**COMMENTS REGARDING PROPOSED REGULATORY CHANGES TO
“LICENSING AND THE PRACTICE OF MEDICINE” (243 CMR 2.00) REGULATIONS
BEFORE THE BOARD OF REGISTRATION IN MEDICINE**

**MAY 18, 2017**

The Massachusetts Medical Society appreciates the opportunity to provide comment on proposed changes to the “Licensing and the Practice of Medicine” (243 CMR 2.00) regulations of the Board of Registration in Medicine. The Medical Society has strong concerns about several changes proposed herein, and suggests modification as detailed below, to ensure the regulations promote the best interests of the patients of Massachusetts.

The Medical Society reminds the Board that this ongoing regulatory review is pursuant to Governor Baker’s Executive Order 592, “To Reduce Unnecessary Regulatory Burden” which mandates a review of regulations to ensure that they are not unduly burdensome, and that there are not less restrictive alternatives. The Executive Order instructs that a review take place to determine if the regulations should be retained or modified to promote administrative simplification. The Medical Society urges additional consideration of these proposed changes with a refocus on this underlying charge, as many of the proposed changes discussed herein actually increase the administrative burden by expanding license application requirements, by increasing administrative burdens of physician offices through expanded record retention requirements, and by consistently expanding the scope of authority of the Board in its licensing determinations- all of which are antithetical to the underlying Executive Order.

 **Expansion of the Purpose of the Board**

The Medical Society opposes changes to Section 2.01(1), which expand the purpose of the Board beyond its current long-standing charge, to ensure that only qualified physicians are licensed to practice medicine in the Commonwealth, to include guaranteeing subjective characteristics, competency and good moral character, for the physicians it licenses. The purpose of the Board has traditionally been to ensure that applicants meet the extensive, detailed, impartial qualifications set out in these regulations and in its detailed, specialized licensure applications. This charge, to certify qualified physicians, provides vital protections for the public, for physicians, and for the Board, as the standards for fulfilling this charge are ratified by extensive regulations and guidances, developed by unbiased experts with oversight from the Department of Public Health and other relevant state officials. Adding determinations of “competency” grossly expands the scope of the Board, and, without a clear definition or explanation of the standard for this charge, fails to establish a structured and predictable set of expectations. It is unfair to presume and mandate that Board members can and should be responsible for determining the competency and good moral character of every physician from the information contained in the licensure application. Instead, we should continue to rely on the many years of thoughtful guidance, training, and observation from qualified faculty medical experts who prepare residents and physicians for high-quality, individual care of patients “within clinical learning environments for development of the skills, knowledge, and attitudes necessary to take personal responsibility for the individual care of patients.”[[1]](#endnote-1) It is through these many years of carefully designed educational and training programs with expert physicians that thorough and accurate evaluations of competency and moral character are developed.

The Medical Society shares the Board’s mission, we also want all licensed physicians in Massachusetts to be competent clinicians. However, this noble end is currently imbedded in the current licensure qualifications of the Board regulations, carefully designed and updated by expert clinicians, experts, and officials, to evaluate competence. Many of the objective requirements for licensure contained in these regulations are designed to ensure competency and good moral character from documented observations during medical education, professional examinations, and post-graduate medical training, which of course has strict, standardized curriculum that ensure competency as a condition of passage. The Medical Society urges striking the addition of “competency” from Section 2.01(1), and instead, suggests the Board continue to imbed qualifications within the regulations and licensure applications that promote assurances of competency.

 **Inclusion of “Good Moral Character”**

The Medical Society opposes the addition of a dozen new references to “good moral character” in these regulations, including an addition in 2.02(1)(b) that implies a shift in the burden of proof to the applicant to provide evidence of their good moral character. The Medical Society has long accepted that a qualification for physician applicants is good moral character. We believe that the current, longstanding references to this as part of the licensure qualifications is more than sufficient. The Medical Society oppose adding this determination of “good moral character” to the general purpose to of the Board in Section 2.01(1), and opposes the addition of this reference in a dozen other portions of these regulations.

Good moral character is not defined in the regulations, and this is likely do to the difficulty of creating such a definition. But this difficulty in defining the term is also the source of the concern by the Medical Society. One person’s definition of good moral character can easily differ from that of another. The Medical Society believes that the better approach to promoting this end is to ensure adherence to the rigorous licensure qualifications put forward by this board, and laws and regulations pertaining to the practice of medicine, which imbed in them so many ethical best practices.

With all of these concerns regarding the determination of good moral character, the Medical Society strongly opposes the apparent shift in the burden of proof of good in Section 2.02(1)(b) by requiring every applicant to “provide satisfactory evidence” of good moral character. The Medical Society believes that this shift to now require affirmative proof of the good moral character is unnecessary, and again difficult to interpret given the lack of definition.

 **Prohibition of the Delegation of Medical Services to non-licensed Individuals**

The Medical Society strongly opposes the proposed prohibition of delegation of medical services by physicians to non-licensed individuals in Massachusetts. Medical assistants, for example, are not licensed in Massachusetts. They assist in medical care exclusively under the delegation authority of these regulations. The regulations, as currently in effect, provide strong safety and quality protections by requiring, 1) that all services be within the skill set of the person to whom the service is delegated, and 2) that the responsibility and liability of the delegate ultimately lies with the delegating physician. The broad definition of “practice of medicine” means that many common procedures such as the taking of blood pressure are considered to be the practice of medicine. Prohibiting physicians’ ability to delegate such a service to a medical assistant—who does not have the ability to become licensed in Massachusetts—would substantially disrupt health care delivery in the state, and would drive up costs unnecessarily by requiring work to be performed by overqualified individuals. The Medical Society urges retention of the original regulatory language, and suggests that if specific instances of delegation are of concern, that the Board utilize the current regulatory protections, or that it consider adding select “non-delegable services” to the regulations.

 **Medical Record Retention, Password Requirements**

The Medical Society opposes the extension of the medical record retention requirement in 2.07(13) from seven to ten years. A recent survey of state laws across the country, with an emphasis in this geographic region, shows 5-7 years is still the predominant requirement. The Medical Society urges retention of the seven year requirement for physician offices, and believes that an arbitrary extension is inconsistent with the underlying Executive Order, and that it unnecessarily burdens physician offices, especially in light of security concerns which have driven up the cost of secure record storage.

The Medical Society also strongly opposes section (f) of 2.07(13) which would require physicians to provide to their executors or administrators passwords for all medical records. Assuming that many executors are not “Business Associates,” there is significant concern that this could lead to the regulations requiring actions that breach HIPAA. The Medical Society urges removal of this section until a better solution is crafted.

**Elimination of Physician Health Services Exemption for Substance Use Disorder**

The Medical Society was dismayed to see, and strongly opposes, the removal of the longstanding substance use disorder exemption in 2.07(23), which has long been a critical avenue for physicians to proactively seek help through a qualified program, such as Physician Health Services. It has allowed physicians with alcohol use disorder or substance use disorder—so long as there has not been a breach of BORIM regulations or any allegation of patient harm—to seek treatment without report to the Board, so long as the physician is compliant with the treatment program. The addition of “violation of Ch. 94C,” the state’s drug laws, to the list of conditions that exclude participation via this pathway, will effectively gut this provision, as physicians will have violated these laws by nature of their misuse of drugs. This proposed change will not allow for those with substance use disorder to proactively seek treatment without report to the Board.

The Medical Society has engaged with the entire Baker administration over the past two of years to engage in a campaign to reduce stigma and to encourage treatment of all persons with opioid use disorder. We all know that physicians are not immune to this disease. We thus strongly urge the Board to retain the full “PHS exemption” by striking the reference to violations of Ch. 94C to ensure that physicians are encouraged to get help, especially in instances where other Board regulations have not been violated, and where there have not been instances of patient harm. Eliminating the exemption for those with substance use issues, and not for those with alcohol use disorders, has the potential to perpetuate stigma and fails to promote the notion of opioid addiction as a disease.

 **Addition of Cancer Treatment Disclosure Requirement**

The Medical Society opposes the addition of section (14) to 2.07, which adds new requirements for the disclosure of a host of information for every patient who accepts treatment for a known or suspected cancer. The Medical Society of course supports fully informed decisions by patients, but believes that laws and regulations are already in place to promote and ensure fully informed consent. Massachusetts law requires that “a physician owes his [or her] patient the duty to disclose all significant medical information that the physician possesses, or reasonably should possess, which is material to an intelligent decision by the patient whether to undergo a proposed procedure.” *Harnish v. Children's Hosp. Med. Ctr*., 387 Mass. 152, 155 (1982). In light of the robust informed consent protection, the Medical Society opposes the addition of this section which pertains solely to cancer treatments. We further oppose the explicit lists of what must be required in these cancer-related disclosures of “alternative methods”, as well as the language regarding physician obligations for information regarding consultations.

The Medical Society opposes the approach of “diagnosis specific” regulatory provisions, and fears that this indicates exceptionalism of cancer diagnoses and treatments from those of many other disease types. Further, the specificity of the requirements in this section are inconsistent with the legal and regulatory oversight of the rest of the practice of medicine. Again, broad informed consent and standard of care requirements have long provided sufficient tools to make ensure proper disclosure of medical information to patients, and the Medical Society urges the Board to strike this new provision and rely upon existing informed consent laws.

**Addition of Informed Consent Language**

The Medical Society again opposes the addition of the informed consent language to 2.01(26). The Medical Society opposed this language in the Patient Care Assessment portion of the Board regulations, and again opposes the language for the same reasons, in part as excerpted below from our previous testimony:

The Medical Society strongly values the concept of informed consent as a vital component of respect for patient autonomy. The Medical Society believes that patients deserve to know material information about surgery- they should know who is leading the surgical care, and they should be informed about what components of a given surgery at which the attending physician will and will not be present.

Massachusetts courts have set forth standards and tests to ensure that all patients have the right to adequate informed consent. Informed consent has long been a careful balancing test of ensuring that the proper level of material information has been conveyed to patients for any given procedure, and that it is provided in the proper manner to ensure patients understand the risks, benefits, and alternatives to a given intervention. Undue burden in policy can also be problematic if it impedes the delivery of high-quality health care and does not prioritize the disclosure of the most material information. The Medical Society is concerned that the present regulations as drafted will have significantly deleterious impacts on the practice of medicine while providing little additional information of value to patients.

The scope of application of the informed consent provisions is overbroad and internally inconsistent. The detailed written informed consent provisions, which were put forward in response to issues with the most advanced surgical procedures, have been written to be broadly applicable to any and all “diagnostic, therapeutic or invasive procedures, medical interventions or treatments.” The redlined regulations seem to imply that modifying this list with “major” was contemplated, but ultimately ignored. In other words, these provisions could have been limited to “major surgeries and procedures,” but the regulations proceeded with the broadest possible application. Again, written informed consent makes good sense in a number of clinical scenarios, primarily those dealing with major surgery or treatment. But at present, as drafted, all of the written informed consent provisions contained in these proposed regulations would apply to every diagnostic or therapeutic action.

The scope of application of the informed consent provisions is also inconsistent within the regulations. Whereas 3.10(1) provides limits to the informed consent requirement, paragraph (c) of the same section modifies the extent to which the informed consent provisions apply to only those where the information would assist a patient in making a decision whether to undergo the proposed procedure.

The details of what is considered adequate informed consent are problematic and do not comport with the health care delivery model in place in Massachusetts for many surgeries and procedures swept into these regulations. First, requiring the attending physician to obtain every written informed consent is not tenable and does not necessarily promote the best care for the patient. Many surgical teams elect to obtain written informed consent at the pre-operative appointment, as patients are often in a better position to comprehend the information and to ask questions, without being overwhelmed with the anxieties of an impending procedure. Often, this pre-operative appointment may be led by a physician or other provider that is not the attending physician. This may be because the attending physician is called into an emergency, or it may be because another team member is the most skilled communicator or has a pre-existing relationship with the patient. In teaching and training settings, it is important to allow fellows to participate in every aspect of the surgical process from providing informed consent to providing discharge instructions and handling follow-up care. While it is important that the attending physician be available for questions, requiring the attending physician to obtain the written informed consent for every procedure is not feasible nor does it promote the best interests of the patient.

The requirement that the attending physician inform the patient at the point of written informed consent the names of all “physician extenders” is infeasible and again does not provide the most material information to the patient. First, the nature of surgical programs, especially those in academic medical centers, is that surgical care teams can be fluid and shift at a moment’s notice. A roster of participants of surgeries for a given operating room prepared at the beginning of a day can be substantially altered based upon unexpected emergency surgeries, illness of surgical team participants, and the educational priorities of residents and fellows. Complications during surgery are by nature unpredictable- surgeons should not be constrained in calling in colleagues for consultation or collaboration. Lastly, complex surgery can be a grueling physician exercise for the surgical team. They should be encouraged to take breaks and to call in support when necessary. The detailed requirements in the informed consent provisions do not take into account many of these important details.

**Removal of Liability Protections for Sponsoring Physicians**

The Board has long had a rarely used licensure category to allow physicians to seek temporary Emergency Restricted Licenses in Massachusetts if they have been displaced from their medical practice or medical training by a federally-declared disaster. We support this licensure category as a compassionate service to other physicians in times of great difficulty. Part of the regulatory requirements for these physician applicants is that they have a Massachusetts licensed physician sponsor. This sponsorship may be important to ensure that the displaced physician has a relationship with a Massachusetts physician so to ensure a basic network in Massachusetts medicine. Being these are licensed physicians in other states, there are no requirements of supervision or oversight by the sponsoring physician. For these reasons, there has also been a longstanding provision in the regulations explicitly indicating that sponsorship does not imply liability for the actions of the physician for whom they are sponsoring. The striking of this liability-limiting language will increase impediments for displaced physicians, and is an otherwise unjustifiable attempt to expand liability exposure for physicians who are simply trying to help out a colleague in need during difficult times. The Medical Society strongly opposes the removal of this language.

**Retention of the Seven-year Rule**

The Medical Society opposes the retention of the seven-year rule. In fact, the Medical Society now has policy encouraging the elimination of the United States Medical Licensing Exam Step 2 Clinical Skills Exam for licensure requirement for graduates of U.S. osteopathic and allopathic medical schools who have passed a medical school-administrated clinical skills examination. The Medical Society urges the amendment to the licensing regulations to reflect this policy that was passed amidst growing concerns that the exam is costly, redundant, and not associated with evidence that it proves clinical competency.

**Addition of Several Factors for Waivers of Substantial Equivalency**

The Medical Society opposes the additional factors added to 2.03(1)(e) which outlines situations in which international medical school graduate physicians can apply for waivers to the substantial equivalency of medical school education. The new factors laid out in section (e) are overly restrictive and will prohibit many well qualified physicians from practicing or training in Massachusetts. Specifically, requirement “2” and “3” in paragraph (1)(e) are very concerning in that they would require any applicant who cannot show substantial equivalency to first have practiced with an unlimited, unrestricted medical license in another state for two years. This implies that Massachusetts is not willing to make the difficult but important determinations of which physicians, who have completed an accredited residency program, are able to become licensed in Massachusetts. This could meant that a graduate of a international medical school that cannot show substantial equivalency, but who completed a US residency, and practiced in Canada for several years, cannot be considered for licensure in Massachusetts. The Medical Society firmly opposes the concept that graduates of international medical schools who cannot show substantial equivalency but who completed accredited residencies are per se barred from application in Massachusetts until they have practiced in another state for two years.

The Medical Society also opposes the requirements put forward in 2.03(2)(e) which place similar requirements on applications of waivers for substantial equivalency for limited license applications. Here, the permissive requirement that applicants have held an unlimited license for 2 years in another is completely illogical and untenable as the applicant is simply applying for a limited license to participate in a residency program. By nature of their application for a limited license, they could not and would not have practiced with an unlimited license in another state.

**Inclusion of Malpractice and Criminal History into Application Requirements**

Lastly, the Medical Society strongly opposes paragraphs 9 and 10 of Section 2.04 which add malpractice and criminal history requirements. They both are overly burdensome, unfounded expansions of the minimum requirements for licensure applications. The requirement in (9) of documentation of “any malpractice claim in which he or she was involved” is overbroad and burdensome to applicant. The Medical Society was recently in touch with a mid-career applicant from out-of-state who was a party to two malpractice suits as a resident. In each instance, he was quickly dropped from the case with no payment, settlement, or decision on the merits of the case. The plaintiff’s attorneys realized in each instance that there were no merits to the inclusion of this physician on the case. But he was forced to spend countless hours to find the documentation required by the board, all on two cases from which he was dropped by the plaintiff very early in the process several decades prior. This section should be amended to only include cases for which a settlement was payed or for which a judgment was made indicating malpractice.

The Medical Society also firmly opposes the inclusion of criminal history into the regulatory requirements of the license application. The term “all criminal proceeds to which he or she was a defendant” is a drastically overbroad standard that would capture countless instances where criminal charges were dropped or where applicants were found not guilty. The justice system in Massachusetts and the country is founded upon the ability to fully respect the criminal process and the concept of innocence. Should an applicant who was falsely arrested for a crime and fully exonerated need to provide such information to the Board? Should an applicant who has had his juvenile record sealed by the courts be required to provide such information to the Board?

This overly broad requirement for information implies that such information could be relevant to the decision of whether to grant an application. The Medical Society believes this terminology is antithetical to the justice system in our country, and does not respect due process afforded to all of its citizens. The Medical Society urges striking of this section.

The Medical Society appreciates due consideration of these comments, and urges re-evaluation of the regulations in light of these comments, and those of many other interested stakeholders.

1. http://www.acgme.org/What-We-Do/Accreditation/Common-Program-Requirements [↑](#endnote-ref-1)