March 3, 2017

George Zachos

Executive Director

Massachusetts Board of Registration in Medicine

200 Harvard Mill Square, Suite 330

Wakefield, MA 01880

**Re: Proposed Amendments to 243 CMR 1.00 and 3.00**

Dear Executive Director Zachos:

Baystate Health, Inc. (“Baystate”) is a not-for-profit, integrated health care system serving over 800,000 people throughout western New England.  The Baystate system includes Baystate Medical Center, a teaching hospital with residency and fellowship programs accredited by the Accreditation Council for Graduate Medical Education (“ACGME”) and the region’s only Level 1 trauma center; three community hospitals – Baystate Franklin Medical Center in Greenfield, Baystate Wing Hospital in Palmer, and Baystate Noble Hospital in Westfield; and a network of more than 80 medical practices.

I am writing to submit comments to the Board of Registration in Medicine (“Board”) on behalf of Baystate concerning the proposed amendments to 243 CMR 1.00 (Disciplinary Proceedings for Physicians) and 243 CMR 3.00 (Patient Care Assessment Programs).

We have read and support the comments of the Massachusetts Health & Hospital Association (“MHA”) on the proposed amendments and offer the following additional comments to highlight specific areas.

***Section 1.00 00 – Disciplinary Proceedings for Physicians***

***Section 1.01(02) (Definition of “Disciplinary Action”):***

The proposed amendments would expand the definition of “Disciplinary Action” to include both “Remediation” and “Probation, including academic probation.” As a threshold matter, neither term is defined in the regulations, and “Probation, including academic probation” is not limited to actions related to the licensee’s competence or a complaint or allegation of a violation of law, regulation, or facility bylaws. In any event, the proposed addition of these two categories of “Disciplinary Action” creates a number of concerns, and we request that the Board remove these proposed amendments.

Given that “Disciplinary Action” is reportable to the Board, the proposed expansion of this definition would undermine efforts to improve the quality and safety of patient care in the hospitals of the Commonwealth. In promulgating 243 CMR 3.00, the Board had, “as its primary goal, ensuring that patients … receive optimal care.” This section of the regulations was “intended to assist the physicians and health care institutions of the Commonwealth in their efforts to identify problems in practice before they occur and to put in place preventive measures designed to minimize and eliminate substandard practice.” *See* 243 CMR 3.01. In this spirit, it is critical that hospitals have the ability to implement measures to improve physician performance without stigma. Remediation, by its very nature, is intended to be constructive and not punitive. If the definition of “Disciplinary Action” were revised as proposed, virtually any efforts by a hospital to improve a physician’s performance could be deemed reportable, which well could discourage efforts to improve physician performance. Such an outcome would not serve patients or physicians, and is not in keeping with the stated goals of 243 CMR 3.00.

The proposed expansion of the definition of “Disciplinary Action” is particularly concerning as it relates to physicians enrolled in graduate medical education programs. Residents and fellows, still in training and at the beginning of their careers, should be encouraged to come forward when they need help, and attending physicians who supervise them should be encouraged to identify areas for improvement. Early and frequent intervention, including constructive feedback and varying degrees of remediation, are at the heart of residency and fellowship training programs. Residents and fellows who encounter difficulties in their training should be encouraged and supported in their efforts to improve their performance, without fear that such efforts might be reportable to the Board as disciplinary action. In the educational environment of a residency training program, remediation frequently results from an isolated low score on an in-service examination. Remediation is vital to ensuring that residents stay on track in their professional development and should be encouraged. Such a routine aspect of professional training is not viewed as disciplinary action by institutions, and it should not be reportable to the Board as such.

Apart from the potential adverse consequences for physician performance, the proposed expansion of the definition of “Disciplinary Action” is not necessary. The practice and performance of residents and fellows is closely supervised by fully licensed physicians, by clinical competency committees within each program, and ultimately by specialty boards and the ACGME (including reports every 6 months concerning the progress of trainees in each program). In addition, the Board already has a vehicle for identifying and monitoring residents and fellows who are engaged in remediation. The renewal application for limited licensees specifically asks whether the physician’s training has been extended for any period of time, and if the answer is yes, the Board follows up with requests for specific information from the Program Director and the resident or fellow. The Licensing Division of the Board, rather than the Enforcement Division, is the appropriate vehicle for identifying and addressing issues regarding residents and fellows engaged in remediation.[[1]](#footnote-1)

Further, the Board does not need to receive reports of remediation or academic probation in order to serve its mission of protecting the public. If a course of remediation or period of academic probation does not succeed to improve a physician’s performance, additional action would be taken concerning the physician – including, for example, termination or non-renewal of a graduate medical education contract with a resident or fellow or the restriction or termination of a physician’s medical staff membership or clinical privileges – which would be reportable to the Board under its current regulations. For all of the reasons stated, we ask that the Board remove “Remediation” and “Probation, including academic probation” from the definition of “Disciplinary Action” in the proposed amendments.

***Section 1.03 (5) (Grounds for Complaint):***

The addition of “conduct which is in violation of the ethical standards of the profession” to the grounds for complaint is problematic in that the term is vague and contains no parameters. Changing the grounds from “gross negligence on repeated occasions” to simply “negligence” conflicts with the enabling statute, MGL c. 112, § 5, which mirrors the language proposed to be removed from the current regulations. Removing all qualifiers on “negligence” means that one instance of negligence could result in discipline, which goes beyond the plain language and apparent intent of the statute.

***243 CMR 3.00 – Patient Care Assessment Programs***

***Section 3.05 (Credentialing):***

The proposal in Sections (3)(c) and (i) to remove the references to “the previous ten years” will result in significant additional burden on health care facilities, without corresponding benefit. The ten-year qualifier regarding health care facilities with which the licensee previously has been affiliated should be left in the regulation. We note that a parallel requirement in Section (3)(e) concerning what carriers are to provide in the credentialing process was left undisturbed.

***Section 3.10 (Informed Consent):***

The proposed amendments to this section raise significant concerns. The removal of the word “major” in Section (1) before “diagnostic, therapeutic, or invasive procedures” is problematic in that it appears to drastically expand the scope of events requiring consent and, at a minimum, creates uncertainty as to the scope of the informed consent requirement. The numerous additional requirements imposed by the proposed amendments would add to the burdens on members of the health care team and will negatively impact efficiencies, education, and team care without corresponding benefits. Overall, given that this section of the proposed amendments raises a number of significant concerns, we support MHA’s request that the Board remove this section in its entirety and form a representative stakeholder group to develop meaningful and appropriate informed consent requirements.

We appreciate this opportunity to provide these comments and would welcome the opportunity to work with the Board to further develop the proposed regulations.

Very truly yours,

/s/

Vanessa L. Smith

Associate General Counsel

1. Additionally, the current definition of “Disciplinary Action” is quite broad and already includes a number of measures that qualify as remediation, such as a “course of education, training, counseling, or monitoring,” if such a course arose out of the filing of a complaint or other formal charges. The current language arguably strikes a balance that encourages and allows for remediation without reporting. [↑](#footnote-ref-1)