100 Front St., 14th Floor

 Worcester, MA 01608

March 2, 2017

Eileen Prebensen

Board of Registration in Medicine

200 Harvard Mill Square, Suite 330

Wakefield, MA 01880

Re: Comments on Proposed Amendments to Regulations

Dear Ms. Prebensen:

I write in response to Board of Registration in Medicine’s Notice of Public Hearing and Comment, which invites comments regarding proposed amendments to 243 CMR 1.00, *Disciplinary Proceedings for Physicians* and3.00, *Qualified Patient Care Assessment Programs*. Specifically, this response addresses three areas of concern: 1. the proposed change to the definition of “health care facility” and how that change will impact patient safety; 2. the lack of clarity for informed consent requirements and the burdens imposed by other changes to that section of the regulation; and 3. the increased burdens on the credentialing process without any benefit to the quality of credentialing.

1. *The Proposed Change to the Definition of “Health Care Facility” Will Negatively Impact Patient Safety and Quality of Care.*

The proposed amendments to 243 CMR 3.00, *Qualified Patient Care Assessment Programs*, make a significant change to the definition of “Health Care Facility.” Under the current regulation, the definition is broad enough to encompass ambulatory surgery centers, medical groups that are licensed pursuant to Mass. Gen. Laws ch. 111, §51, and large physician groups that have more than one episodic walk in centers. By changing the word “entity” to “hospital,” and by removing from the definition entities “maintaining more than one primary or episodic walk-in center,” these institutions will no longer be required to establish and maintain a Patient Care Assessment Program (“PCA Program”) pursuant to this regulation and will lose their peer review protection.

This will have a significant negative impact on quality of care for patients at these institutions. As noted, these institutions will lose the peer review protection that is granted to them as a result of maintaining a PCA Program pursuant to the regulation. Protection of peer review activities is vital to encouraging robust, thorough and honest criticism of medical care within any institution. Peer review protection fosters a culture within institutions where physicians can feel free to critique each other through a peer review program – a process that leads to system improvements and better outcomes for patients. Removing this protection from peer review activities may lead to these institutions dismantling their peer review processes or at the very least will cause a chilling of the willingness of physicians to be critical of one another.

Given the significant potential impact on quality of care and patient safety, Reliant Medical Group suggests that the Board reconsider the proposed changes to the definition of “Health Care Facility.”

1. *The Proposed Changes to the Informed Consent Requirements Create a Lack of Certainty and are Unnecessarily Burdensome.*

At 243 CMR 3.10, the proposed regulations set forth requirements with respect to informed consent. These propose changes raise a number of concerns. First, the proposed regulation includes an overly broad expansion of when written informed consent is required. Second, the proposed regulation appears to exclude providers other than physicians from participating in the informed consent process. Finally, by requiring that the names of all physician extenders be written on the consent form, the proposed regulation creates unnecessary burdens on practices and workflows given the realities of medical practice.

1. The Proposed Changes Create an Unnecessarily Broad Expansion on When Written Informed Consent is Required.

The proposed regulations set forth requirements with respect to informed consent, and provide that “a patient’s written informed consent [is required] before diagnostic, therapeutic, or invasive procedures, medical interventions or treatments.” Proposed Regulation, 243 CMR 3.10(1). Arguably, under this proposed regulation, written informed consent could be a requirement for any and every treatment, intervention or procedure that a provider might suggest for a patient, regardless of the risk involved. For example, performing an EKG, drawing blood or injecting medication intra muscularly would require written informed consent based upon the proposed regulation. While this may not be the intent of the proposed language, the definition is extremely broad and open to variable interpretations. Given the expansion of potential scenarios where written informed consent may be required, a practice could reasonably expect to more than double the number of written consent forms it presents to its patients.

This not only creates workflow problems for the practice, but more problematic it may lead to patients developing fatigue to reading and signing forms, thereby diminishing the value of the written consent form as an education tool for patients.

1. The Definition of “Attending Physician/Primary Operator” Is Too Narrow.

The proposed regulation sets forth a definition of “Attending Physician/Primary Operator” as follows: “the physician…who has been credentialed by the health care facility to independently perform the patient’s procedure, medical intervention or treatment…. **The attending physician/primary operator is responsible for discussing the risks and benefits of the procedure, intervention or treatment and obtaining the patient’s written informed consent.”** Proposed Regulation 243 CMR 3.10 (emphasis added).

Requiring that only a licensed physician (as opposed to a Nurse Practitioner or Physician Assistant, for example) can be responsible for the discussion of risks and benefits is not reflective of the realities of modern medicine, in which advanced practitioners are intimately involved in many aspects of patient care. Depending on the nature of the particular procedure, intervention or treatment at issue, it is well within the scope of practice for an advanced practitioner to perform the procedure and discuss risks and benefits with a patient and obtain the patient’s written informed consent.

The Board’s proposed regulation would reduce the scope of practice for advanced practitioners in Massachusetts by requiring that this activity be conducted solely by physicians, at a time when many primary care practices are relying on the skills of advanced practitioners to ease the burden of the primary care shortage. Reliant Medical Group suggests that the Board not adopt such a limited view of the scope of practice for advanced practitioners, and instead include advanced practitioners with the definition of “primary operator” and recognize that, when appropriate, advanced practitioners may discuss risks and benefits with patients and obtain written informed consent.

1. Requiring All Providers, Including Physician Extenders, Be Identified By Name on Consent Form Is Burdensome and Impractical.

The proposed regulation includes a requirement that “**[p]rior to the procedure**, the attending physician/primary operator must inform the patient of who will be participating in the procedure, intervention, or treatment, including the names of all physician extenders…. The attending physician/primary operator shall note the physician extenders on the written informed consent form.” Proposed Regulation, 243 CMR 3.10(1)(f) (emphasis added). This requirement is burdensome and impractical due to the realities of medical practice; frequently, informed consent discussions and written consent forms are signed many days, sometimes weeks, prior to a procedure. It is not possible for the attending physician to guarantee with certainty which individuals will be participating in a procedure at a future date. Reliant Medical Group urges that the Board remove this requirement from the proposed regulation.

1. *Removing the Time Limitation of “During Previous Ten Years” from Sections of the Credentialing Portion of the Regulations Is Burdensome and Unlikely To Improve the Credentialing Process*

The proposed regulations, in the section addressing Credentialing, remove a ten-year time limit in two areas. One is with respect to how far back in a licensee’s employment history a health care facility must inquire. The second is with respect to malpractice claims and suits.

With respect to inquiring of other health care facilities where the licensee has had employment, removing the ten-year time limit creates a significant administrative burden on the health care facility, with very little meaningful return. Contacting every health care facility a physician has ever practiced with, back to the days of a physician’s residency, is an unreasonable administrative burden, especially in light of the fact that information from decades ago will provide very little meaningful information on which to base a credentialing decision.

Likewise, requiring that a licensee provide a health care facility with information regarding ALL malpractice claims and lawsuits without limitation is burdensome for the licensee and the healthcare facility, and provides no meaningful benefit. Data regarding a licensee’s claims and lawsuits going back multiple decades is simply not instructive or helpful with respect to making credentialing decisions.

With respect to both employment history and data regarding malpractice claims and suits, it is far more instructive for a health care facility to consider more recent data, in conjunction with all of the other information that is gathered, when considering whether to credential a particular licensee. Given this, Reliant Medical Group suggests that the Board keep the ten-year time limitation with respect to employment history and information regarding claims and suits.

 Reliant Medical Group has provided the above comments in the hope that they will serve to improve upon the final regulations that may be adopted by the Board. Thank you for your consideration of the concerns that have been raised above.

Very truly yours,

Michael Sheehy, MD

Chief of Population Health & Analytics

Reliant Medical Group