

February 28, 2017

George Zachos

Executive Director

Board of Registration in Medicine

200 Harvard Mills Square, Suite 330

Wakefield, MA 01880.

**Re: Proposed Regulations 243 CMR 1.00 and 243 CMR 3.00**

Executive Director Zachos:

The Massachusetts Health and Hospital Association (MHA), on behalf of our member hospitals, physicians, and other healthcare providers, appreciates the opportunity to submit the following comments related to the changes proposed to the Disciplinary Proceedings and Patient Care Assessment provisions in the Board of Registration in Medicine’s (Board) proposed regulations.

We believe that some of the proposed changes will bring important and timely updates to the Board’s requirements. However, we are very concerned that certain regulatory proposals as drafted will actually increase reporting and also result in duplicative, costly, and administratively burdensome practices among healthcare providers. In particular, the newly proposed Subsection 3.10 outlines several new informed consent and patient notification requirements that we believe will delay the overall delivery of care for every hospital and nursing home to a degree that is in direct conflict with the Governor’s regulatory reform Executive Order. To that end, we propose in our detailed comments that the Board consider removing that specific subsection and form a stakeholder group to help develop appropriate requirements that improve patient safety but do not add unreasonable operational burdens on healthcare providers.

To that end, we offer the following detailed set of comments, requested clarifications, and suggested amendments to various terms and requirements outlined in the proposed regulations. We believe that our recommendations will ensure that healthcare providers are able to effectively improve their services and facilities in a manner consistent with state and federal healthcare reform implementation and delivery system innovation goals, while also promoting cost containment and administrative simplification.

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

1. **“Complaint” (1.01)(2):**

MHA requests 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. An anonymous complaint that seeks to solely disparage a practitioner should be considered carefully and not included into the record as part of an administrative proceeding. While we believe that the Board operates in such a manner, it is critical that the regulations provide for such practices.

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

MHA specifically requests that the term “remediation” under subpart 15 of the definition “Disciplinary Action” be clarified to refer to specific medical practices such as “retraining and behavior modification within the practice of medicine.” Although the Board also ties the application of this new term to the parameters of subsection (d) in the definition of “Disciplinary Action,” that further clarification also includes references to “any violation of law or regulation.” The rather broad nature of such application provides no guidance or information as to the type of remediation that the Board is seeking to review. It is inappropriate that any type of difficulty in a provider’s training that result in remediation plans (or any action short of termination) should be reportable for disciplinary actions. While this is certainly true of “formal,” written remediation plans, the definition as drafted constitutes “formal or informal” action as disciplinary action meaning virtually any efforts to improve a physician’s performance could be deemed to fall within the definition of reportable licensure action. Requiring reports concerning any form of remediation could discourage appropriate efforts to improve physician performance, which would negatively affect overall patient care.

Currently, most hospitals afford a physician the opportunity for a hearing before any actions are taken concerning their membership and privileges that would be reportable to the Board, as outlined in hospital medical staff bylaws. In addition, remediation that does not result in a restriction of privileges or is not tied to a complaint or formal charges is not reportable to the Board and would not trigger a disciplinary action. We’re very concerned that the expansion of reporting requirements will result in hospitals being constrained in their efforts to impose any form of remediation on a physician without first giving the physician a hearing under the bylaws. This would result in an increase of critical resources, including staff time, efforts, and additional expenses, and could interfere with efforts to improve the safety and quality of care in many healthcare settings. We believe this is the opposite of what was the intent of adding this new term. As a result, the Board should remove the term or provide specific guidance for its application in order to remove redundant reporting and avoid potentially decreased practice improvement efforts within facilities.

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

MHA is opposed to the addition of this new term as drafted. A major concern is that unlike the new definition of Remediation in subpart (15), this new term is not tied to the clarification in subsection (d) of the definition of “Disciplinary Action” to ensure that the only actions to be considered are those related to the practice of medicine. In addition, given the broad nature of the term, we are very concerned that the Board may be trying to access unrelated actions that may have occurred at any point in an individual’s academic career, including those periods prior to medical school or residency programs. For these reasons, we believe that Subsection (d) of the definition of “Disciplinary Action” be amended to include a reference to subpart (16) to ensure that probation reviews are limited to those occurring during medical education. Furthermore, we would also urge the board to clarify the overall intent and provide some examples of the type of probation that would warrant reporting. Given the culture of transparency in many programs, it is essential that individuals feel comfortable to self-report any negative outcomes that may require corrections and formal changes to their practice, including increased supervision. 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.

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

1. **Inappropriately expanding Complaint Filings**

We would urge the Board to reverse its plans to eliminate within 1.03(1), the words “which charges a license with misconduct.” As drafted, the board has inappropriately expanded the basis for filing a complaint for any possible concerns that may have nothing to do with the practice of medicine or actual misconduct. The goal of the overall regulatory changes was to improve the overall reporting system to ensure the agency is not getting more frivolous cases that are not based on factual evidence of inappropriate behavior or practice of medicine. There is no reason for the removal of these words and will only increase the number of reports that will inappropriately use the Board’s staff time and resources that should be focused on cases that are causing patient harm.

1. **Changes the basis of a complaint to simple negligence**

As drafted, 1.03(5) are substantially confusing and will only increase the number of inappropriate reports submitted to the Board. To mitigate unnecessary confusion, we urge the Board to retain the words “gross negligence”. In particular we are concerned that as drafted, the proposed regulation conflicts with the enabling statute, MGL Ch. 112, Section 5, which mirrors the language proposed to be removed. Removing all qualifiers on “negligence” means that one instance of negligence without actual patient harm could result in discipline, which clearly seems beyond the intent of the enabling statute. In addition, there is also considerable confusion as to what the Board is seeking to accomplish as the rest of the subsection refers to gross misconduct and gross incompetence, but there is now a lower standard for negligence within this entire subsection. It is 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 some parameters for what should be reportable to the Board.

1. **Grounds for Complaint (1.03)(5)(a)8:**

MHA is opposed to the new phrase added at the end of this subsection - “or conduct which is in violation of the ethical standards of the profession” and requests the removal of said phrase. Similar to the points discussed above, the Board is adopting a very broad and undefined standard without specific interpretation, thus providing no guidance as to the specific practice that must be followed. Without a provided citation to which ethical standards should be considered (as there could be different ones adopted by a local, regional, or national provider association) this addition will create greater confusion and result in subjective determinations by various staff. This outcome will not lead to improved reporting or the promotion of improved patient safety. In addition, the language in this subsection specifically addresses actual fraudulent practices, not general ethical standards that are subject to interpretation out of context for this specific subsection. For these reasons we suggest removing these new terms in their entirety or providing clarification on their intent.

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

1. **“Adverse Event”**

As drafted, the proposed regulation provides for a very broad use 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 help clarify how this term is used using national evidence-based standards adopted by healthcare providers and facilities. Leaving this to a general term without such clarification could lead to increased reporting that is subjective to whoever makes the determination of what is an “Adverse Event” and not on a definition based on standards developed using scientific and consensus-driven approaches to improve the practice of medicine.

1. **“Close Call”**

Similar to our comments above, we are also concerned with the very broad and undefined nature of this new reporting requirement. At the very least, the Board should clarify or provide some guidance as to how a “close call” has been further defined by a current reporting practice (such as the DPH SRE or other formal reporting systems). Further, as defined, this new definition could inappropriately expand the number of unnecessary reporting if hospital staff needs to make a judgment call that 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.

1. **“Health Care Facility”**

MHA is very concerned with the definition of a healthcare facility, and would strongly encourage the Board to revise the definition to include among those required to report several other provider types, including but not limited to, ambulatory surgical centers, clinics, and providers that are part of an integrated care system. Removing the application of the review process from other hospitals and post-acute level providers that are part of an integrated care model or an Accountable Care Organization diminishes the importance of the patient care assessment program. In addition it is not appropriate that reporting is made from certain facilities, but there is no similar requirement on providers practicing in a clinic or other location who may have worse outcomes than those providers in an institutional location.

1. **“Healthcare Provider”**

Similar to our comments above, we would also strongly urge the Board to not remove the word “clinic” as proposed and to also ensure that the definition is similar to or includes those same facilities as outlined in our comments above.

1. **Medical Peer Review Committee**

As the Board may be aware, the federal Centers for Medicare and Medicaid Services now allows hospitals that are part of a health system or an integrated care system to have a unified medical staff system. As a result, we would urge the Board to further amend this definition in the second line to also include the medical staff of a health system for its enumerated hospitals, nursing homes, and other care providers. In particular, with the Baker Administration promoting the development of integrated care organizations, it is critical that the Board also provide for recognition that the medical staff of a facility or unified system should represent the hospitals, clinics, and other provider types within an integrated or overall health system similar to federal regulations.

1. **“Patient Care Assessment Coordinator”**

While we support the intent of this definition to ensure that the Coordinator has a management role within any institution or facility, there should be some clarification or guidance from the Board related to the expectation that the Coordinator has “a leadership role” within a facility or clinic. While that can be interpreted differently given the size of many facilities or clinics, it may not be possible to require that such individuals also be given a “leadership role” within many entities. We would request a consideration that the leadership role be based on performing the functions of the PCA program. Otherwise, the Board will be adding more duties to various senior leaders in facilities instead of elevating the overall role of the coordinator to perform their essential activities.

**Section 3.04 – Confidentiality of Records and Information**

1. **Technical Correction**

To ensure that the regulation correctly provides for the full range of activities outlined in this section, we request that the Board amend 3.04(1) by adding the word “and activities” after the word “requirement” in the first line. The overall goal is to ensure that there are several different actions that the provider community should take in protecting patient confidentiality; but as drafted this section is requiring substantial activities and therefore the requirement should be read in such a manner.

**Section 3.05 - Patient Care Assessment Program - Credentialing**

1. **Time Period for Credentialing Review**

MHA and our members, including credentialing and medical service staff, are strongly opposed to the removal of the language “during the previous ten years” in subsections (3)(c) and (3)(i). In particular, we are very concerned that the Board has now increased the reporting requirements for the provider community related to prior practices that are reported and available from various national and local sources. As drafted, there is now no threshold to determine an appropriate period of review for providers. This would excessively increase the administrative time and resources necessary to check on a provider's practice history, delaying their ability to treat patients, which does not lead to an improvement in patient care. The goal should be to review current and relevant medical practices for providers that are seeking licensure and credentialing privileges, instead of adding to the overall time and delays in credentialing staff. The intent of this change is unclear as the Board is still maintaining the ten-year period for health plan carriers to only review ten years of records in 3.05(3)(e). 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.

1. **Telemedicine**

While MHA and our members appreciate the inclusion of telemedicine within the Board’s regulations, we do not think that the language as drafted goes far enough. It is critical that the Board allow for the full and appropriate use of telemedicine by any licensee in various levels of care, instead of limiting the allowance of telemedicine to just hospitals and nursing homes as the regulations propose. In addition, the Board should apply an appropriate and measured approach to defining how telemedicine may be used in the state that does not seek to modify licensure requirements for healthcare providers nor change the prevailing standard of care for healthcare services. To that end, we urge the Board to adopt the language that the Massachusetts Telemedicine Coalition endorsed, which will advance and support the use of critical technologies in medicine, 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 urge the board to remove telemedicine from 243 CMR 3.05(3) (k), and instead adopt a new subsection 243 CMR 3.05(4) as follows:

*243 CMR 3.05(4):* Licensees *may follow the requirements of the Centers for Medicare and Medicaid Conditions of Participation, 42 CFR §§ 482.12 and 482.22, to obtain proxy credentialing and privileging to provide telemedicine services from a distant site to a patient receiving services from a healthcare provider. Telemedicine shall mean the use of synchronous or asynchronous audio, video or other electronic media for the purpose of diagnosis, consultation, prescribing, and treatment of a patient's physical, oral and mental health care that meets applicable health information privacy and security standards similar to those provided during an in-person visit. Telemedicine shall not include audio-only telephone or facsimile machine communications, but may include an online adaptive interview. Telemedicine may also include text only email when it occurs for the purpose of patient management in the context of a pre-existing physician patient relationship. For the purposes of this paragraph, nothing herein shall modify any requirements for Massachusetts licensure for individual providers delivering services through telemedicine services to consumers in the Commonwealth; provided further, that this paragraph shall not change the prevailing standard of care for healthcare services delivered through telemedicine.*

**Section 3.07 – PCA Program – Internal Audit and Internal Incident Reporting**

1. **Reporting of Additional Incidents/Events**

Similar to our comments about the definitions of “Adverse Event” and “Close Call”, MHA is very concerned with the newly added subsections 3.07(3)(d) and 3.07(3)(e), both of which require a healthcare facility to add additional reporting for internal incidents outside those included in the list of commonly reported adverse events. As drafted, this section provides an unknown list of incidents without ensuring that any information on an unknown incident be based on uniform definition/criteria that were vetted by a nationally recognized patient safety organization like the NQF or local provider associations or specialty groups. As drafted, the proposed regulation allows broad discretion to the Board without the ability for a provider to appeal or question the need for such reporting. The proposed changes only indicate that the Board will notify the facility/licensee as to why it is asking for an incident, but includes no ability for the facility/licensee to discus the necessity of such reporting or if there is a concern that such reporting is not related to an actual patient harm or inappropriate medical practices at a specific facility. It is critical that the Board provide some specific guidance or parameters for the potential new reporting requirements, which also seem to go against the overall goal of the governor’s regulatory reform Executive Order.

1. **Increased Record Retention Periods**

It is not clear why the Board is increasing the document retention period within 3.07(3)(j) from the current three-year period to now a new ten-year period for all PCA reports, summary reports, and recommendations to and from the PCA coordinator. This appears to go against the goal of the governor’s Executive Order by insisting on a new documentation retention period that only will add more unnecessary administrative costs. The goals should be to ensure that the PCA final reports are maintained; to require additional administrative mandates goes against the spirit of the regulatory reform initiative of the Administration.

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

1. **Clarification Needed for new “Serious Injury” definition and reporting**

MHA is very concerned with the unintended consequences of increased reporting in Sections 3.08(2)(b)2 and 3.08(2)(b)4 as drafted. In any given procedure there may be expected complications that must be monitored and assessed by the treating healthcare provider team to ensure that there is not an adverse event. In addition, depending on patient acuity, there may be a need for higher-level services following a procedure that may require a patient to be transferred to another level of care, despite the procedure being performed following the highest standard of care, quality, and safety. However, as drafted, the proposed regulation would require extensive and inappropriate reporting that would have nothing to do with demonstrating that the procedure or services was inappropriate or inadequate. At the very least, the Board must clarify what national evidence-based standards should be used in 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.

1. **Clarify a technical drafting error**

We believe that the intent of the changes in 3.08(3), was to change the reporting period for the SQR reports to three months following an adverse event. But the first sentence of the subsection, along with the proposed changes, still requires reporting on a quarterly basis. This could lead to duplicative reporting and we would request that this be clarified to require the reports to be submitted quarterly or three months following an adverse event.

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

1. **MHA General Request to Remove 3.10 in its entirety**

The Board is proposing substantial changes to an informed consent process that will cause not only substantial legal confusion but increased administrative time and burden on providers and the healthcare community. While we understand the importance of creating standards related to informed consent practices, we would strongly urge the Board to remove this entire Subsection 3.10 and in the meantime form a small stakeholder working group to consider a more appropriate process for developing the informed consent requirements. There are considerable areas where the language may conflict with federal Centers for Medicare and Medicaid Services Conditions of Participation, Joint Commission Standards, and more. The provisions would also unnecessarily add costs to the overall system and decrease the amount of time that a provider spends with a patient providing clinical services, and instead spend more time doing administrative paperwork for something as simple as a history and physical or for a simple blood draw. Holding a stakeholder meeting would allow the Board to develop reasonable and appropriate informed consent criteria, which could be issued as part of another upcoming set of regulations (such as the licensure and other regulations that have not been issued to date). While we outline several of the key problems in Subsection 3.10 below, we ask your consideration of our proposal to remove this subsection.

1. **3.10 (1) – Informed Consent Requirements**
   1. In general, as drafted, the first paragraph within 3.10(1) is confusing. The provider will now have to provide substantial paperwork for any number of services to be able to prove to the “patient’s satisfaction” the medical necessity of a procedure based on expected benefit among other items. Removing the word “major” before “diagnostic, therapeutic or invasive procedures” will greatly expand the number of detailed informed consents that the provider or certain members of the staff must now complete. Overall the Board is now going to have providers spend more administrative time getting a signed informed consent than they would in providing actual services to the patients. We are also concerned that as drafted, each provider will now have to obtain an informed consent if the patient is now undergoing multiple procedures within the same facility during the same visit or treatment. It is imperative that the Board provide some discretion to the provider or facility to determine the appropriateness of how the informed consent is provided, and to allow administrative streamlining of the process to minimize duplication, among other changes.
   2. We are also concerned with the definition of a “Physician Extender” under 3.10(1)(a), which now appears to require direct supervision by the attending physician. This seems to go against the overall goal of expanding the role of many provider types, including those that are allowed to operate as a primary care provider under the provisions of state law. At the very least, the language should be changed from direct to indirect and include specific categories of providers following statutory and regulatory changes.
   3. The detailed provisions of 3.10(1)(b) through 3.10(1)(d) will put in place a very problematic process of what will now require a detailed informed consent for every single procedure. As drafted, all cases (from minor procedures, exams, and routine follow-up appointments) will require a detailed consent to be performed or started by the attending physician. In addition, it is also confusing as to who among the medical staff may continue to collect and complete the consent form. For example, the last sentence of 3.10(1)(d) does not define “completion of written informed consent documentation,” and this sentence has the potential to weaken the language that comes before it and create confusion about what is required, what the attending has to do, and what other staff can assist in performing. Efficiencies that have been developed in many practice settings (hospitals, clinics and others) where an Advanced Practice Registered Nurse or Physician Assistant routinely perform minor procedures will now have to be changed based on this language.
   4. We are also very concerned that language in 3.10(1)(f) will greatly expand the number of pages and documents that need to be part of the consent form as it requires that everyone that is part of the care team and under direct supervision of the provider must be listed on the form. This now means that each patient form must be unique and that standard forms for administrative ease would be prohibited. Further, it is unclear as to how this form may work for patients who are receiving inpatient care, and on those occasions when the team changes throughout the stay when additional tests or minor procedures need to be performed. Overall the amount of paperwork and costs would increase substantially for all providers who must follow this specific provision.
   5. While we understand the importance of having standards related to documenting the absence of a provider during certain procedures, as drafted, subsection 3.10(1)(g) is very confusing and could also require documenting why an attending physician is not available or present during procedures or treatments where indirect supervision is allowed. As drafted the regulations are imposing a significant documentation requirement on every single procedure and intervention, as it is not defined in the regulations, which will again delay procedures to ensure that this is documented following the board and vague nature of this regulatory citation.
   6. Given the statutory requirements in M.G.L. Ch. 111, section 70 as well as those imposed by the federal HIPAA law and regulations, we would also urge the Board to consider amending Subsection 3.10(1)(i) to reflect that a patient may obtain a copy of their medical record following the copying fee provisions in state statute and federal law.
2. **3.10 (2) – Patient Rights Notifications**

Overall MHA is very concerned that the patient rights requirement within this subsection duplicate the current statutory rights in Chapter 111, section 70E. Instead of referencing the current requirements, the Board is now requiring additional documentation and notices to the patients on who to contact if the patient has a complaint. For these notifications, there are Medicare forms, DPH forms, and now there will be an additional Board notice for patients. The Board has just increased the actual paperwork, costs, and staff time for every hospital in the commonwealth, which is in direct opposition to Governor Baker’s regulatory reform Executive Order.

1. **3.10(3) – Medical Record Requirements**

With regard to 3.10(3)(b), MHA is very concerned that the Board has developed a new standard of care for providers that will create legal and compliance problems throughout the state. Specifically, as drafted, this section states that hospitals and nursing homes must only follow the hospital Joint Commission standards for medical records. In addition, this subsection applies to a healthcare facility that is limited to any hospital licensed pursuant to M.G.L. ch111, Section51; any nursing home, within the meaning of M.G.L. ch.111, section 203(e); any state, county or municipal hospital; and any health maintenance organization within the meaning of M.G.L. ch176G, section 1. Unless this is clarified or amended, this subsection will require a large change in regulatory requirements, EMR system development, and more. We would urge that this entire section be removed or this subsection be changed to reflect federal and state licensure requirements specific to the provider type.

MHA again appreciates the opportunity to provide these comments. MHA and our members are committed to working with the Board to provide any necessary background on the reasons for our requested changes as well as meeting to review these items. Should you have any questions about our comments, please do not hesitate to contact me at (781) 262-6034 or agoel@mhalink.org.

Sincerely,

Anuj K. Goel, Esq.

Vice President, Legal and Regulatory Affairs