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FAQs on BORIM Regulation Chapter 2.00
"Licensing & The Practice of Medicine"

The Board of Registration in Medicine (BORIM) often receives inquiries from physicians, health care facilities and patients. Below is a list of Frequently Asked Questions (FAQs) about recent amendments to 243 CMR 2.00.

Licensing FAQs

1. Do the recent changes in Chapter 2 bring the CME requirement back to 100 hours every two years?

No. Due to Board Policy 17-05, "The Continuing Medical Education (CME) Pilot Program," the current CME requirement is 50 CME credits biennially.

2. Where is the Alzheimer's Disease training requirement?

St. 2018, c. 220, the law requiring that physicians who serve an adult population must take a one-time training on Alzheimer's and related diseases, became effect Nov. 7, 2018. This was after the date of the public hearing on Chapter 2.00 and therefore could not be included in these revisions.

3. How does the inclusion of "good moral character" in the licensing regulations change the licensing process?

There is no change in the good moral character requirement. Many boards of professional licensure require good moral character as a prerequisite to licensure (for example, Board of Registration in Nursing 244 CMR 8.02 and see generally the Department of Public Health's website https://www.mass.gov/lists/department-of-public-health-regulations-policies.) Since 1894, Massachusetts law has required that a physician have good moral character in order to hold a license to practice medicine. The Legislature created the good moral character requirement in Mass. Gen. Laws c. 112, § 2 and 9 at the same time as it created the grounds for discipline in Mass. Gen. Laws c. 112, § 5. These enabling act provisions should be read as a cohesive whole. "…[T]he Legislature has …set up a plan whereby those who practice medicine will have the qualifications which will prevent, as far as possible, the evils which could result from ignorance

or incompetency or a lack of honesty and integrity." Levy v. Board of Registration in Medicine, 378 Mass. 519, 527-528 (1979).

4. It looks like the Board is adding malpractice and criminal history to the licensing requirements.

No, the Board is not adding to the licensing requirements. Applicants for initial and renewing licensure have always had to provide their malpractice and criminal histories to the Board. In the amended regulation, 243 CMR 2.04(9-10), the Board was limiting the criminal histories requirement by not requiring applicants to include minor traffic violations.

An applicant for an *initial* license must include all his/her malpractice and criminal histories in an application. The *renewing* applicant only has to include new or ongoing malpractice and criminal histories from the date he/she signed the last license application to the date of signing the current application.

The Board recently implemented a number of process initiatives to improve efficiency and service to physicians in the licensing process. The amendments to the regulations do not impact the licensing process improvements.

Informed Consent FAQs

5. Can you walk us through an informed consent process in a hospital under the new regulation?

Yes. **The regulation does not change or expand the circumstances requiring the informed consent of the patient; rather, the regulation requires the informed consent be in writing.** If the medical service you provide requires you to obtain an informed consent before the BORIM regulation, then you will need to obtain an informed consent after the regulation was promulgated. The only difference is the informed consent must be in writing and include the required data outlined in the regulation. Likewise, if the medical service did not require you to obtain an informed consent before the regulation was promulgated, you need not obtain an informed consent after the regulation was promulgated.

6. How can you list who will participate in a procedure when informed consent is obtained up to 3 weeks before an elective procedure?

Information known at the time you obtain written informed consent should be included in the written informed consent. New information or changes to information known to you after the written informed consent was signed by the patient, but before the procedure, should be included in the written informed consent and agreed to by the patient reflected by signature or initials.

The attending physician/primary operator will list the name of the other providers that will participate in the surgery, to the extent they are known three weeks in advance. If they know a resident or a fellow will participate, but are not sure of the name, they should explain in writing it

is a resident and what year the resident or fellow is in. The same applies for all physician extenders. After the procedure, the record should be updated to identify all the names of the individuals who participated in the procedure and this must be shared with the patient.

The informed consent must be clear and detailed and must be signed before the procedure, intervention or treatment. While the written informed consent cannot be revised after the procedure, any new information or changes must be reflected in the patients' medical record and the reasons for the changes, and this must be shared with the patient.

7. **Instead of requiring the names of all physician extenders participating in the procedure, would it be sufficient to record this information in the operative notes and provide a general disclosure - something along the lines of, "we are teaching institution, and residents, physicians assistants, APRN's or fellows will likely assist the attending physician in this procedure."**

No, because this defeats the goal of the amended regulation, ensuring patients have necessary information to make informed decisions regarding their health.

8. **Would it be acceptable for the consent form to simply state that the attending physician will be assisted by other physicians and may step out of the room during the procedure, but will at all times be fully responsible for the entirety of the patient's care while the patient is in the operating room and this information is included in the medical record?**

No, because this defeats the goal of the amended regulation, ensuring patients have necessary information to make informed decisions regarding their health.

9. **Now let's say it's the day of the operation, there are changes, what does the informed consent process look like now?**

New information or changes to information known to you after the written informed consent was signed by the patient, but before the procedure, should be included in the same written informed consent and agreed to by the patient reflected by signature or initials. You should include the new information in the written informed consent and obtain the patient's signature or initials. The patient's medical record must also be updated with the new information or changes, including the reasons for the changes, and this must be shared with the patient.

10. **Do you need to record the names of the residents?**

If the names of the residents and trainees are not known prior to the procedure, the written informed consent should identify the position and the level of training of the individual who will

be participating. After the procedure, the medical record should be updated identifying the names of everyone who participated in the procedure, and this must be shared with the patient. If a resident is only observing, you do not need to record a name.

11. What if the attending physician leaves the operating during the surgery?

If the attending physician/primary operator anticipates stepping out of the procedure and someone else will take over the patient's care, the informed consent should be updated to reflect that information.

If the attending physician/primary operator unexpectedly leaves the operating room during the surgery and someone else is taking over the patient's care, the medical record should reflect who left, for how long and who took over patient care.

If the absence is ***anticipated,*** it should be part of the informed consent. If an absence occurs ***unexpectedly***, it should be recorded in the medical record and discussed post-operatively with the patient. The medical record should identify when any individual participating in the procedure leaves or enters the operating room and the time that it occurred.

12. Who records the names of the people involved with the surgery?

The attending physician/primary operator is responsible for talking to the patient about the risks of the procedure and obtaining the written informed consent. The attending physician/primary operator can delegate to the OR nurse the comprehensive recording of everyone who participates in the surgery and at what times. In addition, at all times during the procedure, it should always be clear who is acting as the attending physician/primary operator.

Medical records should identify when any individual participating in a procedure leaves or enters the operating room, the time it occurred and the reason.

13. If a patient is under anesthesia, what happens if a different resident/physician steps in?

The attending physician/primary operator, or if delegated, the OR nurse, is responsible for recording the presence of a new physician, fellow, resident or physician extender who is participating in the surgery and the time they entered the room, as well as the departure of any participating individual.

Medical records should identify when any individual participating in a procedure leaves or enters the operating room, the time it occurred and the reason.

14. How do we deal with an emergency procedure?

An emergency is handled the same way you handled it before the regulation was amended. If the patient's condition permits you to obtain an informed consent prior to the procedure, you make every effort to do so. If not, you document why you were unable to obtain consent in the medical record and share with the patient after the procedure.

15. Does informed consent apply in an office setting?

This regulation applies to all active physicians in Massachusetts, in any practice setting.

16. Does informed consent apply to anesthesiologists providing routine OR care?

Yes. The regulation does not change or expand the circumstances requiring the informed consent of the patient; rather, the regulation requires the informed consent be in writing. If you needed to obtain informed consent before the BORIM regulation amendment, then you will need to obtain informed consent after the regulation amendment becomes effective.

17. A physician's office performs hearing tests, balance tests, blood tests, urine tests, endoscopy; is informed consent required for all of these procedures when they are performed?

The regulation does not change or expand the circumstances requiring the informed consent of the patient; rather, the regulation requires the informed consent be in writing. If you needed to obtain informed consent before the BORIM regulation amendment, then you will need to obtain informed consent after the regulation amendment became effective.

While we may not forsee every clinical scenario, here are some examples you might find helpful:

1) when a physician treats acne with a topical antibiotic, side and adverse effects are reviewed and documented in the medical record, informed consent was not and is not obtained. When a physician treats a young woman with acne with Accutane, in addition to documenting it in the medical record, an informed consent was and is obtained. Now that informed consent must be done in writing.
2) You did not and therefore now do not need to obtain informed consent to obtain a blood pressure.
3) Informed consent was and is required for a prostatectomy. Now that informed consent must be done in writing and include the data outlined in the amended regulation.

18. Is written informed consent necessary for each distinct procedure, intervention, or treatment?

If each distinct procedure required informed consent before the BORIM regulation amendment, then you will need to obtain an informed consent after the regulation becomes effective for each distinct procedure.

Practice of Medicine FAQs

19. Since any illicit drug use violates M.G.L. c. 94C, does the amended regulation, 243 CMR 2.07(26), mean Physician Health Services (PHS) is no longer an option for a physician with a drug problem?

Physician Health Services is always an option for an impaired physician.

The reporting exemption granted in certain limited circumstances under M.G.L. c. 112, § 5F is not available to a physician who has violated laws or regulations or who has practiced medicine while impaired. The "5F exemption" allows a physician making a peer report to avoid reporting the impaired physician to the Board if he/she confirms the physician is in compliance with a drug or alcohol treatment program. If there is no 5F exemption, the impaired physician must be reported to the Board, a case will be opened and an investigation will begin.

There are 4 conditions that must be present for the 5F exemption from reporting to apply.

- There must be a reasonable basis to believe the physician is impaired.
- The physician must not have violated any law or regulation, **excluding drug or alcohol use that is the subject matter of the impairment as long as no other laws or regulations have been violated**. For example, a physician who diverts drugs from the hospital or a patient will not be eligible for the 5F exemption
- There must be no allegation of patient harm and no impairment in the workplace or while "on call."
- The peer reporter must confirm the impaired physician has complied with the treatment program.

The Board felt strongly that a physician who crosses the threshold of the workplace or is on call while impaired must be immediately reported to the Board, because patient safety is in jeopardy.

20. Under the amended Delegation of Medical Services regulation, 243 CMR 2.07(4), can unlicensed Medical Assistants, Audiology Assistants, and other skilled assistants continue to provide care in MA?

Medical Assistants and other skilled assistants can be involved in patient care under the supervision of a licensed physician as long as they are not performing a task that requires a license (eg, MD, PA or NP). The intent of the regulation was to prohibit unlicensed or formerly

licensed persons from performing activities requiring a license to practice medicine. Delegation of medical services is not permitted to individuals not licensed to perform that medical service.

"Medical services" delegated to assistants do not include performing invasive procedures, except when state law specifically authorizes it. For example, M.G.L. c.112, § 265 allows certified medical assistants to perform immunizations as outlined in the statute.

The Board also has regulations on Physician Assistants (243 CMR 2.08) and Advanced Practice Registered Nurses (243 CMR 2.10).

21. You didn't answer my question, what can I do now?

BORIM will continue to field questions on the new regulatory changes. If you have questions, please call our Call Center at (781) 876-8230: **Press** 1 and then **Press** 5.