

September 7, 2010

William Roeder  
Executive Director, State Board of Medical Examiners  
Post Office Box 183  
Trenton  
New Jersey 08625-0183

Re: Proposal Number PRN 2010-129; Board of Medical Examiners; Proposed Readoption and Amendments to NJAC 13:35

Dear Mr. Roeder:

Please accept the following comments on the re-adoption and amendment proposals to the Board of Medical Examiners' (BME) rules governing physician/licensees on behalf of the Medical Society of New Jersey (MSNJ).

MSNJ agrees with the proposal to modify NJAC 13:35-6.17 which allows physicians to offer medical goods and devices such as hearing aids, eye-glasses, contact lenses, prosthetic devices, orthotics, etc., to patients. The current rule's cost structure and 10% administrative cap is cumbersome and difficult to implement. It is not well understood by many licensees who would like to offer goods and service, but are afraid of running afoul of the current cost and discount formula. The proposal to allow the sale at fair market value without an administrative cap is a preferable approach.

MSNJ agrees that further rule-making on this issue may be appropriate and we would like to meet to discuss our concerns in the pre-proposal stage for further changes in NJAC 13:35-6.17. We would offer information on the experience using the fair market value approach and any improvements that could be made to the rule at that time. We will poll our members on concerns and suggestions.

MSNJ also agrees with the proposal to clarify and amplify the recordkeeping requirements under NJAC 13:35-6.5:

1. The additional requirement to give notice of the location of a licensee's medical records when the licensee closes their practice for more than three months is administratively simple and will benefit both patients and physicians. We receive many inquiries from patients who are unable to ascertain the location of their medical records when a practice is closed. We also receive complaints from licensees who are unaffiliated with a practice that has closed but in proximity to the closed practice and, because of their proximity, are the target of inquiries and complaints by patients. This is a frustration to the physicians who cannot help and express confidentiality concerns about becoming involved.
2. The BME's clarification of its position that the patient's medical record includes documents from other licenses or healthcare providers is also helpful. We have advised members to include the documents from other providers when they respond to patients' requests for records, but since this is not specifically stated in the rule some physicians are reluctant to do so. We understand that the BME believes that characterizing these "other" records as part of the patient's medical record is to facilitate continuity of care and agree that it can be helpful in that way.

3. The proposal's requirement that licensees should maintain any printout of computerized records that are part of the medical record when modifying a computer recordkeeping system to comply with regulatory requirements makes sense. We believe that licensees should have a backup when making any recordkeeping modification. We are concerned that this new provision may appear to mandate a printout and that the printout be kept indefinitely. So long as the requirement is to have a backup during transition and not a mandate for printouts or indefinite storage we agree with the proposal and the rationale behind it.

The three above amendments to recordkeeping requirements will provide clarity for physicians and ultimately benefit their patients. Therefore, we fully support these recordkeeping changes.

We must, however, ask that the BME consider a change to the rules on charges for the patient's medical record. NJAC 13:35-6.5(c)(4)(i). Charges are currently capped at \$100, no matter how extensive the medical record may be. While this may be warranted for patients, this cap should be removed for requests from a person other than the patient for reasons other than medical treatment. There are many situations where records are requested for litigation, life insurance or other purposes that are entirely unrelated to the treatment of the patient. In those circumstances, the \$100 cap for duplication costs should be removed. This issue was the subject of MSNJ Resolution #10 - 2010 whereby the membership has formally requested that the cap be removed.

We object to the proposed modification concerning the definition of "attending physicians" for purposes of determination and pronouncement of death responsibilities. NJAC 13:35-6.2. Currently, the regulation defines the attending physician as one who has an ongoing medical treatment relationship with a primary care physician or a specialist who is treating a chronic medical illness which could lead to death. Such a physician, who has written a prescription within six months of the patient's death, is deemed to be the attending for purposes of determining the cause of death.

The current rule is being misinterpreted by enforcement authorities who are calling any physician who has written a prescription found at the scene of a death to the scene to determine cause and pronounce death. It is inappropriate to summon a dermatologist or ophthalmologist, or any physician who is treating for a non-life-threatening condition, to the scene to determine the cause of death simply because a prescription has been found at the scene. Yet, this is how physicians are reporting that the rule is being interpreted.

The rule must be re-crafted in a way to avoid compelling physicians providing episodic care for non-life-threatening conditions to be summoned to the scene to certify cause of death for patients. The proposal would extend the time-period from six months to twelve months for purposes of determining the "attending physician." NJAC 13:35-6.2. It would also eliminate the requirement that the physician be in an ongoing treatment relationship. Physicians who are not in an ongoing treatment relationship for a serious condition that could lead to death should simply not be put in the position of certifying cause of death. These circumstances are appropriate for the County Medical Examiner or Coroner.

We request that the rule ascribing responsibilities to licensees for determination of death and pronouncement of death be strictly limited to situations where it can be established clearly at the scene of the death that

- 1) the decedent was under the current care of a physician;
- 2) for a life-threatening condition;

3) that may have been the cause of death.

Otherwise, this obligation for determination of cause and pronouncement of death should be the responsibility of the County Medical Examiner or Coroner.

The proposal would add language to NJAC 13:35-1.5(k). It would address the situation where a resident is found by the BME not to be a clear and imminent danger to the public health, safety and welfare, but rather deemed to pose a risk to the public health, safety and welfare. Currently, if a resident is believed to be an imminent danger his authority to engage in the practice of medicine may be suspended. The new lesser standard of danger would allow the BME to require the resident to submit to medical or diagnostic testing and monitoring, including psychological evaluation or an assessment of skills, to determine whether the resident may continue to practice with reasonable skill and safety.

MSNJ objects to these changes as duplicative of current requirements. As a threshold matter, residents do not practice at all (they are in a training setting under supervision). Therefore, the judgment as to their ability to render care is a responsibility of the residency faculty and it is their obligation to arrange for any testing, etc. ACGME regulations already require this type of oversight by the Residency Program Director and if there are complaints regarding the abilities of a resident, these questions should be referred to the Residency Program.

The proposal would require that an exam be conducted within six months prior to dispensing of a hearing aid. NJAC 13:35-8.13. MSNJ supports this change.

The proposal would allow certified medical assistants to administer intradermal injections. NJAC 13:35-6.4. MSNJ supports this change with proper supervision by a physician. MSNJ understands this change to be inclusive of injections relating to allergy testing.

The proposal would allow delegation to occupational therapists. NJAC 13:35-6.14. The BME believes that this is already current practice. MSNJ understands the current practice by most physicians is to delegate the choice of treatment modalities under an "evaluate and treat" order. MSNJ agrees with the Board and supports the change.

The proposal would add three substances that could be administered by radiological technologists. NJAC 13:35-6.20. They are filtered sulfur colloid, Lexiscan, and Technetium 99M. MSNJ understands that sulfur colloid and Technetium 99 are never administered as stand alone agents, but in compounds with other substances. The board may wish to revise the rule to allow for compounds containing these agents for accuracy. These agents must be administered with onsite physician supervision

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lawrence Downs". The signature is fluid and cursive, with a large initial "L" and "D".

Lawrence Downs  
Medical Society of New Jersey  
General Counsel

*Above comments were submitted to proposal@dca.lps.state.nj.us on Tuesday, September 7, 2010 at 15:56:57*