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March 3, 2017

George Zachos

Executive Director

Board of Registration in Medicine

200 Harvard Mills Square, Suite 330

Wakefield, MA 01880

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

Dear Executive Director Zachos:

On behalf of UMass Memorial Health Care, I am pleased to offer the following comments regarding the Board of Registration in Medicine’s proposed amendments to its regulations.

UMass Memorial is the largest health care provider in Central Massachusetts and the clinical partner of the University of Massachusetts Medical School. Our system is comprised of our academic medical center in Worcester; a large multispecialty physician practice; three community hospitals in the region (HealthAlliance in Leominster and Fitchburg, UMass Memorial - Clinton Hospital, and UMass Memorial - Marlborough Hospital); and Community Healthlink, the largest behavioral health provider in Worcester County. Nearly 600 University of Massachusetts Medical School residents and fellows train in our facilities annually. Approximately 1,500 physicians are members of our active medical staff. In total, our hospitals have 1,021 licensed beds. In 2016, we treated 50,000 inpatients, and cared for patients in more than one million outpatients visits. We delivered 5,346 babies and our emergency departments handled 222,000 visits.

Our group medical practice employs 1,100 physicians, including hospital based physicians and over 80 office based practice sites at locations throughout Worcester and Central Massachusetts. UMass Memorial Accountable Care Organization consist of 1,775 participating providers. UMMHC has an extensive Managed Care Network which includes more than 400 private practice physicians in addition to our employed physicians. These physicians are responsible for the care of nearly 106,000 patients enrolled in commercial managed care plans and another approximately 14,600 patients participating in Medicare Advantage programs.

We welcome the Board’s efforts to update its regulations, and we are particularly appreciative of the Board’s proposal to address credentialing of physicians who provide care to Massachusetts patients by use of telemedicine technology. However, in our view the majority of the draft regulations, which were developed without input from the provider community, would be difficult to implement and burdensome on providers, adding significantly to the cost of care without improving patient safety.

*The Clinical Partner of the*

*University of Massachusetts Medical School*

In his March, 2015 Executive Order, Governor Baker directed state agencies to eliminate regulations which are confusing, unnecessary, inconsistent and redundant. The proposed amendments to 243 CMR, would do the very opposite. They treat remediation and even academic probation as disciplinary actions at a time when it is broadly recognized that a punitive approach tends to hamper, rather than enhance, efforts to improve the quality of care. They propose that the Board discipline a physician they find guilty of a single act of negligence, an undertaking which would require enormous resources, distract from the Board’s core mission, and force hospitals and physicians to address these claims at the Board as well as in the existing court system. They propose vague and expansive new adverse event reporting requirements for hospitals, increasing the already burdensome duplicative reporting with the Department of Public Health (DPH) rather than streamlining and coordinating their Patient Care Assessment Program reporting regulations with the existing DPH event reporting system, a reform which has been repeatedly requested by the provider community. They seek to regulate the process for obtaining informed consent despite the fact that this process is already heavily regulated by the DPH, the federal Centers for Medicare and Medicaid Services (CMS) and the hospital accrediting agency, the Joint Commission.

UMass Memorial supports the detailed testimony filed by the Massachusetts Hospital Association (MHA). We offer below some additional comments on issues of specific concern.

**243 CMR Section 1.00 – Disciplinary Proceedings for Physicians:**

**Section 1.01(2) Definitions**

**Expansion of Definition of “Complaint”**

The Board proposes to expand the current definition of a complaint to include not just a “communication” filed with the Board which “charges a licensee with misconduct” but also “a document from any source.” Given the Board’s existing authority to investigate complaints and statutory reports, it is unclear what perceived deficiency the Board intends to address by deeming ‘a document from any source” a complaint. We respectfully suggest that a “document from any source,” not communicated to the Board, is not a complaint, and the Board’s authority is appropriately directed to the handling of complaints and statutory reports. Accordingly, we urge the Board to retain the current definition of a complaint. In the alternative, we request that the Board include the word “verifiable” before the words “any source” as it appears in the first sentence of the definition. As drafted, the proposed changes to this definition could inappropriately allow any allegation or comments against a provider to be admitted into the record without considering the facts or source of the case. The provider community needs assurances that allegations of inappropriate practice of medicine are from a source that both the Board and the practitioner, if appropriate, can investigate to determine the basis of the complaint.

**Expansion of Definition of “Disciplinary Action”**

The Board’s existing definition of “disciplinary action” is already expansive, and we believe that further expansion is unnecessary and counterproductive to the efforts of hospitals to address deficiencies in practice or professionalism in a thorough, prompt, and effective way. At a time when the state legislature and the Administration are pushing programs to develop greater cultures of safety, quality, and improvement, while incorporating components of just culture, having broad terminology that seeks to penalize staff if a corrective action plan is implemented is counterproductive to improving patient safety. When an action is deemed a “disciplinary action” by the Board, not only becomes reportable to the Board, it must also, through the credentialing process, be self-disclosed as discipline to any facility where the physician wishes to have medical staff membership or privileges. Sweeping all peer improvement efforts into the definition of discipline discourages the dialogue that it is at the heart of the peer review process. Hospitals are reluctant to be proactive in taking needed, but not necessarily major, corrective action when they know that the action must be treated a disciplinary and reported to the Board. The consequences of a Board report to a physician’s career are such that a hospital will find it necessary to offer a due process hearing to the physician prior to imposing the action, resulting in delays to the corrective action process, and considerable expense and polarization of the parties.

1. **“Remediation” (1.01)(2)(C)(15):**

UMass Memorial strongly objects to the Board’s proposal to deem remediation a disciplinary action. MGL ch. 112, section 5 makes provision for remediation as a positive, non- disciplinary action. Treating any form of remediation as a disciplinary action will discourage appropriate efforts to improve physician performance, which would negatively affect overall patient care. Instead, the Board should put its resources into working with the provider community to develop physician remediation programs. The dearth of Massachusetts based remediation programs for physicians hampers our ability to make the most of the talented community of physicians who practice in Massachusetts.

1. **“Probation, including Academic Probation” (1.01)(2)(C)(16):**

UMass Memorial is strongly opposed to the addition of probation to the definition of disciplinary action. In addition, unlike the proposed addition of “remediation” in subpart (15), this new term is not tied to the limitation of subsection (d) of the definition of “Disciplinary Action.” This limitation is necessary to indicate that the only actions considered reportable as discipline are those related to the practice of medicine. For these reasons, if the Board chooses to approve the addition of probation to the list of reportable disciplinary actions, we believe that subsection (d) of the definition of “Disciplinary Action” should be amended to include subpart (16) to ensure that probation is only reportable if it is related to significant problems arising out of the practice medicine.

With respect to the inclusion of academic probation, we are particularly concerned that treating academic probation as a disciplinary action would have a chilling effect on the ability of teaching programs to address academic issues in a non-punitive, constructive learning environment. By its very nature, academic probation is a tool which a medical school should be able to make use of to foster the trainee’s education without the fear of collateral consequences for the physician’s post-education career. The Board does not have the expertise or the resources to substitute its own judgment for the judgment of the educational institution as to whether the individual meets the criteria for advancement within the educational institution. Furthermore, the Board does not need to receive reports of academic probation in order to serve its mission to protect the public. The type of concerns which pose potential risks to patients will result in actions which are already BRM reportable under the existing regulations.

**Section 1.03 – Dispositions of Complaints and Statutory Reports:**

**Section 1.03(1) - Expanding Subject Matter of Complaints Filed with the Board**

We would urge the Board to reverse its plans to eliminate within 1.03(1), the words “which charges a license with misconduct.” Without the existing qualifier, anyone could file a complaint against a physician regarding concerns that have nothing to do with the practice of medicine or actual misconduct. Regulatory changes should not encourage the filing and Board review of cases that do not even allege that they are relevant to the licensee’s practice of medicine. There is no reason for the removal of the existing qualifier. The change would only increase the number of reports that will inappropriately use valuable staff time and resources that should be focused on cases that may be causing patient harm.

**Section 1.03(5)(a) Specific Grounds for Complaint Against Physicians**

**1.03(5)(a)(3) - Simple Negligence**

By removing the reference to “gross negligence,” this amendment would make simple negligence a ground for complaint and therefore, by means of the regulatory structure, a basis for discipline. As drafted, the proposed regulation conflicts with the Board’s enabling statute, MGL Ch. 112, Section 5, which uses the language the Board proposes to remove. Removing all qualifiers on “negligence” means that one instance of negligence could result in discipline, authority which clearly seems beyond the intent of the enabling statute. Furthermore, as a practical matter, it may be difficult to differentiate a judgment error from “negligence,” but not from “gross negligence.” For these reasons, we urge the Board to retain the term “gross” prior to the term negligence to provide appropriate parameters for what should be grounds for a complaint to the Board.

**1.03(5)(a)(5) – Substance Use Disorders**

We support the Board’s proposal to remove the outdated subsection 5. Subsection 4, which specifies that practicing medicine while impaired is grounds for complaint, appropriately addresses problematic conduct rather than making the physician’s underlying medical condition cause for discipline.

**1.03(5)(a)(8) - Violation of “Ethical Standards”**

We do not support the proposed addition of a new phrase - “or conduct which is in violation of the ethical standards of the profession” and urge that it not be adopted. Similar to the points discussed above, the Board would be adopting a very broad and undefined standard without specific interpretation, thus providing no guidance as to the specific practice that must be followed. Without specifying which ethical standards should be considered binding on the physician (as there could be different ones adopted by a local, regional, or national provider association) this addition would create greater confusion without enhancing the Board’s ability to address problematic conduct. The Board already has sufficient authority to review conduct and impose discipline in situations where a violation of ethical standards is involved.

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

The Board proposes several significant changes which would expand the Board’s authority to regulate hospital quality programs role in ways that UMass Memorial believes are ill-advised, unnecessary, and unduly burdensome. Despite the extensive regulation of hospitals in this area by both DPH and CMS, the Board proposes additional data collecting and reporting requirements of its own.

**Section 3.02 – Definitions related to Patient Care Assessment (PCA) Programs:**

**New, Expansive Definition of “Adverse Event”**

As drafted, the proposed regulation provides a very broad definition of the term “Adverse Event” without clarification as to the types of events subject to review as part of the PCA program. We request that the Board add the words “as defined by the National Quality Forum” after the word “facility’s” to tie this term to national evidence-based standards adopted by healthcare providers and facilities. Definitions used by the Board should be based on standards developed using scientific and consensus-driven approaches to improve the practice of medicine.

**New Definition of “Close Call”**

This new term is similarly proposed by the Board without reference to the substantial existing body of evidence based patient safety standards. It is inappropriately vague in that it relies on hospital staff to assess whether a recurrence has a “chance” of causing serious injury. Requiring a report on an activity that did not cause patient harm, but where there was a chance of causing harm goes against the entire goal of the Governor’s regulatory reform Executive Order to eliminate unnecessary and duplicative reporting that does not improve safety and quality, and inappropriately increases administrative costs.

**Section 3.05 - PCA Program – Credentialing:**

**Section 3.05(3)(c) and (i) - Unlimited Look-Back for Credentialing Review**

We are strongly opposed to the removal of the language “during the previous ten years” in subsections (3)(c) and (3)(i) (malpractice history and required inquiry of other facilities where the physician has provided care). The goal should be to review current and relevant medical practices for providers who are seeking credentialing, instead of adding to the overall time and delays in credentialing staff. The Board offers no explanation of why it believes that a change in this regulation would have any positive effect on patient safety. The draft regulation retains the ten-year period for liability insurance carriers records in 3.05(3)(e), making this proposed change even more inexplicable. This change would go against the goal of administrative simplification that the entire provider and payer community all have been working collaboratively towards on streamlining credentialing processes. We strongly urge that the proposal to remove these words be reversed.

**Section 3.05(3) (k) – Telemedicine**

We appreciate and support the proposal to address telemedicine credentialing within the Board’s regulations. We would like to take this opportunity to urge the Board to adopt an additional regulation which would define telemedicine and recognize the use of critical technologies in medicine, which can improve care for all patients (regardless of whether they live in rural or urban areas), and ensure convenient access to all levels of healthcare services (including but not limited to primary care providers, specialists, and behavioral health clinicians). We support the suggestion of the MHA that the language endorsed by the Massachusetts Telemedicine Coalition is appropriate for adoption by the Board. Furthermore, we would also ask the Board to recognize in its regulations that a physician-patient relationship can be established during a telemedicine encounter, in circumstances where good and accepted medical practice does not require an in person physical examination.

**Section 3.07 – PCA Program – Internal Audits and Internal Incident Reporting:**

**Subsections 3.07(3)(d), (e) – New Board Authority to Require Additional Incident Reporting**

Similar to our comments about the definitions of “Adverse Event” and “Close Call”, we are very concerned with the proposal to add subsections 3.07(3)(d) and 3.07(3)(e), both of which would give the Board unfettered discretion to require a healthcare facility to track in its internal reporting system events selected by the Board beyond those chosen by the hospital or required by any law or national standard. Hospital incident reporting systems already track large numbers of events, and the volume of data is such that it is important to weigh carefully the benefits of collecting any additional data against the increased burden on hospital resources. Expanding the Board’s role in the area of incident reporting further stretches the Board’s resources, and the resources of the provider community without demonstrable benefit.

**Section 3.08 – PCA Program – Safety and Quality Reporting to the QPSD:**

**Sections 3.08(2)(b)(2) and 3.08(2)(b)(4)** - **New “Serious Injury” definition and reporting**

As drafted, the proposed regulation would require extensive reporting without regard for whether the procedure or service was inappropriate or inadequate. Before promulgating such an expansive new requirement, the Board should consider existing national evidence-based standards for 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.

**Section 3.10 – PCA Program – Informed Consent and Patient Rights:**

Section 3.10 of the Board’s existing regulations addresses areas of health care facility operations which are already well regulated by the DPH and other bodies. As set forth below, we believe that this entire section of the regulations should be deleted as duplicative of the standards promulgated by DPH as the licensing agency for hospitals. Unfortunately, rather than eliminating duplicative requirements, the proposed regulations attempt to cover the same ground with predictably confusing results.

**Section 3.10(1) – Informed Consent**

The Board is proposing substantial changes to a well-established informed consent process that will cause not only substantial legal confusion but increased administrative time and burden on providers and the healthcare community. There are considerable areas where the Board’s proposed language would conflict with federal Centers for Medicare and Medicaid Services Conditions of Participation, Joint Commission Standards, and more. The new provisions would also unnecessarily add costs to the overall system and decrease the amount of time that a provider spends with a patient providing care, and instead increase time spent doing administrative paperwork for something as simple as a history and physical or for a simple blood draw.

**3.10(2) – Patient Rights Notifications**

In a new Section 3.10(2), the Board proposes to impose on hospitals its own set of requirements for notifying patients of their rights under MGL Ch. 111, section 70E. This section is duplicative of existing state and federal law, and implementation would be unduly burdensome, in direct opposition to Governor Baker’s regulatory reform Executive Order. We urge the Board not to adopt this new provision.

**3.10(3)(b) – Facility Medical Record Requirements**

This section, which the Board has not proposed changing, states that hospitals and nursing homes must follow Joint Commission standards for medical records. The provision is outdated and does not adequately reflect the current state of health care organizations and electronic medical record systems. Because facility medical record requirements are adequately addressed by DPH and other regulatory bodies, there is no reason that the topic needs to be addressed in the Board’s regulations. In order to further the regulatory simplification directed by the Governor’s Executive Order, we urge that this entire section be removed.

**Conclusion**

In summary, we would like to reiterate that the proposed changes enumerated above, as well as others commented on by the MHA, do not further the Board’s core mission, are directly counter to the Governor's stated goal of reducing redundancy, burden and confusion. and expand the Board’s regulatory reach into systems which are already thoroughly regulated by the Massachusetts DPH. We respectfully suggest that the Board, with the assistance of the health care community, undertake a systematic assessment of the existing body of regulations affecting physicians so that it can identify and eliminate existing regulations which are inconsistent, redundant, and unnecessary, and only add new regulations which are truly necessary to carry out the mission assigned to the Board by its enabling legislation.

UMass Memorial appreciates the opportunity to provide these comments. We appreciate the significant time and effort Board staff and Board members must devote to developing major revisions to regulations, and as noted above we would welcome the opportunity to work with the Board in further developing the proposed regulations.

Sincerely,

*Douglas S. Brown/dll*

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