**COMMENTS REGARDING PROPOSED REGULATORY CHANGES OF “DISCIPLINARY PROCEEDINGS FOR PHYSICIANS” (243 CMR 1.00) AND “PATIENT CARE ASSESSMENT PROGRAMS” (243 CMR 3.00)   
BEFORE THE BOARD OF REGISTRATION IN MEDICINE**

**MARCH 1, 2017**

The Massachusetts Medical Society appreciates the opportunity to provide comment to the proposed regulatory changes of “Disciplinary Proceedings for Physicians” (243 CMR 1.00) and “Patient Care Assessment Programs” (243 CMR 3.00) by the Board of Registration in Medicine. The Medical Society strongly supports the value of a fair adjudicatory process and of a robust patient care assessment program as key drivers of quality of care and patient safety in Massachusetts.

The ongoing regulatory review by the Board of Registration in Medicine 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 definitions of reporting, by grossly expanding periods of review for physician credentialing, and by consistently lowering thresholds for what warrants BORIM action- all of which are antithetical to the underlying Executive Order.

**The Medical Society offers the following comment on 243 CMR 1.00, “Disciplinary Proceedings for Physicians.”**

**The Medical Society opposes the expansion of the definition of “Disciplinary Action” as detrimental to the medical education and training of the medical students, residents, and fellows of the Commonwealth.**

The expansion of the definition of Disciplinary Action under Section 101(2)(c) would sweep into the purview of reportable events for any given licensee the broad, undefined terms of “remediation” and “probation, including academic probation.” Combined with Paragraph (b) of this same section, even “informal, oral” remediation would be considered a disciplinary action. This overreach and expansion of definition is not just a proposed regulatory change that is inconsistent with the Governor’s Executive Order, and which could inconvenience many physicians and overwhelm BORIM staff. This provision has the opportunity to substantially disrupt the medical education and training capabilities throughout the Commonwealth, and could ultimately have detrimental impacts on the training of the next generation of physicians in Massachusetts.

The practice of medicine is one of the most complex professions to learn; the stakes of the education to promote competent care could not be higher. The Board of Registration in Medicine needs to strike the balance of ensuring that it is privy to material information about serious “disciplinary actions” while ensuring that medical educators have authority to engage with students and trainees to facilitate improvement without fear of undue Board involvement.

*Should a residency director who takes time to help a fellow improve bedside manner or talk about how better to have end-of-life care discussions be worried that doing so could be considered a disciplinary action?*

*Should a surgeon who is working with new technology and seeks the mentorship of a senior colleague be nervous that this arrangement could warrant reporting to the Board?*

While these example are likely not consistent with the intent of the Board, they are examples of not-unreasonable interpretations of the proposed changes given the lack of definitions or further guidance.

In addition, the Medical Society strongly supports Physician Health Services (PHS), an organization dedicated to improving the health of the physicians of the Commonwealth. The valuable services provided by PHS are often by nature facilitating remediation. A core value of PHS is that it can be a venue for physicians to proactively seek help with health concerns before they manifest in actions that traditionally warrant reporting to the Board.

*Should a trauma surgeon seeking help from PHS for workplace stress and burnout be* *considered having been subject to a disciplinary action?*

*Should a physician with mild depression seeking consultation with PHS before it affects clinical care be considered to having been subject to a disciplinary action?*

The Medical Society has similar concerns to the inclusion of “probation” into the list of disciplinary actions. Medical schools, residencies, and fellowships have robust systems and policies to promote the best education and training of students and physicians while also ensuring the highest quality for the patients they serve. They are backed by strong federal laws, regulations, and accreditation requirements. The Medical Society strongly urges continued trust and dialogue with these institutions to develop more thoughtful policies, if needed that do not fall to simply considering every probation, including informal and/or oral, to be a disciplinary action. This again contravenes the very tenets of medical education and training which seek to intervene early and often to create improvement plans. In addition, a short period on academic probation again should not be considered a disciplinary action. Often these periods may come after periods of illness, personal crisis, and/or leaves of absence. A probation does not necessarily imply poor or failing performance; rather, it signifies increased attention, support and monitoring for any number of reasons. The Board should be fostering dialogue and trust with the medical schools and residency programs within the Commonwealth rather than considering any action they take to foster improvement and accountability to be a disciplinary action.

In light of these many examples that show unintended consequences of the proposed changes, the Medical Society urges striking these new categories. And while the Medical Society appreciates that the Board has the discretion whether to act on reported disciplinary actions, it is important to underscore that all actions by the Board set up a cascade of other events within the health care system, even if the Board declines to proceed upon report. The Medical Society appreciates the high volume of licensing applications and complaints that the Board staff regularly processes, and urges prioritization to ensure that only categories with potential to identify truly troublesome events be retained. For these reasons, we urge striking 1.01(2)(c)15 and 16 from the final regulations that introduce “remediation” and “probation” to the list of disciplinary actions.

**The Medical Society Opposes the Expansion of Grounds for Complaint**

The Medical Society is strongly concerned with the inclusion of “good and accepted medical practice” in the definition of complaint in 1.01(2), and the striking of “gross” from reference to negligence in the list of grounds for complaint in 103(5)(a)(3). Each of these changes reflects a substantial expansion of Board action by including single instances of negligence or deviations from the standard of care as grounds for Board complaint. These changes which propose altering the standard of care for Board involvement are inconsistent with the overarching designs of the medico-legal system.

Single instances of negligence have long been dealt with in the civil malpractice arena, with requirements beyond negligence that include a duty, causation and damages—all in addition to simple breach of a standard of care. The purpose of the Board of Registration in Medicine is not to replicate the civil courts and to be the arbiter of a single mistake over the course of a long medical career. Instead, the Board’s role is as the protector of the public, as the gatekeeper of those who deserve to be licensed to practice medicine in Massachusetts pursuant to applicable laws and regulations. Retention of the current language, which includes as grounds for a complaint, “gross negligence on a particular occurrence or negligence on repeated occasions”, reflects the appropriate role for the Board.

The Medical Society also opposes the addition to the list of grounds for complaint in 103(5)(a)(8) of “conduct in violation of the ethical standards of the profession.” The Medical Society strongly supports the highest ethical standards of the medical profession, and has a Committee on Ethics, Grievances and Professional Standards solely dedicated to this issue. This committee has developed complex processes and resources to outline how to respond to concerns that a physician has violated ethical standards and to promote our code of ethics to physicians, patients, and the public. A key component of this process is the development and endorsement of complex Codes of Ethics (the most recent of which put forward by the AMA surpassed 500 pages) to provide physicians with expectations of ethical standards to which they may be held. Adjudication of whether a given practice is consistent with ethical standards without a single word in regulation of underlying principles or sources of authority is concerning and strongly opposed by the Medical Society. The complexity and continuing evolution of the ethical standards of the medical profession necessitate a correspondingly nuanced definition for and mechanism through which to address violations of those standards. In the absence of such a definition, the Medical Society fears that the adjudication of complaints regarding physicians’ alleged violation of ethical standards will be arbitrary and subjective.

Physician conduct that this regulation seeks to address will almost certainly meet one or more existing grounds for complaint outlined elsewhere in this list, the broadest of which being “misconduct in the practice of medicine” (103(5)(a)(15)). The Medical Society therefore believes that the addition of “conduct in violation of the ethical standards of the profession” is superfluous at best, and at worst might cause harm, for the reasons outlined above.

**The Medical Society Opposes the Diminution of Due Process Rights for Physicians and Trainees**

The Medical Society opposes omission of a timeframe required of the Board for a decision to be issued on a hearing on the necessity of a summary suspension, as in 1.01(11). These hearings take place on truncated timelines with limited due process rights. The results of a suspension of the license to practice their livelihood warrants, both under a pursuit of justice and compliance with the Constitution of the United States, a prompt disposition of the issues. The Medical Society urges a requirement be added for maximum length for the Board to issue a decision.

In addition, the Board has missed an opportunity to follow through in its pledges of transparency by still not acknowledging the physician’s right to a copy of the complaint, an issue that courts have continually pledged is a right of the physician. The Medical Society urges reconsideration, and suggests modification of paragraphs outlining the “Conference” and the “Order for Answering and Answer” in 1.03 to reflect this right to a copy of the complaint.  
  
The modification of the definition of “Complaint” (in 1.01(2)) which strikes the prior requirement that a complaint must be “filed with the Board” seems to remove requirements that the Complaints actually come through the public complaint process. The Board has a process to file complaints, electronically or by mail. This process should be respected, and all complaints should have a modicum of formal process and requirements that come with being filed with the Board.

Lastly, modification to paragraph 1.03(10) seems to further reflect a move towards a considerable increase in deference to the Board with no justification or understanding of the practical implications. The Medical Society urges that such changes to due process requirements be explained with written justification.

**The Medical Society offers the following comment on 243 CMR 3.00, “Patient Care Assessment Programs.”**

**The Medical Society strongly opposes the elimination of important peer review protections for licensed clinics and other non-hospital entities.**

The proposed regulations strike “licensed clinics” and “entities maintaining more than one primary or episodic walk in center” from the definition of health care facilities eligible for participation in the Patient Care Assessment Program. While participation in this program comes with many reporting requirements, detailed below, it also affords participating entities with important peer review protections. The Scope and Purpose of these regulations, as outlined in 3.01, is to “ensure patients receive optimal care” and to “assist physician and health care institutions in their efforts to identify problems in practice before they occur and to put in place preventative measures designed to minimize or eliminate substandard practice.” The goals and purposes as laid out in this section should not be dependent on the type of licensed facility at which a physician practices or at which a patient receives care. Licensed facilities with the infrastructure to participate in this program should have the protections afforded to them under the current regulations, regardless of whether they’re a hospital, a clinic or an entity maintaining more than one primary or episodic walk in center.

**The Medical Society opposes the expanded reporting requirements for participants of the Patient Care Assessment program.**

The proposed expansion of serious reportable events that must be included in quarterly “Safety and Quality Review” reports is excessive and directly contravenes the Governor’s Executive Order to reduce administrative burden. The expansion of the “Serious Injury” category to include non-fatal physical impairments with no reference to “unexpected” events or regard to other important factors such as comorbidities is an unreasonable reporting requirement. It does not provide proper deference to complex presentations of disease and could discourage the acceptance of patients with high acuity. Reporting of every unanticipated serious illness will result in an enormous increase in reporting that will be administratively burdensome for the reporters and for the Board’s Quality and Patient Safety Committee and staff. If the Board believes that the current requirement of including all licensed clinics is ultimately too broad, the Medical Society urges the a compromise that includes the retention of the clinics most likely to comply with reporting requirements and to utilize the important peer review protections.

**The Medical Society opposes the expanded requirements for credentialing added to the Patient Care Assessment regulations.**

The proposed changes to the credentialing requirements in 3.05 would substantially slow down the already burdensome credentialing process while providing little increase in valuable information to improve the end result. All physicians going through the credentialing process in Massachusetts are already licensed by the Board; the credentialing process should not be a duplication of the lengthy and detailed history that is evaluated by the Board staff. Rather, it should be a verification of primary credentials and a general evaluation that the physician is well qualified to provide good clinical care at a given institution. The change proposed in these regulations that malpractice claims and lawsuits are not just disclosed to every credentialing committee over the past ten years year, but instead over an entire career drastically increases the burden of applicants while only providing outdated, low-value information that credentialing committees will have a hard time evaluating. The proposed elimination of the current exemption to report low-level crimes again does not seem to provide any true improvement in the quality of credentialing but substantially raises the burdens for every credentialing application. And again, many of these matters are best left to the Board in their decisions to provide a medical license.

Finally, the elimination of the current ten-year limit to the requirement that that credentialing facilities inquire with every health care facility where a licensee has ever had employment, practice, or association for his or her entire medical career is unreasonable. It will add significant time to the already lengthy credentialing process. This will further contribute to the growing frustrations that many employers have had trying to recruit physicians from out-of-state. Any benefit from information gained by such a change is grossly outweighed by the burden it will place on every credentialing staff in the Commonwealth, and this provision directly conflicts with the Governor’s Executive Order.

**The Medical Society strongly opposes the amendments and additions of the informed consent provisions.**

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.

*In the course of standard primary care visits, would separate, written informed consent need to be obtained for a strep test, for a blood draw, for an impacted fingernail, for an antibiotic treatment, and for a sling?*

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.

The Medical Society greatly appreciates the opportunity to provide detailed comment regarding these regulations. We urge reconsideration based upon the comment provided herein.