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March 2, 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 1.00 and 243 CMR 3.00

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 1.00 and 3.00. 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. Upon taking office in 2015 Governor Baker issued an Executive Order requesting that all departments review existing regulations with an eye toward eliminating duplication and unnecessary administrative burden. We are pleased that some duplicative reporting of adverse events is eliminated in the proposed regulation. However, we are concerned that other sections add to administrative burden while, in our opinion, adding little value or enhancing patient safety.

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

243 CMR 1.01(2) Definitions

The definition of Disciplinary Action has been expanded to include "Remediation" and "Probation, including Academic Probation". As teaching hospitals, we recognize that timely and effective evaluation and feedback of trainee performance are critical to identifying problems early and at a stage where they can, hopefully, be corrected. We have very serious concerns that if academic probation and remediation are deemed disciplinary actions, and immediately reportable to the Board by the hospital, it will have an adverse impact on the early identification and redress of concerns. In order to maintain a culture of safety, it is vital for training programs to feel they can constructively address concerns without punitive impact, and to have trainees feel comfortable coming forward with concerns and requests for help and this proposed change would negatively impact those efforts. Faculty must feel comfortable raising concerns about trainee performance at the earliest possible stage without the fear of causing harm to the trainee's career. The added requirement to report academic probation or remediation for trainees will likely inhibit faculty members from raising such concerns, which in turn, may cause the concerns to never be addressed or resolved. We are also quite concerned that the term remediation, which is not defined, is very broad and vague, and could include a number of actions that should not be classified as disciplinary actions. Again, requiring that remediation in all its forms be reported will likely reduce the frequency with which it is utilized, depriving trainees of necessary improvement opportunities.

Recommendation: Strike academic probation and remediation from the definition of disciplinary action.

243 CMR 1.03(5)(a)(3) - Specific Grounds for Complaints Against Physicians

The proposed regulation revises grounds for complaints (and for the basis of disciplinary action by the Board) to include simple negligence, while the current regulation states "gross negligence on a particular occasion or negligence on repeated occasions." Negligence is the failure to exercise reasonable care, which by nature is accidental and inadvertent. Gross negligence, however, is when a person exercises little care in their actions that it could be presumed that the person was indifferent to the consequences. By expanding this category of grounds for complaint, many minor incidents which may not warrant further investigation or action would be brought to the Board with little benefit.

Recommendation: Retain the current regulatory language of "gross negligence on a particular occasion or negligence on repeated occasions."

243 CMR 3.05 (3)(i) - Patient Care Assessment Program, Credentialing

Currently, health care facilities are required to make inquiry to other entities where a licensee has been employed during the previous ten years. The proposed revision to this section removes the ten-year time frame, and would require inquiries to be made to all facilities where a physician was affiliated over his/her entire career, possibly 20 years previously. The current process already is demanding administratively and very seldom identifies an issue that has not already been revealed or known through other sources. Extension of the time frame from ten years to unlimited would impose an additional, heavy administrative burden, and in our opinion yield very little that is not available through other sources.

Recommendation: Retain ten- year look-back period by reinserting "during at least the previous 10 years" in 3.05(3)(1)

243 CMR 3.05(3) (k) - Telemedicine Credentialing

We appreciate the Board's inclusion of a telemedicine provision, our hospitals and those across the country are seeing the benefits that telemedicine brings to the healthcare system, increasing access to underserved areas and addressing critical workforce shortage issues. As a member of the Massachusetts Telemedicine Coalition, COBTH recommends adoption of language supported by the Coalition which will support the use of telemedicine technologies and increase access to all levels of care.

Recommendation: Strike 243 CMR 3.05(3)(k) and insert a new subsection 243 CMR 3.05(4) as follows:

Licensees may follow the requirements of the Centers for Medicare and Medicaid Conditions of Participation, 42 CFR §§ 482.12 and 482.22, to obtain proxy credentialing and privileging to provide telemedicine services from a distant site to a patient receiving services from a healthcare provider. Telemedicine shall mean the use of synchronous or asynchronous audio, video or other electronic media for the purpose of diagnosis, consultation, prescribing, and treatment of a patient's physical, oral and mental health care that meets applicable health information privacy and security standards similar to those provided during an in-person visit. Telemedicine shall not include audio-only telephone or facsimile machine communications, but may include an online adaptive interview. Telemedicine may also include text only email when it occurs for the purpose of patient management in the context of a pre-existing physician patient relationship. For the purposes of this paragraph, nothing herein shall modify any requirements for Massachusetts licensure for individual providers delivering services through telemedicine services to consumers in the Commonwealth; provided further, that this paragraph shall not change the prevailing standard of care for healthcare services delivered through telemedicine.

243 CMR 3.07 - Patient Care Assessment Program, Internal Audits and Internal Incident Reporting

We appreciate the Board's change to 3.07 (2) that will eliminate duplicative reporting by requiring reporting of only those events that have not been reported to the Department of Public Health. The proposed changes ensure continued timely reporting of adverse events and is in keeping with the Commonwealth's effort to reduce administrative burden and duplication of effort.

We do however seek **clarification** of 3.08 (2)(b)4 - "a major intervention for correction; such as surgery or transfer to a higher level of care" classified as a "serious injury". Patients are often transferred to a higher level of care for reasons that are not related to serious injury and requiring these to be reported to the Board is overly broad. We seek clarification on what types of incidents this is intended to capture or a narrowing of the language.

243 CMR 3.08(3) - Patient Care Assessment Program - Safety and Quality Review Reporting to the QPSD

It appears that the Board may have desired to change the reporting of SQRs from quarterly to three months after the facility identifies the adverse event for review. However, as currently proposed, the quarterly requirement remains in the first sentence. We request that the intent be clarified and the language amended to reflect that.

243 CMR 3.10: Patient Care Assessment Program - 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 assistant 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 read 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 attending 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 impracticable, if not impossible. There currently are requirements and guidance on best practices, including CMS standards, ACS standards and the BRM's current 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 3.10 should be adopted.

Recommendation: We recommend that the current section of the regulation related to informed consent, 3.10(1), be retained and the following added to that section

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 member hospitals share the Board's goal in having in place systems and processes that identify issues that may compromise patient safety and that provide patients with the information necessary to make fully educated decisions regarding their care. We believe that the recommendations contained here maintain that priority on patient safety and thank the Board for its consideration of them.

Sincerely

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

John Erwin
Executive Director