

BY ELECTRONIC MAIL

October 28, 2016

Monica Bharel, MD, MPH

Commissioner

Massachusetts Department of Public Health

250 Washington Street

2nd Floor

Boston, MA  02108-4619

Re: Comments on Proposed Amendments to 105 CMR 140.000 – Clinic Licensure

Dear Commissioner Bharel

On behalf of Atrius Health, I am writing to provide comments on proposed amendments to the Department of Public Health (“DPH” or the “Department”)) regulations, 105 CMR 140.000, Licensure of Clinics (the “Clinic Regulations” or “Proposed Regulations”).

We provided suggestions to the Department for revisions to the Clinic Regulations in April of this year (“the April Letter,” a copy of which is attached for your reference). We recognize that the Department has recommended some revisions; however, we were hopeful the Department would make more substantive changes and improvements to the Clinic Regulations. We are concerned that some of these changes actually increase, rather than decrease, administrative burden and cost on clinics. Since so few changes were made, we believe the proposed Clinic Regulations continue to be unnecessarily restrictive and out of sync with the current health care environment in Massachusetts and will impede the development of innovative delivery system models and coordinated care. We respectfully request that you reconsider Atrius Health’s comments in the April Letter and the comments set forth below before issuing final regulations.

**Background**

Atrius Health is a Massachusetts charitable corporation under M.G.L. c. 180, tax-exempt under Section 501(c)(3) of the Internal Revenue Code, with a multi-specialty, multi-site medical group practice serving patients throughout eastern Massachusetts. Atrius Health has a long history of delivering integrated health care services to its patients through a care model that focuses on providing patient-centered, coordinated care. Atrius Health continues to use the name Harvard Vanguard Medical Associates, and currently has seventeen (17) Harvard Vanguard locations that are clinics licensed by DPH. The April Letter provides additional background on our organization.

**General Comments**

We appreciate the updating of certain provisions of the Clinic Regulations, such as eliminating the requirement for written emergency transfer agreements with hospitals. However, we believe

that more substantive changes to the Clinic Regulations would be helpful to reflect the dynamics of the health care environment in Massachusetts and give health care organizations the flexibility to adapt while continuing to achieve DPH’s mission to: prevent illness, injury, and premature death; assure access to high quality public health and health care services; and promote wellness and health equity for all people within the Commonwealth

**Specific Comments**

**140.010 Scope**: The Proposed Regulations added language which states that the scope of the Regulations apply to “affiliates of a licensed clinic that are not independently licensed.” “[A]ffiliate” is not defined in the Proposed Regulations and is not included in the statutory definition of Clinic; accordingly, this addition to the Regulations is not clear and adds confusion to the purview of the Department’s oversight of what it might consider “affiliates.” We request that this language be deleted in its entirety and if not deleted, then further defined in a manner consistent with the statutory definition of Clinic as included in the Clinic Regulations.

**140.020 Definitions**:

“Surgical Service.” We are not clear on the intent of the proposed changes which do not appear to be substantive. Under the current regulations, and as proposed, only those endoscopic or operative procedures that require regional or general anesthesia constitute “Surgical Services,” and any procedures (endoscopic or operative) that do not require regional or general anesthesia are not “Surgical Services.” We request that the Department more explicitly state the intent and impact of simply changing the order of two words in the definition.

**140.101 Requirement of License.**

The Proposed Regulations add the following “for all locations at which the clinic provides services”. We request that the Department either delete this clause or provide further clarifying language as to the intent and applicability of this new requirement with specific examples. Based on the current Regulations, a licensed clinic would need to license satellite clinics; accordingly, the meaning of the additional language is confusing. For example, a health system organized under M.G.L. c. 180 may have licensed clinics within its system and also have locations that are not licensed, but by definition these are not locations at which the clinic provides services; it is the health system that provides and arranges for the services at both licensed and unlicensed locations.

**140.303 Posting of Notice of Patients’ Rights**

Requiring that clinics provide patients with the Notice of Patient Rights in the major languages spoken by the clinic’s patients is redundant of new federal requirements under Section 1557 of the Affordable Care Act. Providers are currently struggling with the administrative burden of meeting those requirements; while we support provision of important notices to patients with limited English proficiency, compliance with the federal law in this area should be sufficient. Accordingly, we request that the clause added to this Section be deleted.

**140.510-560 Mental Health Services**

We support the proposed changes to the mental health services provisions, but we strongly urge the Department to revise the Clinic Regulations further to allow greater flexibility in both staffing and service requirements for clinics providing mental health services. The shortage of mental health clinicians and services in Massachusetts has been well documented, and the Clinic Regulation’s staffing and service requirements, even with the proposed changes, limit the ability of clinics to provide mental health services. We have been committed to providing mental health services to our patients despite low reimbursement because we believe that mental health is critical to improving overall health; however, it has become increasingly difficult for us to staff our practice in compliance with the Clinic Regulations. The consensus in Massachusetts and nationally is that mental health care needs to be better integrated into general medical practice, especially primary care. The Clinic Regulations as proposed do not promote this goal. In addition, our mental health clinicians do not believe that simplifying and limiting the regulations will diminish the quality of care. In fact, such changes would open up resources to better provide these services to our patients and to support our primary care clinicians.

Thank you again for the opportunity to provide comments. If you have any questions regarding this testimony or require further information, please contact me at (617) 559-8393 or Kathy Keough, Director of Government Relations at (617) 559-8561.

Sincerely,

Steve Strongwater, MD

President and CEO

cc: Marci Sindell, Chief Strategy Officer and SVP of External Affairs

Kathy Keough, Director of Government Relations

Attachment

Attachment: April Letter

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| Atrius Logo in Color | **Riverside Center**  275 Grove Street, Suite 3-300  Newton, MA 02466-2275  www.atriushealth.org |

April 22, 2016

By Electronic Mail and Federal Express

Monica Bharel, MD, MPH

Commissioner

Massachusetts Department of Public Health

99 Chauncy St., 11th Floor

Boston, MA 02111

Dear Commissioner Bharel:

We understand that the Department of Public Health (DPH) is currently reviewing its regulations as required by Executive Order 562 issued on March 31, 2015. As DPH conducts this review, Atrius Health would like to offer some comments and recommendations for changes in the current regulatory framework related to clinic licensure (105 CMR 140.000 et seq.) and the Determination of Need (DON) (105 CMR 100.00 et seq.) which we believe would reduce the complexity and improve the cost effectiveness of the regulations and provision of health care in the Commonwealth without negatively impacting patient care and clinical quality. We also thought it would be helpful to provide an overview of Atrius Health.

Background

Atrius Health is a Massachusetts charitable corporation under M.G.L. c. 180, tax-exempt under Section 501(c)(3) of the Internal Revenue Code, with a multi-specialty, multi-site medical group practice serving patients throughout eastern Massachusetts. On May 1, 2015, Harvard Vanguard Medical Associates changed its corporate name to Atrius Health, Inc. On July 1, 2015, it merged with Granite Medical Group and Dedham Medical Associates, and their parent Atrius Health, Inc., leaving Harvard Vanguard Medical Associates, now known as Atrius Health, as the surviving entity. Atrius Health filed "doing business as" Harvard Vanguard Medical Associates, Dedham Medical Associates and Granite Medical Group in each community with a clinical site. In 2013, VNA Care Network Foundation became a subsidiary of Atrius Health, although they continue to provide services to non-Atrius Health patients. VNA Care Network Foundation includes VNA Care Network and VNA of Boston which provide home health services, VNA Hospice Care which provides hospice services in the home and in three hospice houses, and VNA Care Advantage which provides some nursing services at assisted living facilities.

As noted above Atrius Health continues to use the name Harvard Vanguard Medical Associates, and currently has seventeen (17) Harvard Vanguard locations that are clinics licensed by DPH (Clinics). Atrius Health also has practice sites that are not licensed by the DPH, most of which were community medical group practices that joined Atrius Health. The clinicians in both settings are Atrius Health employees, following Atrius Health policies and procedures, subject to the same payer contracts and all using the same fully integrated Electronic Medical Record (EMR). Atrius Health's 750 primary care and specialty physicians and their clinical teams currently serve approximately 675,000 adult and pediatric patients across eastern Massachusetts with over two (2) million visits annually. Approximately sixty percent (60%) of our patients have signed up for a patient portal for online access to portions of their medical record. We also have a data warehouse in which we store

Dedham Medical Associates | Granite Medical Group | Harvard Vanguard Medical Associates | VNA Care Network

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**Specific service requirements (e.g., 105 CMR 140.510 et seq., 140.352).** In particular, the regulations dictating the nature and scope of a clinic's behavioral health practice should be significantly revised to reflect

claims data on patients for whom we accept risk, and we utilize sophisticated tools for data analysis and reporting to support management of population health, quality and cost

Atrius Health has a long history of delivering integrated health care services to its patients through a care model that focuses on providing patient-centered, coordinated care. We have also been a market leader in accepting alternative payment arrangements; Atrius Health currently has payer contracts under which we accept full financial risk for the care of about 300,000 of our patients. Under these payment arrangements, we accept accountability for the quality and the total cost of care for our patients, including specialty care provided outside of our own specialists, hospital care, post-acute care, and pharmacy. Atrius Health believes that accepting global risk for the care of our patients results in better, more efficient patient care that allows us to achieve our mission: *We provide the right care with kindness and compassion every day for every person we serve.*

Since the DPH Clinic Regulations have not been thoroughly updated in a meaningful way for a number of years and given all the changes in health care and health care delivery systems we believe that certain of the regulations are somewhat out of sync with the current environment. In just the last 5 years there have been exponential changes to in health care organizational structures, technology, payment models, and out-patient and in-patient clinical services. The following are examples of some of the current requirements that we respectfully suggest should be considered by DPH:

**Requirements for the retention, review and maintenance of administrative and patient records (e.g., 105 CMR 140.301, 140.302, 140.363(4)).** The current regulations do not sufficiently address **the now** common **and** required use of centralized electronic medical record systems. Instead the regulations include outdated requirements that were appropriate for a "paper record" with very little reference to electronic medical records. In addition, with the advent of digital imaging, the requirement for adequate storage space for filing of x-ray films is unnecessary. Other federal and state laws and regulations, including Medicare rules, HIPAA and rules promulgated by the Board of Registration in Medicine, already establish parameters for medical record documentation, maintenance, retention, confidentiality and access. The public health benefit and/or policy rationale is unclear for having a different and often more burdensome (e.g., 20 year record retention requirement versus 7 years for physicians) set of rules for medical records in a clinic practice as opposed to a private practice.

**Requirements for policies and standards of review (e.g., 105 CMR 140.301. 140.303).** These requirements do not permit the exercise of reasonable professional and business judgment in determining what policies make sense for a particular clinic's business model and organization. The range of these requirements is in need of updating: for example, patients are not "admitted" to clinics, and the purpose of "patient admission criteria" is not clear; the need for a non-smoking policy addressing the comfort of patients in waiting areas is from another era; and the requirement that all patients should be provided with a copy of the notice of patients' rights "upon admittance to the clinic" is unnecessary when the notice can be posted on the website, provided electronically, and is posted at the clinic. In addition, not all policies warrant annual reviews and updates. While regulatory or organizational changes should prompt policy review and revision on an as needed basis, and periodic review is desirable, mandated annual review of all policies creates unnecessary administrative burden and cost.

**Requirements for written transfer agreements and other hospital relationships (e.g., 105 CMR 140.305).** The requirement for a written agreement with a hospital for transfer of patients for emergency treatment is unnecessary. The requirements for arranging hospital deliveries for pregnant women is also unnecessary.

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the evolution of behavioral health care and its integration into general medical practice. The mandates for staffing, documentation, and case review are particularly burdensome, and limit clinics in their ability to provide behavioral health services at a time when such services are in short and dwindling supply in the Commonwealth. With respect to laboratory services, the required submission of an annual affidavit seems unnecessary given the other regulatory and accreditation requirements that clinic laboratories are required to meet, including CLIA and CAP.

**Staffing and program requirements (e.g., 105 CMR 140.310 -318; 105 CMR 140.363, 140.370, 140.530).** The current regulations do not provide clinics with flexibility in staffing which they need to accommodate changes in the market, including changes in the scope of practice of various health care professionals and ancillary providers. Mandating an in-service training program for all staff **is** unnecessary when job requirements as well as licensure and certification demand that health care staff stay current and participate in continuing education. Clinics should be clearly permitted to operate centralized quality programs; requiring every clinic satellite to have a separate program is expensive and inefficient.

**Determination of Need Requirements, M.G.L. c. 111, sections 25B, 25C, 25C1/2, 105 CMR 100.** The following are examples of DoN regulations that we believe should be revised: (i) the regulations continue to define Magnetic Resonance Imaging as "new technology" thus making MRIs subject to the DoN process. MRIs have been in use since the 1970s and should **no** longer be considered a new technology subject to these regulations; and (ii) the definition of minimum capital expenditure for clinics should be based on a formula related to the size of the entity, not the type of entity. By way of example the 2016 minimum total capital expenditure requiring a DoN for clinics is $1,906,809 and for hospitals is $17,826,988. Given the range in the size of various hospitals and clinics, this discrepancy seems somewhat arbitrary and burdensome to organizations like Atrius Health, which has annual revenues greater than a number of Massachusetts hospitals. Thank you for your consideration of these issues. We hope this input provides you with potential opportunities to update and/or streamline the regulations without negatively impacting the quality of patient care. We would be happy to meet with you or DPH staff to discuss these or any other matters. We have met with DPH staff a number of times and find their approach and willingness to seek input from Atrius Health and other organizations regarding DPH programs and regulations very worthwhile and constructive. Please let us know if you have any questions regarding the above.

Sincerely,

Steven Strongwater, MD

President and Chief Executive Officer

cc: Eric Sheehan, Interim Director, Bureau of Health Care Safety and Quality

Sherman Lohnes, Director of Health Care Facility Licensure and Certification Suzanne Cray, Director of Health Care Integration Lauren Nelson, Director of Policy and Planning