

Comments of the Independent Regulatory Review Commission



State Board of Pharmacy Regulation #16A-5429 (IRRC #3272)

Administration of Injectable Medications, Biologicals and Immunizations

December 23, 2020

We submit for your consideration the following comments on the proposed rulemaking published in the October 24, 2020 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Pharmacy (Board) to respond to all comments received from us or any other source.

1. Section 27.402. Application, renewal and reactivation procedures. – Protection of the public health, safety and welfare; Reasonableness.

Under this section, a pharmacist who is the holder of the authority to administer injectable medications, biologicals and immunizations (injectables) must renew the authority every two years along with the pharmacist's license to practice pharmacy. As part of that renewal process, a pharmacist must complete two hours of continuing education related to injectables and provide proof of current CPR certification.

Subsection (b)(2) of this section states that a pharmacy intern's authority to administer injectables, "is valid so long as the intern remains registered under § 27.26 (relating to pharmacy internship) and may not be renewed." Section 27.26(c) provides that a pharmacy intern registration is valid for six years. We are concerned that a pharmacy intern can administer injectables for this time frame without current training on the topic and question whether this is adequately protective of the health, safety and welfare of the citizens of the Commonwealth. In the Preamble to the final-form regulation we ask the Board to explain why it is reasonable to allow a pharmacist intern to administer injectables for a period of up to six years without updated training or education on the topic. In addition, how can the Board ensure that pharmacy interns are current with their CPR certification?

We suggest that the final-form regulation be amended to include provisions to ensure pharmacy interns, similar to pharmacists, are up-to-date on the most recent information regarding injectables and also current with their CPR certification.

2. Section 27.403. Conditions for administration. – Clarity.

Subsection (e) states that injectable immunizations shall be administered, “in accordance with treatment guidelines established by the Centers for Disease Control and Prevention and which have been approved by the Board.” Act 8 of 2015 (Act 8) recently amended Section 9.2(a)(3) of the Pharmacy Act (Pharmacy Act (63 P.S. § 390-9.2(a)(3))) to require administration of injectables to be administered in accordance with guidelines established by a physician and “the Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices Guidelines or another competent authority.” (Emphasis added.) We suggest that the final-form regulation be amended to more accurately reflect the language of statute.

3. Section 27.406. Notification requirements. – Clarity.

Paragraph (1) requires pharmacists or pharmacy interns administering injectables to notify the “ordering prescriber and the patient’s primary care provider, if known, as soon as practicable, but no longer than 48 hours after the administration of certain information. Similarly, Paragraph (2) requires notification of “the patients primary care provider, if known and the participating/protocol physician” within the same time frame. Paragraph (3) requires notification within 24 hours to the primary care provider and the participating/protocol physician when a patient experiences an adverse event or reaction. We have two concerns.

First, as noted by a commentator, how is a patient’s primary care provider to become known to the pharmacist and/or the pharmacy intern? The commentator also seeks additional guidance on the notification requirements for pharmacists when an injectable was administered by an intern under their supervision. We ask the Board to clarify these issues in the Preamble and the final-form regulation.

Second, we believe the clarity of the rulemaking could be improved by defining what a “participating/protocol physician” is or including a reference to the section of the Board’s regulation that address protocol agreements between physicians and pharmacists.

4. Section 27.408. Professional liability insurance. – Implementation procedures; Clarity.

Act 8 amended the Pharmacy Act to require pharmacists to maintain professional liability insurance. This section of the proposal implements that requirement. We have two questions. First, does the insurance cover negligent supervision by a pharmacist that is supervising a pharmacist intern that has authorization to inject? Second, since the pharmacy intern is not required to maintain professional liability insurance by this section, is there any insurance coverage if the pharmacist’s supervision is proper, but the pharmacy intern is negligent in administering the injection? We ask the Board to explain how this provision will be implemented in the Preamble to the final-form regulation.