March 3, 2017

Eileen Prebensen

Senior Policy Counsel

Board of Registration in Medicine

200 Harvard Mills Square, Suite 330

Wakefield, MA 01880

**Re: Regulatory Review, 243 CMR 3.00 *Qualified Patient Care Assessment Programs***

Dear Ms. Prebensen:

The Betsy Lehman Center for Patient Safety is pleased to submit observations and recommendations in support of the Board of Registration in Medicine’s regulatory review process. Our testimony specifically concerns 243 CMR 3.00, *Qualified Patient Care Assessment Programs*.

The Betsy Lehman Center commends the Board’s efforts to clarify definitions, eliminate duplicative reporting, strengthen physician credentialing, and promote voluntary reporting of close calls and other adverse events that can illuminate persistent or emerging risks to patient safety. We also applaud the newly proposed provisions regarding informed consent that emphasize transparency and clear, accountable communication. We do, however, want to share a few comments for the Board’s consideration.

**Reporting of Serious Reportable Events (SREs).** The Board’s proposed revisions to 243 CMR 3.08 (2) advance the cause of reducing administrative burden on healthcare facilities by eliminating duplicate reporting of Serious Reportable Events (SREs) to the Board’s Quality and Patient Safety Division (QPSD). If approved, facilities will no longer be required to report adverse events that they have submitted as SREs to the Department of Public Health (DPH). The Betsy Lehman Center strongly supports efforts to streamline mandated reporting as long as they are coupled with adequate interagency sharing of mission-critical data. QPSD’s ability to carry out its quality/safety improvement activities depends on access to as much information about the presence of critical patient safety threats in Massachusetts as possible. SRE reports are an important source of such information, so we would hope that a structured process through which QPSD can receive these reports from DPH on a regular basis is put into place if one does not exist already.

**Reporting by Ambulatory Surgery Centers.** The Board’s proposed amendments to 243 CMR 3.00 appear to remove clinics, including ambulatory surgery centers (ASCs), from the scope of the Patient Care Assessment (PCA) Program, therefore exempting ASCs from adverse event reporting to QPSD. If our reading is correct, such a change is concerning. As some of the highest volume surgical procedures continue to shift from hospitals to ASCs, the risks to patients in both settings merit scrutiny. Moreover, ASCs and hospitals benefit from opportunities for shared learning from the adverse events reported by others. As already noted, QPSD’s ability to support shared learning depends on its ability to access comprehensive system-wide data. One case in point is QPSD’s recent collaboration with the Betsy Lehman Center on cataract surgery initiative, in which QPSD was able to contribute highly informative data on major incidents connected with cataract surgery in both the ASC and hospital settings. If ASCs are no longer covered by the PCA Program, an important source of useful information will be lost.

**Additional comments:**

* “Serious injury” definition. We believe that the definition of “serious injury” in 243 CMR 3.08(2)(b) will offer helpful guidance to reporters. Given that “serious injury” is referenced throughout the regulation, we suggest including the definition up front in section 3.02. The Board might also consider adding “prolonged hospital” as an indicator of serious injury.
* Credentialing of temporary licensees. We suggest the Board revisit its provisions on the credentialing of temporary licensees in 243 CMR 3.05(b), which allow providers to practice at a facility for up to 30 days without fulfilling all of the credentialing requirements of 234 CMR 3.05(3). While recognizing the need for expedited credentialing under certain circumstances, we suggest that the regulations require facilities to establish formal onboarding policies for all new staff, including locum tenens providers. Such policies would set forth minimum orientation and oversight procedures for any new staff involved in patient care. The need for basic essential onboarding was among the [key findings and recommendations](http://www.betsylehmancenterma.gov/initiatives-and-research-medical-errors-massachusetts/cataract-surgery-report-massachusetts) by an expert panel convened by the Betsy Lehman in response to a cluster of cataract-surgery adverse events in Massachusetts.
* Informed consent. We were pleased to see the following new language on informed consent in 243 CMR 3.10(1)(3): “*informed consent means that the physician has disclosed and explained to the patient’s satisfaction the process used to arrive at the medically reasonable and recommended procedure, intervention or treatment, based on reliable evidence of the expected benefit and risk of each alternative, free from any impermissible bias.*” It is unclear to us whether the requirement is for physicians to disclose and discuss major treatment alternatives with the patient, or if it is sufficient for the physician to discuss a single recommended course of treatment, so long as it is based on the provider’s own weighing of the risks and benefits of alternatives. We suggest that the Board clarify its intent.

We recognize the Board’s thoughtful review of 243 CMR 3.00, and thank you for the opportunity to comment. The Betsy Lehman Center looks forward to continued collaboration with the Board towards our shared goal of ensuring safe health care throughout the Commonwealth.

Sincerely,



Barbara Fain, JD, MPP