

March 3, 2017

George Zachos

Executive Director

Board of Registration in Medicine

200 Harvard Mills Square, Suite 330

Wakefield, MA 01880.

**Re: Proposed Regulations 243 CMR 1.00 and 243 CMR 3.00**

Dear Mr. Zachos:

On behalf of Cambridge Health Alliance, we are pleased to offer comments on the proposed amendments to 243 CMR 1.00 and 3.00 regarding the Disciplinary Proceedings and Patient Care Assessment provisions in the Board of Registration in Medicine (Board).

We fully support the written comments submitted by the Massachusetts Health and Hospital Association, the Conference of Boston Teaching Hospitals, and the Massachusetts Medical Society. Our comments focus on a few specific areas of notable concern by the section numbers in the proposed regulations.

While some of the proposed changes will bring important and timely updates to the Board’s requirements, we echo the concerns that certain regulatory proposals as drafted will actually increase reporting without adding value; result in duplicative, costly, and administratively burdensome practices among healthcare providers; and run counter to a transparent and effective peer review process.

**243 CMR 1.01 (2) Definitions and Disciplinary Proceedings for Physicians**

We ask that “academic probation and remediation” be stricken from the proposed expanded definition of disciplinary action. As a teaching hospital, we recognize that timely and effective evaluation and feedback of trainee performance are critical to early identification and learning. We share 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 early identification and redress of concerns because programs will feel compelled to consider the unintended potential consequences of mandated Board reporting. In order to maintain a culture of safety, it is vital for training programs to constructively address concerns without punitive impact.

We also ask that the word “verifiable” be added before the words “any source” as it relates to the first sentence of the definition for complaints. As drafted, the proposed changes to this definition could inappropriately allow any allegation or comments against the provider to be admitted into the record without considering the facts or source of the case.

**243 CMR 3.07 Patient Care Assessment Program – Internal Audit and Internal Incident Reporting**

1. **Reporting of Additional Incidents/Events**

We are concerned with the newly added subsections 3.07(3)(d) and 3.07(3)(e), both of which require a healthcare facility to add additional reporting for internal incidents outside those included in the list of commonly reported adverse events. As drafted, this section provides an unknown list of incidents without ensuring that any information on an unknown incident be based on uniform definition/criteria that were vetted by a nationally recognized patient safety organization like the NQF or local provider associations or specialty groups. As drafted, the proposed regulation allows broad discretion to the Board without the ability for a provider to appeal or question the need for such reporting. The proposed changes only indicate that the Board will notify the facility/licensee as to why it is asking for an incident, but includes no ability for the facility/licensee to discuss the necessity of such reporting or if there is a concern that such reporting is not related to an actual patient harm or inappropriate medical practices at a specific facility. It is critical that the Board provide specific guidance or parameters for the potential new reporting requirements.

1. **Increased Record Retention Periods**

We request that the proposed document retention period within 3.07(3)(j) from the current three-year period to a new ten-year period (for all PCA reports, summary reports, and recommendations to and from the PCA coordinator) be removed. This new documentation retention period will add unnecessary administrative costs.

**243 CMR 3.08 – Patient Care Assessment Program, Safety and Quality Reporting to the QPSD**

We are concerned with the unintended consequences of increased reporting in Sections 3.08(2)(b)2 and 3.08(2)(b)4 as drafted. In any given procedure there may be expected complications that must be monitored and assessed by the treating healthcare provider team to ensure that there is not an adverse event. In addition, depending on patient acuity, there may be a need for higher-level services following a procedure that may require a patient to be transferred to another level of care, despite the procedure being performed following the highest standard of care, quality, and safety. However, as drafted, the proposed regulation would require extensive and inappropriate reporting that would have nothing to do with demonstrating that the procedure or services was inappropriate or inadequate. At the very least, the Board must clarify what national evidence-based standards should be used in determining what qualifies for a change in a patent’s risk category (where there is no actual injury) and when it is inappropriate to transfer cases to a higher level of care to trigger a reporting requirement.

In addition, it appears that the intent of the changes in 3.08(3) was to change the reporting period for the SQR reports to three months following an adverse event. However, as currently drafted, the quarterly requirement remains in the first sentence. Therefore, we request that the intent be clarified through a technical correction to avoid duplicative reporting.

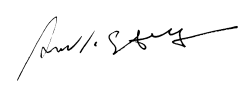
**243 CMR 3.10 – Patient Care Assessment Program, Informed Consent and Patient Rights**

In particular, the newly proposed Subsection 3.10 outlines several new informed consent and patient notification requirements that as currently drafted would apply to any “diagnostic, therapeutic, or invasive procedures, medical interventions, or treatments,” in a manner that is so broad that it could be interpreted to apply to nearly every patient/physician interaction. Therefore, there is concern that without needed refinement and clarity of scope that such a provision could delay the overall delivery of care for every hospital and nursing home. To that end, we respectfully request that the Board remove this specific subsection and form a stakeholder group to help develop appropriate requirements that improve patient safety but do not add unreasonable operational burdens on healthcare providers.

There are considerable areas where the language may conflict with federal Centers for Medicare and Medicaid Services Conditions of Participation, Joint Commission Standards, and more. The provisions would also unnecessarily add costs to the overall system and decrease the amount of time that a provider spends with a patient providing clinical services, and instead spend more time doing administrative paperwork for routine health care activities such a physical exam.

Thank you for the opportunity to submit comments. We appreciate the Board’s consideration of the recommendations in our letter and those from Massachusetts Health and Hospital Association, the Conference of Boston Teaching Hospitals, and the Massachusetts Medical Society. We welcome the opportunity to respond to any questions and to collaborate with the Board.

Sincerely

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