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

May 19, 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 2.07(26)**

Dear Executive Director Zachos:

On behalf of Atrius Health, we are writing to provide comments on proposed amendments to the Board of Registration in Medicine (the “Board”) Regulations, 243 CMR 2.07(26) (“Regulations”). We want to thank the Board for undertaking this review and we support many of the proposed changes. However, Atrius Health believes the Board should reconsider the proposed revisions to the informed consent requirements set forth in the proposed Regulations at 243 CMR 2.07(26) and 243 CMR 3.10.

**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”).

**Comments - 243 CMR 2.07(26)**

The new language regarding informed consent set forth in 243 CMR 2.07(26) and 243 CMR 3.10(1) provides in part: “Informed Consent. A physician has the obligation to obtain and record a patient’s written informed consent before diagnostic, therapeutic or invasive procedures, medical interventions or treatments.” The redlined Regulations show that the word “major” between the words “before” and “diagnostic” has been deleted in the current draft of the proposed Regulations. Atrius Health believes that deleting the word “major” results in an overly broad and burdensome application of the written informed consent requirements for physicians, which are inconsistent with well-established legal standards regarding informed consent.

George Zachos, Executive Director

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As a multi-specialty ambulatory medical group practice, Atrius Health clinicians provide care and treatment to their patients for a broad range of conditions that require “medical interventions or treatments.” Atrius Health physicians have expressed appropriate concern that the proposed Regulations could be construed to require written informed consent for virtually all care and treatment, including common prescriptions, chest x-ray orders, and minor dermatology procedures. Atrius Health requests that the Board provide further clarification on the intent of the new requirements including examples of the specific “diagnostic, therapeutic or invasive procedures, medical interventions or treatments” for which the Board expects the physician to obtain written informed consent. In addition, Atrius Health supports the comments previously submitted by the Massachusetts Medical Society and the Massachusetts Health and Hospital Association, as well as the comments submitted by many other provider entities, with regard to the proposed informed consent language set forth in 243 CMR 3.10(1) (which is identical to the language in 243 CMR 2.07(26)).

Atrius Health fully supports a patient’s right to understand all care and treatment and related risks, benefits and alternatives and to make personal choices as to such care and treatment. The proposed Regulations, however, establish requirements for obtaining and documenting informed consent that are unnecessary, extremely burdensome, and go well beyond what are the well accepted legal and community standards traditionally required for informed consent. At a minimum, we request that the Board reinsert the word “major” as described above. We believe, as currently drafted, the requirements to obtain written informed consent would involve significant provider resources, taking providers away from actually treating patients.

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

Chief Legal Officer