Comments Delivered for the Professional Liability Foundation

To the Board of Registration in Medicine

Concerning Proposed Changes to 243 CME 1.00 and 3.00

March 1, 2017

The Professional Liability Foundation (PLF) is a Massachusetts non-profit membership organization, established in 1996, which addresses issues of concern to health care providers and their patients with a concentration in the courts and with state government concerning issues of professional liability. Our members provide services to the overwhelming majority of physicians in the Commonwealth. As a broad based organization, we hear significant concerns in the medical community concerning the proposed regulatory changes and the direction the Board is taking in its oversight of the practice of medicine.

**Procedural Issues**

There are several specific sections of the proposed regulations on which we will provide comments. As a preliminary matter, however, there is a procedural and ethical issue regarding the process which is of concern to the PLF and the medical community. The proposed regulations, as detailed below, if adopted would change the standards of care and duties of physicians. They also have implications for peer review protections. The proposed changes would be of direct benefit to plaintiffs’ attorneys, particularly through establishing per se negligence claims in the areas of informed consent and concurrent surgeries. While standards are evolving in the courts and in practice in these areas, the standards adopted by the Board are extreme and inconsistent with current practices and recent court cases. The PLF requests that Kathleen Meyer, Esq. recuse herself from all participation in the review of the proposed regulations. This request is based upon Ms. Meyer’s past work for the largest medical malpractice firm in the state and her being married to a named partner in the firm.

A second procedural question regards the inconsistency between Governor Baker’s directive to all state agencies to simplify their regulations with regard to reduce the impact on small businesses of regulatory burdens. For example, in its questionnaire on impact, there are questions raised about when it is appropriate to establish operational standards. The Board does not appear to have justified specific new operational standards in the areas of informed consent. Additional concerns in the small business impact statement cover areas such as additional recordkeeping requirements and administrative oversight requirements. A current copy of the Board’s response to the required Small Business Impact Statement was not readily, if at all, available on the state site reserved for such documents. Has the impact statement been filed? Does it accurately reflect the impact of the proposed regulations?

The Board itself cites “the reduction or stabilization of the frequency, amount and cost of claims against physicians and institutions” among its goals and the goals of the legislature in section 3.01 Scope and Purpose of the proposed regulations. We argue that the regulations in many specific areas do the exact opposite and need significant modification and editing.

**Section by Section Comments**

The main area of concern of the PLF is with 243 CMR 3.00, the patient care assessment program regulations.

Areas of concern include:

**Section 3.01 (Definition of Medical Peer Review Committee):**The PLF has long supported the recognition in Massachusetts of the national standard on peer review which allows for system wide peer review protection as opposed to systems based in individual hospitals. The definition of medical peer review committee should be expanded to refer to a committee of a medical staff of a health system that performs peer review functions.

Section 3.02 Definitions of adverse events are proposed to include potential harm and close calls. These are areas of redundant reporting for hospital based services. Potential harm and close calls are often appropriate for peer review activities. Should issues relevant to the Board be detected they could be reported as required under current regulations.

This section adds Utilization Review and Credentialing functions to those monitored by PCA programs. Frequently, these functions are not the exclusive responsibility of licensees of the Board. It is unclear what role the Board would have in reviewing such decisions.

The definition of a health care facility is narrower and may strip facilities such as ASC's of peer review protections in some cases. It is unclear why the Board has changed its definition

Section 3.04(2) says the BRM "may" designate peer review as confidential when it should say shall. The PLF has a long history of successfully supporting the confidentiality of peer review in cases before the Massachusetts Supreme Judicial Court. The Board should strongly support a robust peer review system.

Section 3.05(3)(i) eliminates the ten year period for review of applicants and leaves it open ended. This clearly greatly increases the administrative burden on facilities and is inconsistent with the Governor’s initiative.

Section 3.06(2)(d) is a new section which allows open ended reporting requirements of events added by the BRM based upon events at other facilities. Clearly this creates a potential for excessive demands by the Board staff of materials undefined in regulations. This is inconsistent with the Governor’s initiative and should be deleted.

Section 3.07(3)(j) increases report keeping requirements from three years to ten with no rationale presented.

Section 3.08(1) appears to eliminate duplicative reporting of events reported to the DPH. However, it does appear to increase mandated reports through a very broad definition of serious injury. Literal reading of the definition of a serious injury would mandate a significant number of reports on a daily basis. Is the Board equipped to deal with this information and what is the potential benefit to the public?

**THE PLF’s MAJOR AREA OF CONCERN: INFORMED CONSENT**

Section 3.10 (2) Eliminates the word "major" before diagnostic events requiring consent. Clearly physicians engage in diagnostic activities at every patient encounter. The Board requires informed consent before all “diagnostic procedures:” Mosby’s Medical Dictionary defines procedure as “the sequence of steps to be followed in establishing some course of action.” These proposed regulations therefore could arguably apply the detailed informed consent rules to all physician encounters. There is clearly no benefit to patients, physicians or oversight agencies in creating massive paperwork and direct physician actions to comply with providing routine patient care. The members of the PLF are active in risk management and patient safety. Our member organizations strongly support obtaining and documenting informed consent for patient care. No evidence exists that increasing the legal standards for providing informed consent will improve patient care outcomes.

Subsection (a) creates a "duty" that requires the attending physician or physician of record to get the consent, and also defines physician extenders to be under the control of physicians. Physicians are responsible for insuring that the patient understands and consents to significant actions on their behalf. It is a simplistic approach to require that one physician must perform all aspects of providing patient information. Also this section defines physician extenders as being those care givers under the supervision of physicians. This is not always the case and may raise liability issues for physicians for the acts of individuals not under their control and creates an ambiguity regarding extenders who are not under supervision.

Subsection (b) contains overly detailed requirements for what constitutes written informed consent for all diagnostic work. Does this include physicals? What is the benefit for creating a regulatory requirement of such specificity? Does the Board intend to discipline all physicians in all circumstances for non-compliance? Would this apply even if the particular circumstances and real standards of care did not allow for such consent and necessary patient care?

Subsections (d,e) create a detailed duty of physicians, including signing the consent. The PLF is concerned that the establishment of a duty to a patient is a specific threshold requirement in establishing negligence. The regulation also requires that the forms be sufficient for the “reader” to determine consent was informed. Who is the proposed reader? Why isn’t sufficiency for the patient sufficient? We suggest that this section be deleted.

Subsections (f,g) require consent forms to identify all participants, including physician extenders in the proposed care. Medical records must show absences of identified attending physician at any point. What is the model health care facility that can honestly guarantee everyone who will participate in all of a patient’s care? If an emergency arises is it a violation of patient rights and the proposed regulations to bring in additional care providers? Who benefits from documentation in the medical record of all movements of care providers during all patient care? The reports in the media on the faults of concurrent surgery appear to be driving these regulations, the clinical evidence is not supportive of this conclusion.[[1]](#footnote-1) The PLF suggests that these sections be deleted as overly prescriptive and inconsistent with the role and capabilities of the Board of Registration in Medicine.

Subsections (h) contains new mandates on sterility. Again it is not clear what role or scientific basis the Board has, as opposed to the Department of Public Health, in establishing regulatory standards for sterility. Clearly repeated violations of established standards of care or violations resulting in patient harm are of interest to the Board and within their mandate. It is unclear why this issue needs to be spelled out in regulations.

This concludes our comments on 243 CMR 3.

Disciplinary Regulations 243 CMR 1.00

The PLF has concerns with the following sections:

**Section 1.01(2) – Definition of Disciplinary Action:**  The PLF has concerns that requiring remediation and probation to be grounds for reporting disciplinary actions is inconsistent with the fundamental nature of medical education. In recent years, the Board has appeared, to many observers, to have an intolerant view of the academic challenges many medical students and residents have experienced in learning the profession. These additions should be struck.

Section 1.03(1) expands the grounds for a complaint to include malfeasance, not just misconduct and allows a complaint to arise from any source and through any communication. The PLF supports the role of the Board in maintaining standards of professional licensing for physicians. Malfeasance can be defined as any improper performance of a legal act. It is unclear whether the Board is creating an obligation to formally open complaints based upon virtually all communications about physicians, even anonymous sources.

Section1.03 (5)(a)(3) Makes simple negligence the grounds for a complaint. Previously gross negligence or repeated negligence was required and reflects the language of the enabling statute. Is a single error, even absent patient harm, really within the resources of the Board to investigate? Will this be a productive area or will it act as a deterrent to patient safety, peer review and aggressive work to find and correct medical errors.

Section 1.03 (5) (8) Adds conduct in violation of the ethical standards of the profession. It isn’t clear what standards of the profession the Board is referencing here. Clearly the Board has had the ability to discipline its licensees for behavior which violates the established standards for good medical care.

The PLF thanks the members of the Board for their service to the public and the medical community and hopes that our comments will serve to improve the final regulations that are adopted and the work of the Board in the future.

William J. Ryder, Esq.

1. <http://www.massgeneral.org/overlapping-surgery/reviews.aspx> This website has links to many articles and peer reviewed evidence showing that concurrent surgery meets the standards of care. [↑](#footnote-ref-1)