May 19, 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 2.00 *Licensing and the Practice of Medicine***

Dear Ms. Prebensen:

The Betsy Lehman Center for Patient Safety is pleased to submit comments regarding 243 CMR 2.00, *Licensing and the Practice of Medicine.*

The Center applauds the Board of Registration in Medicine’s proposed amendments to the regulations, particularly its augmentation of the provisions on informed consent. We also would like to call the Board’s attention to one specific provision—mandated reports of adverse events occurring in a licensee’s office under 243 CMR 2.14 (4)(d).

243 CMR 2.14 (4)(d) leaves in place a licensee’s obligation to “report any **unplanned hospital transfer** or **unexpected patient death** that is precipitated by a treatment or procedure administered in a licensee’s office setting.” Given the increasing number of procedures conducted in medical offices, we would encourage the Board to amend this provision by adding **serious injury** as an outcome that makes an adverse event subject to mandatory reporting to the Board.

We also would note that licensees have no reporting obligations under this provision—or any other regulation—for a wide array of life and health-threatening patient harm events that are known to occur in the medical office setting. Some of these events result from failures to implement adequate error prevention systems as opposed to failures of clinical judgment. For instance, diagnostic delay, now recognized as a leading patient safety threat in outpatient practice, is often caused by “inadequate follow-up planning, delayed scheduling for unspecified reasons, inadequate tracking of test results, and the absence of a system to track patients in need of short-term follow-up.” [(Giardina, 2013)](https://www.ncbi.nlm.nih.gov/pubmed/23918480).

Given the evolving medical office practice landscape, we would encourage the Board to consider whether additional types of serious patient harm events should be brought to the Board’s attention through mandated reporting by licensees.

Again, we very much appreciate the opportunity to comment on the Board’s proposed regulatory amendments.

Sincerely,



Barbara Fain