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October 16, 2020

Lawrence R. John, MD
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Juan A. Ruiz, Board Counsel
State Board of Pharmacy
P.O. Box 69523
Harrisburg, PA 17106-9523

RA-STRegulatoryCounsel@pa.gov
Re: State Board of Pharmacy
Proposed Regulations: Administration of Injectable Medications, Biologicals,
and Immunizations
IRRC # 16A-5429

Dear Mr. Ruiz:

On behalf of the Pennsylvania Medical Society (PAMED), I would like to comment on the proposed regulations for the State Board of Pharmacy (Board) regarding the administration of injectable medications, biologicals, and immunizations. PAMED appreciates the opportunity to comment on this draft regulation.

PAMED has specific questions related to §27.406 (which relates to notification requirements of pharmacists who administer injectable medications, biologicals, and immunizations).

The proposed regulations update the Board's existing regulations to reflect statutory changes made to the Pharmacy Act by Act 8 of 2015 (Act of Jun. 26, 2015, P.L. 29, No. 8). Pursuant to Act 8 of 2015, pharmacists who administer injectable medications, biologicals, and immunizations must notify a patient's primary care provider, if known, within forty-eight hours of administration. The proposed regulations amend the Board's existing regulations regarding notification requirements to incorporate this requirement to notify a patient's primary care provider.

The proposed regulations require notification to a patient's primary care provider if known, but do not offer any guidance as to how a patient's primary care provider is to become known and whose responsibility it is to identify.

PAMED respectfully requests that the Board clarify exactly how primary care providers are to become known. Specifically, is it the patient's responsibility to inform the pharmacist as to who their primary care provider is, such as on an intake form, or must the pharmacist actively ask the patient for this information?

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Additionally, PAMED also requests clarification as to the role of a supervising pharmacist regarding notification requirements when an administration has been performed by a pharmacy intern. Pursuant to §27.405, record keeping requirements are the sole responsibility of the administering pharmacist or the pharmacist who supervises an administration by a pharmacy intern. Among these record keeping requirements is identifying information of the patient's primary care provider and information regarding who was notified if there was an adverse reaction. However, under §27.406, either the supervising pharmacist or the pharmacy intern may fulfill the enumerated notification requirements.

Given that the supervising pharmacist is ultimately responsible for patient care when an administration has been performed by a pharmacy intern and a pharmacy intern must be under the direct, immediate, and personal supervision of a pharmacist when providing an administration to a patient, PAMED asks the following:

- What is the supervising pharmacist's role regarding notification requirements when a pharmacy intern has been involved in an administration of an injectable medication, biological, or immunization?
- Should the supervising pharmacist be the only party to fulfill notification requirements to the primary care provider and other specified individuals?
- If the pharmacy intern may fulfill notification requirements, what is the supervising pharmacist's role in ensuring proper notification occurs?

Adequate communication between pharmacists and primary care providers regarding the administration of injectable medications, biologicals, and immunizations is crucial to not only assisting in the management of possible adverse reactions, but to also ensuring continuity of care and that patients' primary care medical records are maintained accurately. These considerations are especially critical when providing influenza immunizations to children, as Act 8 of 2015 and the proposed regulations authorize pharmacists to do.

PAMED appreciates the opportunity to provide comments for the Board's consideration on these proposed regulations. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Lawrence R. John, M.D.".

Lawrence John, MD
President