

BY ELECTRONIC MAIL Eileen.Prebensen@state.ma.us

March 3, 2017

George Zachos

Executive Director

Board of Registration in Medicine

200 Harvard Mills Square

Suite 330

Wakefield, MA 01880

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

Dear Executive Director Zachos:

On behalf of Atrius Health, I am writing to provide comments on proposed amendments to the Board of Registration in Medicine (“BORIM” or the “Board”) regulations, 243 CMR 1.00 (Disciplinary Proceedings for Physicians) and 3.00 (Qualified Patient Care Assessment Programs) (collectively, the “BORIM Regulations”). We want to thank the Board for undertaking this review and we support many of the proposed changes. However, Atrius Health believes there are several revisions, primarily regarding certain definitions and 243 CMR 3.00, *et seq*. that warrant further consideration by the Board. Set forth below are specific comments and suggested alternatives that we believe support the Board’s overarching objectives noted in 243 CMR 3.01 Scope and Purpose, which begins with: “The Board of Registration in Medicine, in promulgating 243 CMR 3.00, has as its primary goal, ensuring that patients receive optimal care.”

**Background**

Atrius Health, an innovative nonprofit healthcare leader, delivers an effective system of connected care for more than 675,000 adult and pediatric patients in eastern and central Massachusetts. Atrius Health’s 29 medical practices, with more than 35 specialties and 750 physicians, work together with the home health and hospice services of its VNA Care Network Foundation subsidiary and in close collaboration with hospital partners, community specialists and skilled nursing facilities. Atrius Health continues to do business as Harvard Vanguard Medical Associates, and currently has seventeen (17) Harvard Vanguard practice locations that are clinics licensed by the Department of Public Health (“DPH”) in accordance with M.G.L. c. 111 s. 51 and 105 CMR 140 (“Clinics”).

**Specific Comments**

**243 CMR 1.01(2). Definitions**

Complaint. We believe that “communication or a document from any source” is overly broad and could significantly lower the bar for complaints triggering Board investigation. For example, does the Board intend to initiate investigations based on postings to social media? We agree that patients should have the ability to file concerns and complaints with the BORIM; however, it is also important that such complaints are made in good faith and from verifiable sources. We request that the Board further clarify in the definition what is intended by “any source.”

Disciplinary Action. Atrius Health requests that the Board reconsider the list set forth in subpart (c), including the qualification provided in subpart (d), in its entirety. Many of the actions included on the list are somewhat ambiguous and broad, such as “censure”, “admonition”, and “remediation.” Why is a “revocation or suspension of a right or privilege” always a reportable Disciplinary Action, while “restriction, non-renewal or denial of a right or privilege” only a Disciplinary Action if the actions were taken for the reasons stated in subpart (d)? Atrius Health respectfully suggests that since the Board has taken the time and effort to amend and revise the Regulations that the Board reconsider this section as a whole and redraft the definition in a manner that more clearly defines the categories that constitute reportable disciplinary actions.

**243 CMR 3.00**

Since 1987 when the BORIM Regulations were first promulgated, Atrius Health and its predecessor organizations have been subject to, and have complied with, the provisions of 243 CMR 3.00, initially as both Clinics and an HMO, and since 1999 as Clinics. Accordingly, Atrius Health has very robust quality, safety and risk management programs which have been structured to meet and based upon the BORIM requirements including establishing a Patient Care Assessment Program (“PCAP”). In accordance with the Regulations, the Atrius Health Bylaws establish a Board level committee that serves as the Atrius Health Patient Care Assessment Committee (“PCAC”), which is a Medical Peer Review Committee. A critical component of the PCAP and the activities of the PCAC is that reviews and assessments conducted pursuant to the Regulations are subject to the statutory peer review privilege as appropriate and applicable.

Under the proposed revisions (243 CMR 3.02, Definitions), the Board has explicitly amended the definition of Health Care Facility to no longer include Clinics. As was expressed during a call with you, Susan Giordano, and Eileen Prebensen on January 31, 2017, we were unclear about the reasoning for the Board’s decision to delete all references to “Clinics” from the Regulations. We continue to be perplexed as to the Board’s rationale for this significant and highly impactful change to the Regulations, which have been in effect for thirty (30) years. In fact, the change is somewhat at odds with the overarching objectives and goals articulated throughout 243 CMR 3.00, *et seq*., since removing Clinics from the regulatory requirements and protections further limits oversight by the BORIM of clinical quality in the community.

As noted above, the PCAP and PCAC requirements are embedded in our system-wide quality program and corporate structure. The proposed changes would result in a loss of peer review protections that Atrius Health and other DPH licensed clinics have relied on since the regulations at 243 CMR 3.00 *et seq*. were first promulgated. This change would have a detrimental and chilling effect on our quality and safety programs since we will no longer be afforded the peer review protections we rely on to help identify problems in their practices and ensure patient safety and improve patient care. We respectfully implore the Board to reconsider the revision to the definition to Health Care Facility, and revert back to the existing language, and reinstate 243 CMR 3.14 in its entirety. In the alternative, we respectfully request that the BORIM consider expanding the scope of entities subject to 243 CMR 3.00, *et seq*., to include Accountable Care Organizations certified by the Health Policy Commission, physician practices organized under M.G.L. c. 180 as non-profit organizations, and/or Clinics of a certain size (number of physicians, patients, etc.).

With respect to other proposed revisions to 243 CMR 3.00, we offer the following comments:

* 243 CMR 3.02. We share both MMS and MHA’s concerns about the broad definitions of “Adverse Event” and “Close Call.” Varying interpretations of these terms is likely, which will result in increased and inconsistent reporting of questionable value.
* 243 CMR 3.05(3)(c) and (i). We do not support the removal of the 10-year look-back for malpractice claims and lawsuits and inquiry to every health care facility where a licensee was employed or otherwise affiliated. A mandated infinite/indefinite reporting period is burdensome for both individuals and institutions. The deletion of the time limitation in (c) is also inconsistent with the provision of (e) which requires the licensee to authorize release information by malpractice liability insurance carriers for only the previous ten years.
* 243 CMR 3.05(3)(k). Although we greatly appreciate the Board’s recognition of telemedicine, the lack of a definition of “telemedicine” in these regulations and the applicability to only those entities which meet the definition of “Health Care Facility” in 243 CMR 3.02 limits the utility of these changes. As noted above, removing Clinics from the definition of Health Care Facility has additional consequences, such as excluding Clinics from the telemedicine regulations.
* 243 CMR 3.07(d). We agree with MMS and MHA written comments in this regard and share their concerns about the lack of definition in this section, and the discretionary authority for the QPSD to require a health care facility to report additional incidents following a determination that such a requirement is in the best interests of patient safety without prior notice to, or discussion with, the health care facility.
* 243 CMR 3.08. We are concerned about the burden of the addition of new reporting requirements as well as the lack of clarity of the definition of “serious injury.” The subjectivity and breadth of this definition will likely result in additional and inconsistent reporting of events, and reporting of events that may actually be anticipated given a patient’s condition and are not indicative of poor quality care.
* 243 CMR 3.10(1). We support MMS and MHA’s comments regarding removal and reconsideration of this section; many of the proposed requirements for obtaining and documenting informed consent are administratively burdensome, impractical and go beyond what is traditionally required for informed consent. At a minimum, we urge the Board to require the proposed detailed written informed consent only before *major* procedures, interventions or treatments. As currently drafted obtaining written informed consent for this scope of care would require the dedication of significant provider resources in creating and obtaining consents, taking providers away from actually treating patients.

We hope that the Board will consider Atrius Health’s comments and recommendations and finds them helpful. In addition, we also support many of the comments and recommendations made by both the Massachusetts Medical Society and the Massachusetts Health & Hospital Association submitted to the Board in their written testimony.

Thank you again for the opportunity to provide comments. If you have any questions regarding this testimony or require further information, please contact Kathy Keough, Director of Government Relations at (617) 559-8561.

Sincerely,

Joe Kimura, MD

Chief Medical Officer

Kim Nelson, JD

Chief Legal Officer

Cc: Kathy Keough, Director of Government Relations