April 28, 2008

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Senior Policy Counsel

Commonwealth of Massachusetts

Board of Registration in Medicine

560 Harrison Avenue, Suite G4

Boston, MA 02118

RE: Proposed Revisions to Board of Registration in Medicine Regulations, 243 CMR

Dear Ms. Prebensen,

On behalf of UMass Memorial Health Care and the University of Massachusetts Medical School, we are pleased to offer the enclosed comments regarding the Board of Registration in Medicine’s latest draft of its proposed new regulations.

UMass Memorial Health Care (“UMass Memorial”) is the largest health care system in Central and Western Massachusetts, and the clinical partner of the University of Massachusetts Medical School. UMass Memorial includes UMass Memorial Medical Center (Worcester, MA) and four community hospitals: Clinton Hospital (Clinton, MA), HealthAlliance Hospital (Leominster and Fitchburg, MA), Marlborough Hospital (Marlborough, MA) and Wing Memorial Hospital (Palmer, MA). Our physician group practice, UMass Memorial Medical Group, employs approximately 750 physicians. Group members - both primary care and specialist physicians - deliver care on the three campuses of UMass Memorial Medical Center. In addition, through its Community Medical Group Division, UMass Memorial Medical Group operates practice sites in 22 communities in and around Worcester. The UMass Memorial system also includes home health and hospice programs and behavioral health programs. Approximately 1,500 physicians are members of our active medical staff, and we have 13,000 employees, including 3,000 registered nurses. In total, our hospitals have 1,093 beds. In 2006, we treated 58,762 inpatients, and counted more than one million outpatients visits. We delivered 5,346 babies and our emergency departments handled 233,500 visits.

As the Commonwealth’s first and only public medical school, the University of Massachusetts Medical School (UMMS) provides affordable, high-quality medical education to the residents of Massachusetts, with a founding mission to support the training of primary care physicians practicing in underserved areas of the state. Through our undergraduate and graduate medical education programs, UMMS currently supports 408 medical students and approximately 520 residents and fellows in 42 separately accredited training programs. Over 50% of our graduates enter primary care disciplines, with UMMS consistently ranking among the nation’s top 10% of medical schools in primary care education by U.S. News & World Report's “America's Best Graduate Schools.”

We applaud the Board for undertaking the complete revision and updating of its regulations. We recognize that this revision involves a significant effort by Board staff as well as members and appreciate the Board’s commitment to quality health care. We do, however, feel strongly that the public interest would best be served by delaying finalization of these regulations until the Board has a full complement of members, including the two public members required by the Board’s enabling statute.

With this serious reservation noted, we offer the following testimony on the proposed regulations, 243 CMR Sections 1.00 - 3.00 and 6.00 - 7.00. Our comments are based upon perspectives of our teaching hospital, medical school, community hospitals, and physician practices. Issues related to the practice of acupuncture (243 CMR Sections 4.00 and 5.00), are not addressed.

Overall, this draft is better organized than either the current regulations or prior drafts. We note several areas in which the Board has also made important substantive improvements based upon earlier public comments. Unfortunately, the Board’s issuance of multiple drafts which reorganize the content and fail to mark changes from the current regulations or prior drafts make it challenging to provide comment in the brief public hearing period specified by the Board.

This draft places discipline first among all of the sections. While we believe that placing licensing or general provisions first would be more reflective of a positive approach toward the Board’s licensees, in the interests of simplicity we will comment on these draft regulations using the framework proposed by the Board.

**243 CMR Section 1.00 Disciplinary Proceedings for Physicians**

**1.01 Grounds for Discipline**

We strongly support the Board’s efforts to promote quality health care and protect patient safety, including through imposition of physician discipline when appropriate. We are concerned, however, that instead of providing helpful guidance to licensees and the public, the proposed regulations’ long list of proposed grounds for discipline (expanded from 11 to 29) only serves to communicate a negative message about the Board’s view of the professionalism of Massachusetts’s physicians without either strengthening the Board’s ability to take prompt disciplinary action or providing physicians with an improved understanding of the kind of conduct that would warrant discipline.

Most notably, a number of the proposed new grounds are based upon behavior that is not related to medical practice. We recommend reinstatement of the current regulation’s introductory clause relating grounds for discipline to the practice of medicine. We also urge the Board to revisit the entire list of proposed grounds for pertinence and precision. The following comments are illustrative of our concerns.

Several proposed grounds for discipline create problems of interpretation rather than clarifying expectations. We believe that the Board has already demonstrated an ability to impose discipline when appropriate*,* and it is unclear how adopting this language would improve the Board’s effectiveness. For example, grounds (o) and (p) (“Engaging in conduct that undermines public confidence in the integrity of the medical profession;Engaging in conduct that demonstrates a lack of good moral character”) are so broad and subjective that they do not appear to provide any meaningful guidance on what conduct would warrant professional discipline. The vagueness and subjectivity of the terms used become even more problematic when viewed in the context of the definition of “good moral character” found in Section 6 (see further discussion below).

Other proposed grounds put the Board in the position of trying to duplicate existing processes without any apparent benefit to the public. We are pleased to see that in this draft the Board does not attempt to expand its review into the difficult and time-consuming arena of medical malpractice, given the Board’s limited resources and the fact that existing processes are in place to address such concerns. However, retention of grounds (u), failing to comply with “recognized ethical standards of the profession, specialty or subspecialty,” and grounds (x), failing to comply with “accepted research standards, ethics, principles, or procedures, or with governmental statutes, regulations, or policies regarding research” suggest that the Board contemplates applying its resources to reinterpreting standards that are already being ably interpreted by the institutions that create and enforce them. In addition to being redundant, this can lead to interpretations inconsistent with those institutions, and can have the unintended effect of turning aspirational ethical standards into grounds for discipline. To the extent that Board discipline based on these types of violations is the appropriate sanction, the Board has already shown a capacity to address these issues with its existing regulatory authority. Accordingly, we urge the Board to eliminate the proposed grounds (u) and (x).

We also recommend that other proposed grounds for discipline be modified to eliminate the most problematic and subjective aspects, including removing language that suggests physicians will be disciplined for conduct that has not occurred, but that may possibly occur in the future. We accordingly recommend deleting the phrase “or has the potential to” from (v), so that it reads “engaging in disruptive behavior that affects the delivery of professional medical services." This rephrasing should clarify that the Board does not contemplate disciplining physicians who speak up about possible quality problems (an activity that by its nature can be disruptive to smooth operations) but only those whose conduct affects the ability to deliver quality care. We also recommend that other grounds which include the phrases “or has the capacity to,” or “has the potential to” be modified in the same manner. These revisions will remove an unnecessary element of vagueness and subjectivity from the categories and retain focus on the conduct most effectively regulated by the Board.

**243 CMR 1.02(7) Board Access to Medical Records**

The current draft addresses physician records only and reserves the provision applicable to hospital records. Section (a) of this provision gives the Board access to any patient's medical records “in the custody or control of the licensee” so long as the treatment relates to a complaint or statutory report being investigated by the Board. While we welcome the establishment of a legal basis for the Board’s asserted authority to access patient records in the absence of patient authorization, and appreciate the new language acknowledging that Massachusetts statutory privileges prohibit access without specific patient consent or court order, we believe that the proposed language still requires modification in order to be consistent with existing Massachusetts law.

The revised proposal still fails to recognize existing Massachusetts common law that limits a physician’s ability to release medical records that are not statutorily privileged. Federal HIPAA regulations do not pre-empt state common law that is more protective of patient privacy. See 45 CFR § 160.203(b). Accordingly, we recommend that the Board seek legislative authority to access patient medical records without patient consent, to the extent that such access may be in the public interest.

We note that proposed Section 1.02(7) also has serious implications for physicians who are themselves patients. Particularly when read with proposed Section 1.02(5), which grants the Board access to “all information it deems necessary to assist in the furtherance of its investigation,” “except as prohibited by federal or state law,” this language will provide support for a contention that the Board has limitless access to even the most private information about a physician, without being subject to impartial review of relevance.

Section (b) of the current draft regulations reserves the topic of the Board’s authority to access hospital medical records. We believe any such provision, like the one governing physician office records, must be preceded by a legislative change.

**243 CMR Section 2.00 Licensing**

**243 CMR 2.01(5) (j)(1) General License Requirements: Duty to Update Information**

This proposed regulation requires that licensees continuously report to the Board whenever there are any changes in information submitted as part of their approved application for licensure or renewal, regardless of where they are in the two year renewal cycle for a full license or the annual cycle for a limited license. We are concerned that this regulation would oblige physicians, including trainees, who are diverted to Physician Health Services pursuant to the 5F exception to report health conditions to the Board immediately. One purpose of the confidential diversion to Physician Health Services is to eliminate the requirement of immediate Board reporting when there is no allegation of patient harm and the physician has entered into a PHS monitoring contract. This change would be inconsistent with the preventative, non-punitive approach to health problems that allows physicians to report PHS involvement on the regular renewal cycle.

**243 CMR 2.02(3) (a) Examination Requirements: USMLE and COMLEX**

This revision proposes that after three failures at Step 3, an applicant must take an additional year of ACGME approved clinical training, before s/he is authorized to take Step 3 a fourth time. As the sponsor of our graduate medical education programs, UMass Medical School does not necessarily disagree with the Board's proposal, however we are recommending clarification which stipulates that the individual resident's current training program is under no obligation (financial or otherwise) to provide this additional year of training.

**243 CMR 2.11 (4) (b) Lapsed License**

Under existing regulations, when a licensee does not renew his or her license by midnight on the designated day, the license is deemed lapsed. To reactivate the license, the licensee must pay a fee and file a lapsed license petition, which, because of the additional documentation, usually takes 4-6 weeks, during which time the physician cannot practice. Under the proposed regulation the Board would have an additional six months before it is required to rule on the petition. While we support the Board’s attempt to reinforce the importance of timely renewal, we recommended that the Board adopt a shorter period for its review. This will have the effect of sending a clear message to physicians without causing undue interruption to patient care.

**243 CMR 3.00 Establishment of and Participation in Qualified Patient Care Assessment Programs**

UMass Memorial appreciates that the Board has responded to public comments urging it not to initiate a major expansion and revision of the existing Patient Care Assessment (PCA) program structure as contemplated in prior drafts of these regulations. However, while these proposed changes to the PCA section of the Board regulations are modest as compared to those contemplated in prior drafts, they nevertheless further establish and expand the PCA program in ways that UMass Memorial believes are ill-advised and unduly burdensome.

These new draft regulations appear to expand the current regulations in several significant ways. The regulations further formalize the structure of the PCA Division despite the lack of any clear legislative guidance. They also impose additional data collecting and reporting requirements on health care facilities. For example, proposed Section 3.07 (5) (a), would require, in addition to the current reporting, the collection of patient primary language and race for every hospital incident report. Proposed changes to facility Annual Report requirements are even more burdensome. Current Annual Reports must include summary analysis of patient complaints and their disposition. Proposed new language (Section 3.07 (8) also requires that the analysis include “but not [be] limited to, data, data analysis, trending, corrective actions, findings and recommendations for quality assurance, quality improvement, performance improvement, including recommendations related to credentialing, peer review, utilization review, risk management, and training and education.” While UMass Memorial supports development of such data systems as a means to promote quality, this regulation appears intended to justify requests currently being made by the PCA Division that are resource intensive, duplicative to work already being done by and for other groups and do not appear to result in meaningful feedback to hospitals. There is also a concern that the Board may use this broad expansion of Annual Report requirements to attempt to assert new authority to access information developed as part of the individual peer review process. We do not believe that current statutes permit health care facilities to disclose information developed within the peer review process except in the specific circumstances authorized by law. When reviewing challenges to the PCA regulations, the Massachusetts Supreme Judicial Court has specifically rejected the argument that the Board is permitted to access the work product of a peer review committee through the Patient Care Assessment Program.

UMass Memorial is also concerned that the current draft does not sufficiently clarify the Board’s intention with respect to establishment of formalized PCA programs in physician offices. It was our understanding that after receiving extensive public comments in 2006, the Board decided not to extend the PCA requirements into physician offices, and most of the proposed revisions to Section 3 are consistent with that decision. UMass Memorial strongly supports the decision not to expand the PCA requirements into physician practices and suggests that the Board clarify this intention by removing the phrase “licensee office setting” from the two places it appears in Section 3.01, and delete Section 3.11 in its entirety. Also, we request that the Board clarify the definition of Health Care Facility in the new draft of Section 3.02. This definition includes “any entity maintaining more than one primary or episodic walk-in center.” It is unclear what type of facility is intended by this reference. The prior draft used the term “clinics,” but included in that definition physician practices as well as clinics within the meaning of 105 CMR 140.020. Assuming the Board intended to remove physician office practices from the scope of the required Health Care Facility programs, clarification might be made by replacing “any entity maintaining more than one primary or episodic walk-in center.” with "any clinic within the meaning of 105 CMR 140.020." This language would serve to distinguish the facilities from both hospital based clinics (already included in the definition of Health Care Facility) and physician practices.

In conclusion: current PCA regulations, as expansively interpreted by the PCA division, already constitute a significant resource burden on hospitals, and in a number of ways duplicate existing quality regulation such as that imposed on hospitals by their licensing agency, the Massachusetts Department of Public Health, and their accrediting organization, the Joint Commission, as well as the Centers for Medicare and Medicaid. New quality measurement structures continue to develop at the state and national level, including the initiatives of the Betsy Lehman Center and the National Quality Forum. Accordingly, UMass Memorial strongly recommends that the Board defer any revision of the PCA regulations, in order to avoid unnecessary duplication of effort with other governmental and non-governmental initiatives. Developing quality programs that are complementary rather than duplicative of other programs will enable the Board and health care facilities to use their resources where they can have their greatest effect in promoting safe and high quality care.

**243 CMR 6.00 General Provisions Relating to the Practice of Medicine**

243 CMR 6.01 (1) inserts a definition of “good moral character” into the regulations, as follows:

*Good Moral Character means those aspects of morality, attention to duty, forthrightness and self restraint that are usually associated with the accepted definition of good moral character, as determined by the Board. Any conduct, whether or not arising in the context of medical practice, which calls into question an applicant’s or licensee’s fitness or ability to practice medicine, or which is antithetical to the promotion of the public health, safety and welfare, as determined by the Board, constitutes a lack of good moral character.*

This definition is unacceptably broad and vague, in that it grants Board complete discretionary authority to set standards of propriety, including standards for conduct unrelated to the practice of medicine “as determined by the Board.”Inclusion of lack of good moral character as the grounds for discipline creates other serious problems. Since the grounds for discipline form the basis of the obligation to file a peer report about another physician’s conduct (the failure to do so also an enumerated basis for discipline), such broad and subjective grounds can only result in much uncertainty about what sort of conduct physicians are required by law to report. This is particularly problematic and invasive with respect to the definition’s inclusion of conduct unrelated to the practice of medicine.

If the Board remains persuaded that providing such a definition in its regulations would be helpful in the context of applications for licensure (Massachusetts General Laws, Ch.112, Section 2 requires physician to demonstrate good character when applying for a license), it should delete proposed disciplinary ground 1.01(p), which makes “engaging in conduct that demonstrates a lack of good moral character” a grounds for discipline. As discussed above, we believe that as articulated, this standard is simply too vague to provide an adequate basis for either disciplinary action or mandatory peer reporting.

Section 7.00 Mandated Reporting

243 CMR 7.02 Reporting by Health Care Facilities; Annual Summary of Disciplinary Action

Under the existing regulations, the Annual Summary of Disciplinary Action lists the names of all licensees against whom the health care facility has taken a “disciplinary action,” as defined by the Board, within the past year. This proposed revised section requires that the names of all full licensees who have terminated their relationship with a health care facility in the past calendar year *regardless of reason* be included in the facility's Annual Summary of Disciplinary Action. The vast majority of terminations included in this report will be voluntary (such as physicians who have retired or relocated their practices and residents and fellows with full licenses who have completed their training or transferred to other programs for legitimate reasons) and not the result of any disciplinary action by the facility. Current regulations (Section 3.12) require this information to be submitted in the facility’s Annual Report to the PCA division, where the information is not associated with a list of disciplinary actions. We believe that this information should not be included in the facility’s Annual Summary of Disciplinary Action so as to avoid any implication that these departing physicians have been subject to discipline. If the Board wishes to make this information more readily available as a means of keeping affiliation information up to date, we suggest that the information be submitted either under the existing system or in a separate document with a more descriptive title.

**243 CMR 7.03 Exception for Reports to the Board under M.G.L. c. 112, § 5F**

UMMHC urges the Board to expand the exception from mandated reporting to include mental health problems. Physician Health Services has demonstrated a willingness and ability to expand its programs to address these important physician health needs. For a physician who is providing good patient care, providing a confidential, non-punitive opportunity to address health concerns promotes patient safety as well as physician well-being. The public is served any time that a physician who is facing health challenges quickly obtains structured remediation, and this can only be achieved when there are non-punitive incentives to do so.

UMass Memorial and UMMS appreciate the opportunity to offer comments on this draft of the proposed regulations. We look forward to further discussions of this important topic when the Board once again has a full complement of members.

Sincerely,

Stephen E. Tosi, M.D. Terence R. Flotte, M.D.

UMass Memorial Health Care University of Massachusetts Medical School

Chief Medical Officer Dean, Provost, and Executive Deputy

SET/dvh Chancellor