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**121 Revere Street, Unit B**

**Canton, MA 02021**

**phone: 860-690-1146**

**email: maorthoexec@gmail.com**

[**www.massortho.org**](http://www.massortho.org)

**TESTIMONY RELATIVE TO PROPOSED**

**CHANGES TO 243 CMR 3.10**

**RELATIVE TO QUALIFIED PATIENT CARE ASSESSMENT PROGRAMS**

**MARCH 1, 2017**

The Massachusetts Orthopaedic Association (MOA) wishes to comment on proposed changes to 243 CMR 3.10: (1) (c) and 3.10 (2).

The MOA is a strong proponent of patient safety, transparency and full communication between physicians and patients. Orthopaedic surgeons support the need for greater transparency, monitoring, and safety regulations to ensure the best possible care is given to patients at all times. However, we have concerns about the ability of orthopedists to fully comply with all the newly proposed requirements at all times.

Given the fluidity in the operating room throughout surgical procedures based on unpredictable events, surgical times, other concurrent staff changes, it is critical that flexibility with responsibility be maintained during any surgical procedure. Limiting distractions and monitoring burden for surgeons and anesthesia teams is important to remain focused on the care of the patient in front of them. Moreover, all personnel directly involved with patient care are already recorded by hospital staff and nurses, readily available for review. We support the additional transparency and documentation to ensure it is known who is interacting with a patient at any given time, but it would be detrimental and practically infeasible for the attending surgeon to him or herself be responsible to document staff fluidity during the procedure, and it would furthermore not be possible to predict beforehand.

With these principles in mind, the MOA wishes to comment on the following provisions:

3.10 (1) creates a new definition of informed consent which strikes the word “major”, thus obligating a physician to obtain and record a patient’s written informed consent before any diagnostic, therapeutic or invasive procedure, intervention or treatment. Written informed consent is defined as meaning “that the patient, who has demonstrated capacity, or the patient’s representative, has been given ample opportunity to ask questions, with all questions having been answered to the patient’s or representative’s satisfaction, and with the patient or representative giving consent in writing to the procedure, intervention or treatment.”

The problem with this provision is that it is too broad and will include minor procedures and that it does not account for unexpected procedures, interventions or treatments, not all of which are completely predictable. A literal interpretation of this language could require a physician to stop in the middle of a procedure and obtain new, written informed consent upon realizing an unexpected minor procedure is necessary to achieve the desired surgical outcome. Also, to expect separate written consent for minor procedures such as injections, suture or drain removal, diagnostic X-rays, casting, etc is burdensome and adds unnecessary burden to patient care. The MOA feels strongly that “major” must be included as a modifier for procedures requiring documented informed consent

Also, under 3.10 (1) Informed Consent:

* Add the words “or physician extender” to the first sentence so that “a physician or physician extender has the obligation to obtain and record a patient’s written informed consent before major diagnostic, therapeutic or invasive procedures.” This will enable physicians to see more patients and ultimately reduce wait-times for patients. Attending physicians remain available if there were any questions that arose during the consent process with a physician extender.
* Add the word “anticipated” to the last sentence so that “Written informed consent is defined as meaning that the patient, who has demonstrated capacity, or the patient’s representative, has been given ample opportunity to ask questions, with all questions having been answered to the patient’s or representative’s satisfaction, and with the patient or representative giving consent in writing to the anticipated procedure, intervention or treatment.” Without such change, something as minor as sutures could be considered a procedure, intervention or treatment.

3.10 (1)(f) Patient’s Medical Record Must Reflect Who Will Participate in the Procedure.

The MOA suggests the words “is anticipated to be” be added to the first sentence so that the patient is fully informed of who is anticipated to be participating in the procedure, intervention or treatment. This is due to the reality that the physician’s primary concern is to the patient and he/she does not always know what extenders are or will be in the room. The situation is oftentimes more fluid than can reasonably be expected to be accounted for in real time.

 It is not always possible or practical to write on any consent form ahead of time who will be involved in the procedure beyond just the attending physician’s name. Consent forms are signed ahead of procedures (for example at the pre-operative visit), and with large team procedures, it is unrealistic to know who all the assistants will be. Often during procedures, there are changes of team members for many reasons, including the fluidity of staff schedules and unpredictable operating room timings. Most hospitals intra-operative records already reflect who each of the participants’ different parts of the care team are. For an involved procedure, there may be large adjunctive teams working with the attending surgeon. For example, radiology technicians, electrophysiologists for neuromonitoring, equipment representatives for specialized equipment as well as residents, medical students, NPs, PAs all may be assisting at various time points. The attending surgeon should be able to focus on the patient and not on documentation of all of these personnel.

Moreover, restricting care providers to only those names pre-written on a form may adversely limit patient care in situations when 1 or more providers (aside from the attending surgeon) are required to step away (either by duty hour limits, mandatory breaks, staffing changes, or other emergent patient care issues). In such situations, replacements are critical to continue the best patient care and must not be restricted. Adding in the words “who is anticipated to be” in the procedure, intervention or treatment will allow the surgeon to fully comply with the regulation while protecting patient safety by ensuring that the procedure continues smoothly, efficiently and without unnecessary delays.

3.10 (1) (g)

Patient’s Medical Record Must Reflect Any Absence of Attending Physician/Primary Operator.

While the MOA is fully aware of the incidents that gave rise to this provision, we are concerned that it would be difficult for surgeons to fully comply with. We therefore request that the provision be amended to allow physician extenders or the facility to aid in the documentation of the attending physician/primary operator’s presence or absence, as follows:

The attending physician/primary operator or physician extender at a medical procedure, intervention or treatment requiring the patient’s written informed consent shall be responsible for including in the patient’s medical record, or having included, written documentation of the attending physician’s presence or absence during the procedure, intervention or treatment. If the attending physician/primary operator was absent for any part of the procedure, the facility shall ensure that the medical record reflects the time of the absence(s) and who was the attending physician/primary operator during the absence(s).

The MOA appreciates the work of the Board of Registration in Medicine and share the Board’s goal of patient safety and full transparency. We hope that our suggested amendments to the regulations would make that goal more achievable and realistic for the patient and the physician.

Thank you.