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Pennsylvania
MEDICAL SOCIETY®

June 7, 2013

Kerry Maloney, Counsel
State Board of Pharmacy
Department of State
P.O. Box 2649
Harrisburg, PA 17105

Re: Collaborative Management of Drug Therapy—16A-5425

Dear Mr. Maloney:

As President of the Pennsylvania Medical Society (PAMED), I would like to comment on the proposed regulations for the State Board of Pharmacy regarding Collaborative Drug Therapy Management between a physician and a pharmacist. PAMED is supportive of physician-led, team-based medicine where physicians and other practitioners work collaboratively to accomplish shared goals within a given practice setting. The functioning of a team-based approach to maximize efficiency for high-quality, patient-centered care is, as always, a priority. The Society appreciates the opportunity to comment on this proposed regulation.

A review of the regulatory package indicates that the proposed regulation largely follows the language found in Act 29 of 2010; however, there are several areas of concern that we believe merit consideration. Our recommendations regarding those concerns are provided for your consideration.

Recommendation #1: Controlled substances should be excluded in drug therapy management.
Under the Act, pharmacists are now able to administer, as well as adjust strength, regimen and frequency of drugs in non-institutional settings. Though this regulation mirrors much of the language within the Act, we believe that there should be limitations on the types of drugs being managed under a collaborative agreement. While we recognize that pharmacists are able to manage controlled substances in institutional settings where standards and protocol exist, the same appropriate safeguards may not be as consistent in non-institutional settings.

Recommendation #2: Collaborative agreements should be approved and filed with the relevant physician licensing board.
While we understand that the Pharmacy Board does not have jurisdiction over physicians, we encourage the Board to work in cooperation with the State Board of Medicine and Osteopathic Medicine to jointly promulgate regulations. For example, the joint regulations could address the physician's responsibilities when notified of any changes in dose, duration or frequency of medication prescribed, such as a countersignature requirement. This approach will ensure that agreements

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are appropriate and that the management of drug therapy for patients is safe. It is important to note that there is a requirement that the written protocol be filed with the Bureau of Occupational and Professional Affairs (BPOA) in institutional settings, but no such requirement is outlined in the regulation for non-institutional settings.

Recommendation #3: Authorizing physicians should have access to pharmacist records for regular review.
It appears that any documentation regarding drug therapy management is made within the pharmacist's record, not the patient's medical record. While the pharmacist has access to patient records, there is nothing in regulatory language that allows physicians to have access to pharmacist records for review. Although a method for documenting decisions and a plan for communication to the physician are to be specified in the collaborative agreement, the Society recommends that individual physicians should have access to records and determine the level of personal review needed.

Recommendation #4: Changes in drug therapy should be notified to the physician in 48 hours or less.
Current regulation in institutional settings require that documentation of each intervention be recorded in pharmacist's record, and any changes in dose, duration or frequency of medication prescribed be notified to the physician as soon as practicable, but no longer than 72 hours. This may be appropriate for institutional settings where standards and protocols exist and the patient is consistently monitored, but should be lowered to a minimum of 48 hours for non-institutional settings.

Recommendation #5: Consider workload limitations on pharmacists performing drug therapy management.
While we understand that collaborating with several physicians will increase a pharmacist's workload, we believe that patient safety can be compromised when the workload is increased in managing drug therapy for various patients. We suggest that the Board examine this issue and consider developing a mechanism to address these concerns (i.e. limiting the number of physicians a pharmacist can collaborate with, or limiting the number of patients a pharmacist can manage).

Again, I appreciate the opportunity to provide comments to this regulation as it progresses. If there are any questions or concerns regarding these comments, please contact Amy Green, Director of Governmental Affairs at agreen@pamedsoc.org.

Sincerely,

C. Richard Schott MD FACC

C. Richard Schott, MD
President

cc: State Board of Medicine
State Board of Osteopathic Medicine