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December 30, 2010

Thomas R. Calcagni
Acting Director
New Jersey Division of Consumer Affairs
124 Halsey Street
P.O. Box 45027
Newark, New Jersey 07101

VIA FAX

Re: PRN 2010-270; Healthcare Professional Reporting Responsibility; Proposed at 42 NJR 2577 (a) (November 2, 1010).

Dear Mr. Calcagni:

The Medical Society of New Jersey represents approximately 9,000 physicians in the state of New Jersey and is the largest physician organization in the state. We appreciate the opportunity to comment on the proposed regulations concerning healthcare professional reporting responsibility.

We commend the efforts of the Division of Consumer Affairs to codify the "Healthcare Professional Responsibility & Reporting Enhancement Act" that was meant to address the unreported murders committed by a nurse, Charles Cullen. Because his conduct was not reported, he was able to jump from job to job despite a questionable employment record. Our comments focus on balancing the important public safety issue crystallized by the Cullen case against the rights of physicians and other healthcare professionals who may be wrongly accused and suffer damage to their reputations and livelihoods.

MSNJ is concerned that some of the proposed standards that trigger a reporting obligation are subjective, vague, and could be easily "trumped up." In these cases, the public interest is not strong enough to override a professional's right to be free from unwarranted reporting that may negatively impact their ability to find other employment. For example, NJAC 13:45E-3.1(a)(3)(i)(1) sets the standard for reporting where the professional has voluntarily resigned from the staff and the entity is "undertaking ...a review" of "[t]he quality of patient care rendered by the health care professional."

There are two problems with this standard. First, whether an entity is "undertaking an investigation or a review" is not defined and is subject to interpretation. It does not require a "formal" or "actual initiation" of a review. It could easily be "backed into" after the voluntary resignation. Second, we question the triggering conduct in sub-section (1). Can "quality of patient care" alone be a trigger to a report? In an age of "continual

improvement" something as simple as a mistake, without harm, could be deemed by an entity to be worthy of review. Is a facility duty-bound to report a quality issue that it intended to discuss with an employee when the individual voluntarily resigns? We urge the Division to carefully consider the triggering conduct standards since their breadth may require reporting of virtually any conduct by an individual who voluntarily resigns. Surely, the Legislature did not intend for the Clearing House to be flooded with such reports or for the affected board to act on the matter. Employees regularly leave when they realize that their lack of professionalism is not being countenanced by their employer. This is not the type of conduct that the Legislature intended to address. Clearly, the Legislature intended to address dangerous conduct. In fact, the proposed definition of "conduct relating adversely to patient care or safety" excludes certain behaviors that are not likely to harm patients. Moreover, the enabling statute appears to require a nexus between the conduct and patient harm. [See NJSA 26:2H-12.2b 2a (1) "impairment...which relates adversely to patient care or safety"]

MSNJ is similarly concerned with the standard set out in NJAC 13:45E-3.1(a)(4) where the professional voluntarily relinquishes some clinical privilege or authorization. Again, a report may be required if the entity is undertaking a review of "quality of patient care."

We believe that there may be a drafting error that, if corrected, would satisfy some of our concerns. NJAC 13:45E-3.1(a)(1) establishes triggering conduct that is not present in subsections discussed above. The conduct is "impairment, incompetency or professional misconduct, which incompetency or professional misconduct relates adversely to patient care or safety." This conduct and some predicate of patient danger should underlie any reporting obligation.

MSNJ agrees that healthcare entities shall be exempt from reporting a professional who agrees to participate in an intervention program. MSNJ was the founder of the Physicians Health Program (now the Professional Assistance Program of New Jersey) the first full-time program of its type in the nation. We have a long history of supporting physicians who participate in such intervention programs. We note that professionals employed by the entity who may be aware of the conduct and the person's participation in such a program should also be exempt from any reporting obligation. We suggest that this be stated in the proposed regulation.

MSNJ agrees that the reports generated by the proposed regulations should not be considered public records and thereby available to the public. We also agree that any response to an inquiry from a healthcare entity should require a written authorization for the release of the information from the subject healthcare provider. The responsibility for the Clearing House Coordinator to review and reject reports that are not required is an important function. We urge the Division to ensure that this review is not *pro forma* and to ensure that the Coordinator will reject reports that are unfounded and do not rise to the level of misconduct contemplated by the Legislature.

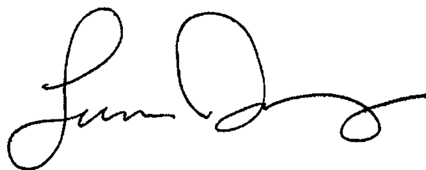
MSNJ is concerned that there is no specific obligation for an entity, the Clearing House Coordinator or the appropriate Board to either actively investigate or to dismiss the investigation. Under the proposal, a "disposition" of a matter can be accomplished in

a number of ways, including a finding of no cause of action. However, there is no established timeline for dispositions. The enabling statute requires both prompt notification to the practitioner and a prompt investigation. (See NJSA 45:9-19.9.a (c)). Physicians and other healthcare professional have a strong interest in investigations being promptly resolved. We suggest that the Clearing House Coordinator be required to move reported incidents to a final disposition promptly. Without some resolution deadline matters may languish either at the facility level, Clearing House, or the Board level. Open investigations can be harmful to physicians in terms of employment opportunities and reputation. Therefore, we urge the Division to reiterate the standards for prompt resolution in the implementing regulations.

We urge the Division to consider the basic elements of due process to address any triggering conduct under the proposal. All covered healthcare entities should have specific due process procedures in place. To the extent that a covered entity does not have existing legal due process requirements, the proposal should require them. For any healthcare entity investigation there should be specific written notice of the conduct, the allegations, and persons making the allegations in a timely manner. There should be an opportunity for a prompt hearing and resolution. Physicians should be permitted to utilize counsel and to have peer review of the conduct at issue. Any entity decision should be made by a body that has members independent of the facility.

We note that disruptive behavior is a specified conduct that may result in an investigation, report, and board action under the proposal. The Joint Commission recently required that hospitals have a code of conduct that defines disruptive behavior and implements a process for managing such conduct. To the extent that this proposed regulation covers hospitals there is already a mechanism in place to evaluate and address this conduct. In response to the Joint Commission Leadership Standard, the American Medical Association adopted policy H-225.956 which recommends that medical staffs develop and implement their own code of conduct in the medical staff bylaws and procedures to address this conduct. Medical staffs have done so and the by-laws contain due process mechanisms that assure an independent and timely review of the conduct, including peer participation. MSNJ is concerned that the proposal is duplicative of existing processes to address this type of conduct, at least in the hospital setting. Where a medical staff has adopted a staff code of conduct that is the exclusive means for review and disciplining medical staff members for inappropriate or disruptive behavior we urge the Division to permit that process to satisfy the regulatory requirement and only require a report to the Clearing House Coordinator if there is a finding of misconduct.

Respectfully submitted,



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