Comments Delivered for the Professional Liability Foundation

To the Board of Registration in Medicine

Concerning Proposed Changes to 243 CME 2.00

May 18, 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 an ongoing procedural matter that remains unaddressed from our testimony at the March hearing. Again the Board is attempting to change the standards of care and duties of physicians in a way that would be of benefit to plaintiffs’ attorneys. A review of the Board’s minutes and staff memoranda, made available through public records requests, does not present evidence of the need for the proposed changes to enhance patient safety nor do the provided materials indicate in depth discussions and deliberations that meet the requirements of Governor Baker’s directive quoted in an endnote below.

The PLF notes that Kathleen Meyer, Esq. was not present for the March 9th vote which sent the proposed regulations on their way to today’s hearing. This may be coincidental but if not such action does not constitute a recusal or erase the issues involved in her participation in the regulatory process. Unfortunately, it is unclear from the record who suggested expanded informed consent, record keeping and other new requirements much less a rationale for such requirements. In response to an inquiry, the Board has no record of any conflict of interest statements from its members.

Governor Baker’s directive to all state agencies to simplify their regulations with regard to reducing the impact on small businesses of regulatory burdens remains unmet in the proposed regulations. (see endnote) [[1]](#endnote-1) The Board is so concerned with establishing new and excessive records requirements that the same issues are included in the regulations in the March and May hearings. At a minimum Governor Baker’s directive would call for elimination of duplication.

**Section by Section Comments**

The PLF is concerned with the following sections of 243 CMR 2.00:

Elimination of the existing delegation of medical services is not well thought out. The Board’s memorandum on the proposal states that the new wording would allow the Board to prevent delegation of medical services to an unlicensed but medically trained physician and the current regulations do not. The existing language, quoted below, covers this and other issues well and gives the Board broad authority over its licensees.

***2.07 (4) Delegation of Medical Services****. A full licensee may permit a skilled professional or non-professional assistant to perform services in a manner consistent with accepted medical standards and appropriate to the assistant's skill. The full licensee is responsible for the medical services delegated to a skilled professional or nonprofessional assistant. Nothing in 243 CMR 2.07(4) shall be construed as permitting an unauthorized person to perform activities requiring a license to practice medicine. A full licensee shall not knowingly permit, aid or abet the unlawful practice of medicine by an unauthorized person, pursuant to M.G.L. c. 112, § 9A, M.G.L. c. 112, § 61, and 243 CMR 1.05(6).*

The proposed new language states:

“. *There shall be no delegation of medical services to an individual who is not licensed to perform those services in Massachusetts.”*

The new language has no definition of medical services and makes no allowance for medical assistants who are unlicensed in Massachusetts yet perform many services that might be considered medical services. It raises the issue of whether a licensed provider is licensed specifically to perform particular services even though those services have been within the accepted scope of practice for such a licensee for many years. The existing regulations cover the issue well, are well understood in the medical community and create no new issues of potential unlawful delegation.

**13)   Medical Records.(a)   Length of Time to Maintain Patient Records.**

 *A licensee shall maintain a medical record for each patient that is complete, timely, legible, and adequate to enable the licensee or any other health care provider to provide proper diagnosis and treatment. Any records received from another health care provider involved in the care and treatment of the patient shall be maintained as part of the patient's medical record. With respect to patient records* ***existing on or after the effective date of these regulations****, and unless otherwise required by law, a licensee must maintain a patient's medical records for a minimum* ***period of 10 years f****rom the date of the last patient encounter.*

This proposed language raises two issues. First, existing regulations require a seven year retention of records based upon the Massachusetts statute of repose. Thus under the existing rules, physicians could legally dispose of records [[2]](#footnote-1) from 2010 the day before the regulations went into effect. On the next day, a purging of such records would be a violation of the regulations. Physicians cannot be expected to be aware of such requirements and their date of implementation. Changing records retention requirements is often complex, particularly for electronic records.

The rationale for retaining records for ten years is unclear. While prominent trial attorneys have won appeals which limited the application of the statute of limitations in medical malpractice cases, the seven year rule of repose is still the standard of care. There is no information available as to why retained medical records storage requirements should be increased by more than 40% (3/7ths) and costs increased accordingly. The PLF requests this requirement be deleted.

(f) **Medical Records of Deceased Physicians**

This section raises several issues. First, the regulations create a responsibility for each member of a medical group for the medical records of a physician in that group. It is unclear that individual physicians have the ability to control the records of their peers. Not all members of a group have the same authority over the actions of a group. Does this provision create liability among all members of a group for the availability, quality and content of one member’s records? The basis for this provision is unclear nor its means of enforcement.

The Board’s statement on executors is poorly worded and thought out. First, a living physician should not give a password to access his patient’s medical records to an executor who is not involved in the patient’s care. Second, how is the Board going to enforce requirements on an executor of an estate if that executor is not a licensee of the Board?

Finally, the ten year requirement is excessive. The issue of medical records availability for retiring and deceased physicians is a significant one. The expenses for small practices which close are very significant. Extending records requirements to ten years creates an extreme burden on older, retiring physicians.

**(14)   Providing Cancer Patients with Treatment Information**

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There is no statutory basis for this new requirement nor is there an apparent articulated and publicly debated rationale for this requirement. There are several drafting and conceptual problems here. First, the rule applies to all physicians who accept a patient for treatment with known or suspected cancer. Thus all physicians must comply with these rules. If the regulation stated instead “for treatment **of** known cancer” then it wouldn’t apply to physicians treating cancer patients for other reasons, psychiatrists, dermatologists, anesthesiologists etc etc.

Second, what alternative treatments are required to be described in an understandable format and documented? Is naturopathy included? In the current environment where the loss of a chance of a better outcome, even if it is a slight chance, has been recognized by the Supreme Judicial Court, the Board is setting up a system where all physicians who treat a patient with cancer or suspected cancer may have their records subpoenaed to determine whether they complied with a requirement to provide alternative treatment options and referrals. If they did not then perhaps a case can be made that they failed to meet a regulatory duty to that patient and cost that patient a chance for a better outcome.

The Board should not create this new requirement in regulations. The Board is free to discipline physicians and respond to complaints where a physician’s work with a patient did not meet the standards of care in providing information on their alternatives to care. The requirements of this proposed section need to be eliminated.

**Informed Consent in Section 26 Appears Identical to Requirements in 243 CMR Section 3.10 (2)**

Our prior criticisms of these sections remain relevant. The proposal eliminates the word "major" before diagnostic events requiring consent. Clearly physicians engage in diagnostic activities at every patient encounter. The Board proposal would require 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 specific 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 suggested in March that this language should be deleted. The complete duplication of these requirements in two sections of regulations is not a good way to proceed.

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.[[3]](#footnote-2) 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.

Finally there is a difference in today’s proposal on informed consent from the language in March. Today’s proposal adds a section (i) which entitles a patient to a copy of their informed consent and their medical records on request. Clearly patients have a well established right to obtain their medical records. This right is established in regulations, clinical practice standards and the law. It is unclear why the Board is so heavy handed in wishing to establish such standards for physicians. The members of the Board should ask who benefits from this initiative.

Proposed section 2.15:   The Physician Profile Program(2)   Content of a Profile

2 Dispositions of paid claims within the Commonwealth shall be reported in a minimum of 3 graduated categories indicating the level of significance of the award or settlement.

3. Dispositions of paid claims in other jurisdictions shall not be reported in graduated categories unless this information is provided to the Board by the medical board in the other jurisdiction where the claim occurred.

The profiles program was created through a legislative initiative of the Massachusetts Medical Society. Mass General Law Chapter 112 Section 5 outlines with specificity the content of profiles and the duties of the Board. The law addresses the content of profiles on judgments as follows:

“all medical malpractice court judgments and all medical malpractice arbitration awards in which a payment is awarded to a complaining party and all settlements of medical malpractice claims in which a payment is made to a complaining party; **provided, however, that dispositions of paid claims shall be reported in a minimum of 3 graduated categories indicating the level of significance of the award or settlement;”**

The Board’s proposed language in subsection 3 above is ambiguous. Is the intent of the Board to not report out of state settlements and judgments which are not ranked as to level of significance? Is the intent to accept the categorization of other jurisdictions regarding severity, which may or may not be similar to the Massachusetts model? Settlements and judgments differ widely among jurisdictions so the Board does have a difficult task if it is to include out of state information. As a participant in the process which lead to the adoption of profiles in 1996, I will state that the intent was to include only reliable information on the profiles and to put it in perspective. There was never any intent in Massachusetts to put specific dollar amounts on profiles. In a comprehensive report the Federation of State Medical Boards stated:” Dollar amounts of awards, judgments and settlements should not be included for malpractice cases.”[[4]](#footnote-3)

The ambiguity of the proposed regulation regarding out of state cases leaves open the possibility that the Board may intend to simply pass through reports from other jurisdictions of cases, including dollar amounts, onto individual profiles. The language of the statute clearly prohibits such a course and that was the legislative intent at the time. Providing a database of payments which may or may not be presented to a jury could benefit the plaintiffs’ bar and contradicts the intent and statutory basis of profiles.

The PLF appreciates the difficulty the Board has in compiling case information from other states and categorizing such reports consistently with the requirements of the statute. However, the Board is given a specific line item by the legislature for profiles in order to meet its requirements. The proposed language should be clarified to be consistent with the statute.

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.

1. In conducting such review, which shall be coordinated across all Agencies and participating governmental bodies, only those regulations which are mandated by law or essential to the health, safety, environment or welfare of the Commonwealth's residents shall be retained or modified. In order to find that a regulation meets this standard, the Agency must demonstrate, in its review, that:there is a clearly identified need for governmental intervention that is best addressed by the Agency and not another Agency or governmental body;

	1. the costs of the regulation do not exceed the benefits that would result from the regulation;
	2. the regulation does not exceed federal requirements or duplicate local requirements;
	3. less restrictive and intrusive alternatives have been considered and found less desirable based on a sound evaluation of the alternatives;
	4. the regulation does not unduly and adversely affect Massachusetts citizens and customers of the Commonwealth, or the competitive environment in Massachusetts;
	5. the Agency has established a process and a schedule for measuring the effectiveness of the regulation; and [↑](#endnote-ref-1)
2. For simplicity these comments do not address the records of minors but the issues are similar. [↑](#footnote-ref-1)
3. <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-2)
4. Report of the Special Committee on Physician Profiling The Federation of State Medical Boards of the United States, Inc. [↑](#footnote-ref-3)