develop an adequate implementation plan. Our hospitals would be happy to assist in this effort.

243 CMR 2.07(4) Delegation of Medical Services

The proposed change to this section eliminates any allowance for the delegation of medical services. At a time when new models of team based care delivery - such as patient centered medical homes and accountable care organizations - are being encouraged by state and federal policy makers, we do not understand why the existing ability to delegate some medical services is being disallowed. If enacted, the provision would conflict with the Centers for Medicaid and

Medicare Services' Conditions of Participation. These federal regulations (42 CFR 482.12(c)(1)(i)) provide physicians with authority to delegate medical services to qualified professionals and establishes standards on the individuals' licensure or certification.

Recommendation: We recommend that no changes be made to 243 CMR 2.07(4).

243 CMR 2.07(14) - Providing Cancer patients with Treatment Information

Section 2.07(14) is new and would require physicians to provide certain information on treatment options to patients with "known or suspected cancer" and further require the physician and patient to document that such information was provided. Discussing the options available for treatment and outlining the potential benefits and risks of those options is a standard of care for all physicians, regardless of whether they are treating a patient for cancer or any other disease or condition. This new requirement would not enhance the care of patients but would add to the already considerable regulatory requirements that often, while certainly not intended, serve to weaken the patient-physician relationships.

Recommendation: We recommend that 243 CMR 2.07(14) as proposed be deleted.

243 CMR 2.07(23) - Exemption Reports of Drug or Alcohol Misuse to the Board Under MGL c. 112 s 5F

We are concerned that the removal of the words "other Board" in (23)(a)(2) may have unintended negative consequences and be inconsistent with what we believed to be the intent of the exception or exemption to reporting. It is our understanding that the exception had been in place to encourage those who suffer from addiction **and** their addiction had not resulted in harm, to get the help they need rather than be disciplined. If enacted, it is hard to imagine the exemption ever be allowed given that by very nature those addicted to drugs will have at some point have violated at least any one of a number of drug laws.

Recommendation: We recommend that the term "other Board" in 243 CMR 2.07(23) be retained.

243 CMR 2.07(26) - Informed Consent and Patient Rights

It appears that the new informed consent requirements are primarily intended to address consent as it relates to overlapping surgeries. As you are aware, to be eligible for payments from Medicare or Medicaid, hospitals must comply with health and safety standards known as Medicare Conditions of Participation (COP). CMS's COPs and corresponding interpretive guidelines require hospitals to ensure that patients consent to planned surgeries. Among other things, the guidance states that a well-designed informed consent policy should include a discussion of a surgeon's possible absence during part of the patient's surgery, during which residents or fellows may perform surgical tasks; the informed consent policy also should ensure the patient's right to decline treatment. In addition, the American College of Surgeons (ACS) recently issued extensive guidance on informed consent in the context of overlapping surgeries, and offers best practice standards in this area.

As currently drafted, the proposed informed consent requirements apply to any "diagnostic, therapeutic or invasive procedures, medical interventions or treatments." This requirement is so broad that it could be read to encompass nearly every patient/physician interaction, and therefore is overbroad and does not provide adequate clarity as to the scope of the informed consent requirement.

The proposed regulation also requires informed consent to include information that may not be known at the time of consent. For example, the proposed regulation requires that prior to a procedure, the patient must be informed of "who will be participating in the procedure, intervention or treatment, including the names of all physician extenders." While a physician may

know that residents, fellows, physician assistants and others will be present during the procedure, in a teaching hospital with a large number of residents and complex trainee schedules, he or she will most likely not be aware of the particular trainees assigned to the case until shortly before or even during the procedure.

Further, the requirement that a clinician's presence or absence during a procedure be documented in the medical record is also highly impractical. Surgeons often need to step away from a lengthy procedure to take a break, use the rest room or get a drink. They may also need to take care of clinical tasks related to the surgery outside the OR, such as reading a radiology or pathology report. During this time, residents or fellows as a matter of course remain with the patient. Requiring that surgeons document a brief personal break during a surgery and assign another attending to the case during this time is both unnecessary for safe patient care and highly burdensome to OR staff, with no discernible benefit. CMS requires that surgeons be present for all critical portions of a procedure and assign another qualified attendings if they are not immediately available during the other parts of the procedure; their presence or absence during the critical portions must be documented in the record. Accordingly, effective regulations already are in place to address this area of clinical activity.

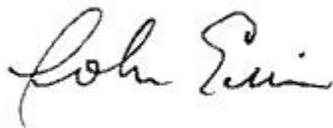
We believe that the proposed requirements for informed consent are overly prescriptive and in many cases impractical, if not impossible. There currently are requirements and guidance on best practices, including CMS standards, ACS standards and the BRM's current existing regulations, which we believe are clear and highly effective in ensuring that patients are provided with all relevant information prior to deciding on a clinical course. Accordingly, we do not believe the proposed amendments to section 2.07(26) should be adopted.

Recommendation: We recommend that this new section, 243 CMR 2.07(26), be deleted, and as recommended in our March 2, 2017 testimony , that the current section of the regulation related to informed consent, 3.10(1), be retained with the following addition:

The informed consent shall state whether qualified medical practitioners other than the attending physician will perform parts of the surgery or administer the anesthesia, and that such practitioners will be performing only tasks within their scope of practice under the supervision of the attending.

COBTH and member hospitals appreciate the opportunity to provide comments on these important regulations and thank the Board for its consideration.

Sincerely

A handwritten signature in black ink that reads "John Erwin". The signature is written in a cursive, flowing style.

John Erwin
Executive Director