

**MASSACHUSETTS RADIOLOGICAL SOCIETY, iNC.**

CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY

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**Board of Registration in Medicine**

**Proposed Regulations 243 CMR 3.10**

**Patient Care Assessment Program**

**March 1, 2017**

My name is Deborah Levine, M.D. I am a radiologist and president of the Massachusetts Radiological Society (MRS) as well as Vice Chair of Academic Affairs in the Department of Radiology at Beth Israel Deaconess Medical Center. I am submitting these comments on behalf of the Society, which represents over 1000 member Radiologists, Radiation Oncologists, and Radiation Physicists who practice in the Commonwealth. The MRS is the state chapter of the American College of Radiology (ACR). For over three quarters of a century, the ACR and its constituent chapters have devoted their resources to making imaging safe, effective and accessible to members of the public who need it.

I would like to focus my comments on the provisions of the proposed regulations governing informed consent within the Patient Care Assessment Program regulations, 243 CMR 3.10. While MRS is a strong proponent of engaging patients in informed decision making regarding a patient’s decision to undergo a diagnostic imaging test, we have serious concerns that the required informed consent provisions proposed in the regulations are overly broad and vague, deviate from accepted medical standards, and sweep in tests that ordinarily do not require written informed consent and in doing so would greatly impede patient access to routine imaging tests.

**I.** Section 3.10 (1). Our primary concern is predicated on the removal of the word “major” from the current regulations governing the therapeutic and diagnostic procedures where informed consent “should” be obtained. The proposed regulations state that “a physician has the obligation to obtain and record a patient’s written informed consent before diagnostic, therapeutic or invasive procedures, medical interventions or treatments.” By removing the word “major” from the regulations and inserting the term “has the obligations to obtain,” the proposed regulations can be interpreted to require written informed consent for all diagnostic, therapeutic or invasive procedures, medical interventions or treatments. Without the word “major” diagnostic procedures subject to mandatory written informed consent could include such minor, routine tests as blood draws, and imaging procedures such as X-ray, ultrasound, CT and MRI. These are commonly performed procedures with minimal risk. MRS believes that information should be available to patients regarding these diagnostic tests before they are performed, but written informed consent and the process for obtaining such consent, as required under the proposed regulations, is not needed for such tests and requiring this would constitute a major deviation from nationwide standards of practice. For many imaging tests such as X-ray and CT and MRI, the performance of the test is done by a radiologic technologist, under general supervision by the interpreting physician without direct interaction between the radiologist and the patient, since the

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images are interpreted separate from the performance of the imaging study. We do not dispute that major interventional procedures involving imaging should be subject to written informed consent, as would any interventional or surgical procedure involving meaningful risk.

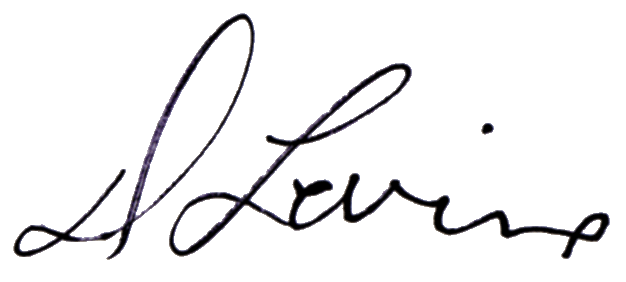
**II**. Section 3.10 (1) (a) and (d). Both of these sections require the attending physician/primary operator to be responsible for discussing the risks and benefits of the procedure, intervention or treatment and obtaining the patient’s written informed consent. A resident and fellow are considered a physician extender under the proposed regulations, which imply that that the primary operator cannot be a resident or fellow. However, residents and fellows commonly obtain patient consent procedures at a level appropriate to their training and under the supervision of an attending. As written, the proposed regulations unnecessarily disrupt the commonly accepted practice of obtaining consent for procedures in academic centers. The inclusion of the word “major” in describing the procedures that require written informed consent as described previously in my comments would minimize the concern that residents and fellows cannot obtain consent for routine procedures under the supervision of an attending at a level appropriate to their training.

**III**. Section 3.10 (c). When Informed Consent Is Required. The proposed section states “written consent should be obtained before all [emphasis added] diagnostic, therapeutic or invasive procedures, medical interventions or treatments where disclosure of significant medical information, including risks involved, would assist a patient in making an intelligent decision whether to undergo the proposed procedure, medical intervention or treatment.” MRS is concerned about the use of the word “all” and its implication as to whether it would include minor diagnostic tests or procedures as discussed previously. We recognize that the requirement is somewhat limited by the terms “significant medical information.” However, the broadness of the word “all” is concerning. Here too, MRS would propose that the word “major” be substituted for the word “all.”

**IV**. Section 3.10 (f) Patient’s Medical Record Must Reflect Who Will Participate in the Procedure. The proposed regulations states: “Prior to the procedure [emphasis added], 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 who are under the direct supervision of the attending physician/primary operator. The attending physician/primary operator shall note the physician extenders on the written informed consent form.” In practice, it may not be known at the time informed consent is obtained the identity of the physician extenders who will be working under the direct supervision of the attending physician/primary operator. For example, shift changes and duty hours can require change in personnel that might not be known at the time of obtaining informed consent. The identity of those individuals would be in the medical record of the procedure, but to require the attending physician/primary operator to identify those individuals in the informed consent form by name prior to the procedure may not be possible in all circumstances. MRS would recommend that this provision be revised by deleting the requirement that the names of the physician extenders be identified in the written informed consent. It should be sufficient to indicate that the attending physician/primary operator will be assisted by the appropriate category of physician extenders. In addition, unexpected emergencies may require input of additional attending physicians, and this would not be known ahead of time. This should be allowed for in the regulations as a matter of patient safety.

V. Section 3.10 (h) Sterile Technique At All Times. The proposed regulation states: “A physician must observe sterile techniques at all times in the practice of medicine, including but not limited to when a physician moves from one surgical procedure to another.” This is problematic since it falls under the header of informed consent, but should be in a separate section.  We agree that sterile technique is needed during interventional and surgical procedures.  When practicing medicine, physicians frequently talk to patients without using sterile technique and examine patients without sterile technique.  This requirement is impossible to achieve. When moving between surgical procedures, physicians must break sterile technique after leaving one room in order to re-scrub and re-gown prior to entering a new room per best practices and Joint Commission requirements.  This is neither “all times in the practice of medicine” nor “when moving from one procedure to another.” MRS recommends that the language be revised to reflect appropriate medical practice.

Respectfully submitted,



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President