

May 17, 2017

George Zachos

Executive Director

Board of Registration in Medicine

200 Harvard Mills Square, Suite 330

Wakefield, MA 01880.

**Re: Proposed Regulations 243 CMR 2.00**

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 for the Licensing and Practice of Medicine provisions (243 CMR 2.00) in the Board of Registration in Medicine’s (Board) proposed regulations.

Similar to our comments regarding the proposed changes to 243 CMR 1.00 and 243 CMR 3.00, we are very concerned that these proposed changes will have several unintended consequences that will increase unnecessary administrative burdens, costs, and legal liability on providers and the state. In particular, the newly proposed Subsection 2.07(26) establishes several new informed consent and patient notification requirements (similar to those proposed in 243 CMR 3.10) that we believe will delay the overall delivery of care for every hospital and nursing home to a degree. These changes would be in direct conflict with the Governor’s regulatory reform Executive Order and we once again strongly urge the Board to remove this 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 these 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 2.01 (4) – Definitions:**

1. **Good Moral Character**

MHA is strongly opposed to the very broad and vague reference to “good moral character” as a prerequisite for licensure throughout the regulations, specifically as outlined in the sections listed below. The interpretation of “Good Moral Character” to our understanding is based on subjective case-by-case determinations that have no clear application in these regulations. Placing such a broad definition into a regulation without any further guidance or clarity allows different interpretations by the Board, hospitals, physicians, and clinics and is a set-up for conflict with potential for inconsistent application of this definition. The lack of clarity is particularly problematic given this definition is unrelated to the practice of medicine. This standard is simply too vague to provide an adequate basis for a licensure requirement meant to determine the skills, education, experience, and ability of a person to provide quality level medical care. Furthermore, without prior knowledge of what constitutes “Good Moral Character” the Board is asking applicants to sign a statement legally stating that they meet an unknown and subjective moral code that the Board has not outlined or provided, and which can change throughout the course of the licensure period. As a result, providers are legally binding themselves to a subjective review without prior knowledge of the issues or concerns that the Board is reviewing. ***As a result, these provisions MUST be removed in the following areas:***

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| * ***243 CMR 2.01(1)***
 | * ***243 CMR 2.02(11)(a)***
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| * ***243 CMR 2.02(1)***
 | * ***243 CMR 2.02(12)***
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| * ***243 CMR 2.02(1)(b)***
 | * ***243 CMR 2.02(13)***
 |
| * ***243 CMR 2.02(n)***
 | * ***243 CMR 2.03(1)***
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| * ***243 CMR 2.02(6)***
 | * ***243 CMR 2.03)(1)(e)1***
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| * ***243 CMR 2.02(7)***
 | * ***243 CMR 2.03(2)(e)(1)***
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| * ***243 CMR 2.04(5)***
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1. **Healthcare Facility Definition (243 CMR 2.01(4)):**

The definition of Healthcare Facility is inconsistent with the definition provided in Section 3.02 of the regulations. Of concerns is the inclusion of – “any location where medicine is practiced” – which is not further defined or outlined anywhere in the regulations or policy documents. As a matter of course, this interpretation would mean that a clinic, physician office, or other settings of care would be defined the same as a hospital or nursing home. This goes against the federal and state statutory use of the definition and we strongly believe that the use of key terms must be the same throughout all regulations to allow for consistent application for various practices by the Board. Creating different definitions for different Board operations will cause more confusion and wasted staff time (for providers and the state) trying to decipher whether one part or another of the regulation may apply to Board oversight. ***To ensure consistency, the definitions should be the same that is outlined in 243 CMR 3.02 for “Healthcare Facility.”***  As a result, we would remind the Board that in any updated definition, that the term facility should include those required to report, including but not limited to, ambulatory surgical centers, clinics, and providers that are part of an integrated care system.

1. **End-of-life (243 CMR 2.01(4)**

The hospital community has been and remains committed to working with our patients and medical staff to ensure that there are policies in place to educate providers, patients, and families on appropriate end-of-life treatment considerations. However, it is critical that as part of the update to its regulations, that the Board ensure that the definition and use of the term “end-of-life” is aligned with the requirements and use within the DPH hospital licensure regulations (105 CMR 130.1900). Those regulations focus on palliative care that includes end-of-life and is tied to the specific requirements that providers (those within a facility, clinic, or practice that is part of a hospital) must be in compliance. Having different definitions is confusing and creates problems for regulatory reviews completed by both DPH surveyors and Board staff. We strongly urge the Board to update its definition to be consistent with the DPH requirements.

1. **MassHealth Participation Requirements (243 CMR 2.02(2)(k) and 243 CMR 2.06(2)(f)):**

MHA understands and appreciates that the federal Affordable Care Act requires licensed healthcare providers to also meet certain Medicaid participation requirements, including enrolling as a billing or non-billing provider for certain services. While we commend MassHealth and EOHHS for agreeing to work with the provider community as they roll out these requirements, we are very concerned that the proposed regulations by the Board could create unintended problems for licensed providers. In particular, the regulations stipulate that this is a one-time licensure requirement, but this stipulation appears to be in place for all initial and renewal licensure requirements. Furthermore, there is no flexibility on the timing to submit the MassHealth participation agreement given the long delays in processing a Board application and the delays in receiving both the state Massachusetts Controlled Substance Registration and the Drug Enforcement Agency number. To that end, we would strongly urge that the Board amend these two sections by removing the proposed language and replacing it with the following:

*Participation in the MassHealth Program. Pursuant to M.G.L. c. 112, §§ 2 and 9, applicants and licensees shall apply to participate in MassHealth, either as a provider of services or as a nonbilling provider for the limited purpose of ordering and referring services in the MassHealth program, as a condition for licensure. A physician who is not engaged in the practice of medicine is exempt from the MassHealth participation requirement. This is a one-time licensing requirement, which shall occur 180 days following receipt of the initial licensure or a copy provided by the applicant for purposes of individuals seeking renewal, revival or reinstatement of a license following promulgation of this requirement. Provided that this requirement may be delayed until the applicant is also able to secure their Massachusetts Controlled Substance Registration and Drug Enforcement Agency number prior to applying to participate with MassHealth.*

1. **Balance Billing of Medicare Beneficiaries (Section 2.02(1)(i), Section 2.02(2)(h), and Section 2.02(7)(b)(5)):**

MHA is very concerned with and would request substantial changes to the requirements that the applicant agrees to solely accept the Medicare fee schedule and not balance bill. This provision creates a conflict and obstacle to federal and state healthcare reform proposals, specifically for those accountable care or alternative payment provisions where the patient may be required to provide some amount of cost sharing amounts. For many programs where the Medicare beneficiary is also eligible for a dual enrollment (e.g., MassHealth, a commercial plan, or a Medicare Advantage plan) there are some required level of patient payment obligations. Without addressing or accounting for this concern, then every provider would be in violation of the licensure standards even though they are obligated to seek payment from a patient based on the plan policies. While we understand the general intent of this provisions, it is critical that this language is updated to reflect or allow for any patient payment obligation rules for which the provider must seek payment from a Medicare beneficiary(such as co-pay, deductible, or co-insurance).

1. **License for graduates from International Medical schools (243 CMR 2.03)**

MHA is strongly concerned with and would urge the Board to make several changes throughout the licensure requirements for graduates of an international medical school. While we agree with the various provisions that appropriately require that a graduate must be able to demonstrate that the education program content and classes of their international medical school are similar to those provided by an American medical school, we believe other provisions are not appropriate and create substantial hardship for students who have the same trainings, skills, competency and experience as providers who trained in programs in America. In particular, the Board must revise the substantial equivalency requirement (where the applicant must demonstrate that they have an unlimited full license in another state for two years prior to applying, not including any time spent in another state in a post-graduate training). In addition, there are specific requirements within the substantial equivalency waiver (e.g., demonstrating the receipt of certain distinctions like awards, honors and others as a criteria – something that graduates of an American residency program are not required to demonstrate) that should also be removed. Generally speaking, many of the provisions are both antiquated and discriminatory. At a time when both the Massachusetts Attorney General and the Massachusetts Executive Office of Health and Human Services has advocated against inappropriate discrimination based on federal immigration policies for medical staff, now is the time for the Board to make the necessary changes to provide an aligned and fair approach for graduates of international programs similar to those that graduate from an American school or program. So to that end, we would strongly urge the Board to remove provisions that are not aligned with and similar to those required of a graduate from an American medical school or residency program.

1. **EMR proficiency – Licensure Renewals (243 CMR 2.06(2)(d)1.b.)**

While this requirement was developed to provide some flexibility for providers to demonstrate proficiency based on their knowledge and use of an EMR system currently utilized in hospitals, there have been subsequent and updated changes that were adopted as part of the new Medicare physician fee schedule (MACRA). Specifically, many providers and hospitals will no longer be required to demonstrate meaningful use certification once MACRA is fully adopted and phased in as part of the payment structure. Therefore we would urge that the Board remove the words “with a CMS-certified meaningful use program” and instead insert the words “that have implemented an electronic health records (EHR) system.” Allowing for this change would continue the flexibility for providers who are working within a hospital that has adopted an EHR system and where they must have the EHR knowledge, but without the federal standard that will soon be phased out by federal CMS.

1. **Delegation of Medical Services (243 CMR 2.07(4))**

As drafted, the proposed changes to the delegation of medical services would be in violation of federal Medicare Conditions of Participation. As a result, providers who are working in a facility that must meet those standards would be seeking a waiver from the Board for each and every area that would be delegating medical services. The federal regulations 42 CFR 482.12(c)(1)(i) – provides broad authority for a physician to delegate task and services to qualified medical personnel. Specifically the facility must demonstrate that the individuals have the license, certification, or permit in accordance with state and local requirements. CMS has further interpreted the minimum requirements to include a review of qualifications, training/education, and experience of the individual to perform such services. Such individuals do not need to be credentialed with the hospital, but can demonstrate the ability through a review of these services through the human resources office similar to other non-credentialed medical staff. Therefore we strongly urge the Board to update this requirement to prevent every hospital from having to submit a waiver request with both the Board and DPH to ensure that the hospital can meet federal requirements and not jeopardize their physician licensure status.

1. **Medical Records of Deceased Physician (243 CMR 2.07(13)(f)):**

We are very concerned with the proposed language in this subsection that would allow an executor or administrator of a physician access to the patient medical records of the deceased physician. These records should still be maintained following federal and state privacy and security rules, which includes preventing any access by an individual who does not have the patient’s legal authority or is a treating provider to access the information. As a result, we strongly urge the Board to revise this entire section or remove it and develop a policy document for the maintenance of medical records by the group. While the records should be maintained in a secure manner for patients or others to access, the burden should not be on the executor or administrator of an estate to manage or have the unauthorized ability to view protected health information. The Board is developing a new access authority for the physician’s executor (not the patient’s executor) that is not allowed in state or federal law.

1. **Providing Cancer Patients with Treatment Information (243 CMR 2.07(14))**

MHA is very concerned with the increased and unnecessary informed consent requirements outlined in subsection 2.07(14) that will cause more time to be spent on administrative requirements instead of working directly with patients to discuss appropriate care options or providing actual services. As drafted, this subsection will require oncology providers to develop a detailed and patient specific informed consent form that outline every possible alternative method for cancer treatment. This form must be signed by the patient, the medical record must indicate the form and discussion occurred, and the form can only be signed by the physician conducting the procedure. As we have outlined in our comments to 243 CMR 3.10 and later in this comment letter to 243 CMR 2.07(26), there are efficiencies that have been developed to allow other medical staff to conduct such reviews with patients. In addition, there has to be flexibility for the treating provider to determine what alternative therapy is appropriate to suggest or discuss the options with the patient. This provision as drafted changes the practice of medicine by not allowing the treating provider to determine which course of treatment or alternative treatment is appropriate for a particular patient. If the provider must consider any and all treatments that are appropriate for the patient, but does not mention those that are possible but not viable for the patient’s condition, that will be a violation of these proposed regulations. The proposed regulations also require the treating provider to provide the names of other consulting providers, many of whom are not specialists for cancer treatment, without any authority for the treating provider to determine what is appropriate for the patient. Again this will require a very long and extensive list of consulting providers that would only increase the documentation, decrease care and treatment so the provider can spent more administrative time going over the options and consulting provider list, and possibly delay necessary care and treatment. Further, requiring an extensive informed consent review that can only be done by the treating provider goes directly against the Governor’s administrative simplification executive order. Currently, all providers discuss the options available for treatment and outline the potential benefits and risks of those options as a standard of practice, regardless if the patient is being treated for cancer or any other medical condition. This new requirement only adds to the already considerable regulatory requirements and, while certainly not intended, could serve to weaken the patient-physician relationship.

1. **Informed Consent (243 CMR 2.07(26))**

Similar to our comments that were filed on February 28, 2017 related to the informed consent requirements within 243 CMR 3.10, we would also request that the entire section of 243 CMR 2.07(26) be removed. The Board is once again 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 overall 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 2.07(26) 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 conflicts with federal CMS 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, due to the increase in 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 2.07(26) below, we ask your consideration of our proposal to remove this subsection.

* 1. In general, as drafted, the subsections of 2.07(26)(b) and (26)(c) is confusing. The provider will now have to provide substantial paperwork for any number of services to be able to prove the medical necessity of a procedure based on expected benefit among other items. 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. The requirements of 2.07(26)(c) 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. For example, 2.07(26)(d) places the burden solely on the primary operator or supervising physician. 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 or delayed until the attending physician comes and spends significant administrative time to do a detailed informed consent before procedures can occur. This will substantially delay care in every practice setting across the state.
	3. While we understand the importance of having standards related to documenting the absence of a provider during certain procedures, as drafted, subsection 2.07(26)(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.
	4. 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 2.07(26)(i) to reflect that a patient may obtain a copy of their medical record following the copying fee provisions in state statute, the Board regulations at **243 CMR 2.07(c),** and federal law.
1. **Physician Profile (243 CMR 2.15)**

MHA is strongly opposed to and is concerned with the inclusion of new physician profile requirements that have several unintended consequences. In particular we are concerned with the following items below and request that they be removed in their entirety:

* 243 CMR 2.15(2)(e) sets forth several new standards for reporting to the state’s physician profile record if the provider resigned or did not renew their medical staff privileges for reasons related to character or competence. While we appreciate that there are reasons to seek information when there is an adverse event with actual harm to a patient, seeking information that is unrelated to the practice of medicine or the ability of a provider to perform their services is inappropriate and unrelated to the needs of the Board. We urge that this provision be removed in subsection 2.15(2)(e).
* 243 CMR 2.15(2)(m) through (p) also is confusing as it is not relevant to the practice of medicine or the ability to provide specific services. This is an unnecessary reporting burden that is specifically what the Governor’s administrative simplification executive order was developed to prevent. Instead the Board has artificially increased reporting that will add more time and costs to the overall system without providing improved information to better patients on the ability and competence of their providers.

Massachusetts hospitals and physicians are committed to providing the best possible care to their patients and communities, and to be publicly accountable for the work they do. To that end, MHA and our members are committed to working with the Board to provide any necessary background as well as revised language per the points in our comments above. 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