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September 15, 2010

Joanne Boyer, Executive Director
New Jersey Board of Pharmacy
Post Office Box 45013
Newark, New Jersey 07101

Re: Notice of Pre-Proposal on Collaborative Practice, 42 *NJR* 1492(a), July 19, 2010; Supplementing PRN 2009-347, Jointly Proposed New Rules, N.J.A.C. 13:35-6.27 and 13:39-13 (November 16, 2009) by the Boards of Medical Examiners and Pharmacy

Dear Ms. Boyer:

Thank you for the opportunity to comment on the proposed new rule N.J.A.C. 13:35-6.27. MSNJ previously provided comments on collaborative drug therapy management on January 15, 2010 to the Board of Medical Examiners (BME). This Board of Pharmacy ("the Board") is currently seeking information on three questions to which we will limit our comments.

We appreciate that the Board is focusing on post-graduate education, clinical practice experience, and experiential training. We believe that each of these is essential to ensure patient safety. By definition, the pharmacist will be delegated responsibilities that are ordinarily the physician's under the proposed collaborative practice regulation. This, coupled with the likelihood that the patient communication may be over the phone and will be without the benefit of any physical exam or prior patient history by the pharmacist, causes concern for patient safety if the pharmacist does not have an adequate measure of the essential training and experience of a physician licensed to practice in New Jersey. The BME has expressed a similar concern about the propriety of writing a prescription without a prior physical exam and history. N.J.A.C. 13:35-7.1A requires that a physician perform an appropriate history and physical examination, among other things, before prescribing medication. Exceptions to this regulatory requirement are specific and limited.

The board has asked: *What type of post-graduate training is necessary to qualify a pharmacist to engage in collaborative practice?*

Ideally, a pharmacist qualified to engage in collaborative practice would be one who has completed medical school and a significant portion of a residency in internal medicine, emergency medicine or a specialty related to the type of chronic disease that will be treated under the collaborative practice. There are individuals who attend both medical and pharmacy school and these individuals would be the best qualified candidates to participate in a collaborative practice.

We recognize that the pool of dually trained professionals may not be significant, so we agree that post-graduate training is necessary. The post-graduate training should be as analogous as possible to the type of training received in medical school and residency. At a minimum, we believe that the pharmacist should attend a post-graduate *clinical residency* program. We recommend at least a two year residency of post-graduate training in clinical pharmacy practice which should include the specialty area in which the pharmacist will engage in a collaborative practice. For example, post graduate clinical residency programs offered through Rutgers in General Practice and Emergency Medicine in hospital settings would be appropriate. These programs rotate through

departments such as Cardiac/Medical Critical Care, Emergency Medicine, Internal Medicine, Infections Diseases and Surgical Clinical Care. The post graduate clinical residency programs in Managed Care and Ambulatory Care would not be appropriate. (The managed care program, with Horizon, is focused on formulary management, research, prior authorization, and policy and benefit design review, none of which would enhance a collaborative agreement for patient treatment.)

The board has asked: *What components are necessary to constitute a clinical practice setting such that practice in the setting would qualify a pharmacist to engage in collaborative practice?*

We assume that this question is related to qualifying pharmacists for eligibility to enter into collaborative practices, not a designation of the settings in which a collaborative agreements might occur. A clinical practice setting is one in which the treatment of patients occurs. It could be a hospital, clinic, or private practice. The most essential component is that there be direct patient care. The pharmacy collaboration candidate must be engaged in patient care in a way that will give a measure of experience analogous to what a resident in medicine would receive. For example, participation in one of the Rutgers Post-Graduate Clinical Residency Programs focused on general practice or emergency medicine would be appropriate.

The board has asked: *What experiential training is necessary to qualify a pharmacist to engage in collaborative practice, and should such training be disease-specific?*

Since the authorizing statute calls for an identification of the disease states appropriate for the authorized laboratory tests prior to including them in a collaborative agreement we believe that the New Jersey Legislature intended for the pharmacists to have disease-specific training. We believe that disease specific training, including clinical experience in treatment of the specific disease state is essential.

It is possible that experiential training may occur during the post-graduate clinical residency program, but if that program does not have the disease specific training for the specific collaborative agreement then that training must occur outside of the post graduate program. This experiential training could occur through employment in a clinical setting practice. The practice setting could be academic, hospital-based, a private practice, or a clinic such as a federally qualified health centers (FQHCs). It is critical that this experience be clinical, including patient interaction under the supervision of a physician, not administration or research oriented. The experiential training might also be satisfied through work as a trained emergency medical technician.

Consistent with the statutory intent and our concerns about patient safety, we recommend that the diseases appropriate for collaborative treatment should be specific, jointly designated by this board and the BME, and limited. We suggest that consideration be given to treatment of diabetes and hypertension as a starting point. In that way, the boards' determination of pharmacists qualified to participate in collaborative agreements by satisfying the three above educational and training criteria can focused.

Finally, we must reiterate a point from our prior comments that the collaborative partner must be an *individual*, not a particular pharmacy or chain of pharmacies, and that the individual pharmacist have no financial incentive and provide none to physicians, to participate in a collaborative arrangement. It is imperative that the individual collaborating pharmacists then meet each of the three qualification criteria set out above. In addition, we recommended that the collaborating physician already have an established relationship and medication regimen with the patient who is the subject of the collaborative agreement. Otherwise, the BME regulation (referenced above) requiring a physical examination and a patient history may be short-circuited.

Respectfully submitted,



Michael T. Kornett
Chief Executive Officer
Medical Society of New Jersey