RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Administration of Injectable Medications, Biologicals and Immunizations

The State Board of Pharmacy (Board) amends §§ 27.12, 27.401—27.407 and adds § 27.408 (relating to professional liability insurance) to read as set forth in Annex A.

Effective Date

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

Section 4(j) of the Pharmacy Act (act) (63 P.S. § 390-4(j)), authorizes the Board "to promulgate rules and regulations governing standards of practice and operation of pharmacies including, but not limited to, rules and regulations governing the method of advertising, promotion and standards for dispensing prescriptions, such regulations to be designed to insure methods of operation and conduct which protect the public health, safety and welfare and prevent practices or operations which may tend to lower professional standards of conduct, so as to endanger the public health and welfare." Section 6(k)(1) and (9) of the act (63 P.S. §§ 390-6(k)(1) and (9)), also authorizes the Board "to regulate the practice of pharmacy" and "to promulgate rules and regulations to effectuate the purposes of this act and to regulate the distribution of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare." Section 9.2(a) of the act (63 P.S. § 390-9.2(a)), states that the Board "shall by regulation establish education and training standards and practice guidelines to which pharmacists shall be authorized to administer injectable medications, biologicals and immunizations. . ."

Background and Need for the Amendment

Section 9.2 of the act permits the Board to regulate a pharmacist's ability to administer injectable medications, biologicals and immunizations. This final-form rulemaking amends Chapter 27 (relating to State Board of Pharmacy) to conform to amendments made by the act of June 26, 2015 (P.L. 29, No. 8) (Act 8 of 2015). Act 8 of 2015 amended section 9.2 of the act to allow a pharmacist to administer influenza immunizations by injectable or needle-free delivery methods to children 9 years of age or older. Additionally, section 9.2 now allows a qualified and authorized pharmacy intern to administer injectable medications, biologicals and immunizations to persons 18 years of age or older and administer influenza immunizations by injectable or needle-free delivery methods to children ages 9 years of age or older. Section 9.2 also requires pharmacists authorized to administer injectable medications, biologicals and immunizations to maintain professional liability insurance a minimum of $1 million per occurrence or claims made.

Summary and Responses to Comments and Description of Amendments to the Final-Form Regulation

Notice of the proposed rulemaking was published at 50 Pa.B. 5844 (October 24, 2020). Publication was followed by a 30-day public comment period during which the Board received comments from the Pennsylvania Medical Society (PAMED), the National Association of Chain Drug Stores (NACDS)/Pennsylvania Association of Chain Drug Stores (PACDS), the Pennsylvania Society of Physician Assistants, the Pennsylvania Pharmacists Association and the Pennsylvania Osteopathic Medical Association (POMA). The Board also received comments from the Independent Regulatory Review Commission (IRRC) as part of its review under the Regulatory Review Act (71 P.S. §§ 745.1—745.14). The Board received no comments from the House Professional Licensure Committee (HPLC) or the Senate Consumer Protection and Licensure Committee (SCP/PLC).

Comments from the PAMED

PAMED and IRRC commented regarding the notification requirement to the primary care provider. Both PAMED and IRRC question how the identity of the primary care provider is to become known to the pharmacist. While neither the act nor the regulations indicate how the identity of the primary care provider is to be discerned, it is usually accomplished by the pharmacist requesting the information from the patient. Pharmacists are only authorized to administer injectable medications, biologicals and immunizations by either order or under a written protocol. If the pharmacist is administering under an order, the order must have the minimum information that is required under § 27.404(b) (relating to authority and requirements). One of the requirements is that the name of the prescriber needs to be listed. Under § 27.406(a)(1) (relating to notification requirements), the ordering prescriber must be notified, and if known, the primary care provider. If the pharmacist is administering under a written protocol, the written protocol must have the record keeping requirements and procedures for notification of administration, which may include notification requirements to primary care providers. See § 27.404(c). While pharmacists will know the ordering prescriber or the participating/protocol provider, the Board is aware that not every patient will have or identify a primary care provider.

In reviewing the concerns raised by PAMED and IRRC, the Board has determined that additional clarification is needed. In this final-form rulemaking, the Board amends the notification requirements to clarify that pharmacists and pharmacy interns administering injectable medications, biologicals or immunizations must request primary care provider information. To implement this requirement, the Board adds § 27.406(b), which requires a pharmacist or pharmacy intern to request and document the name and address of the patient's primary care provider. The Board does not see a need to specify how this request occurs; it could occur verbally, on an intake form or in another manner. The Board acknowledges that not all patients have primary care providers or will provide information; however, this provision clarifies the obligation to ask for the primary care provider information and to document it for recordkeeping purposes. Adding this provision helps ensure that pharmacists have available primary care provider information for notification purposes. This requirement is consistent with the Board's current record keeping requirements at § 27.405(a)(4) (relating to recordkeeping), which requires a pharmacist to maintain the name and address of the patient's primary health care provider if that information is identified by the patient. Moreover, this final-form

amendment facilitates and ensures appropriate communication between pharmacists and primary care providers regarding the administration of injectable medications, biologicals and immunizations, which as PAMED noted, is crucial to assisting in the management of possible adverse reactions and ensuring continuity of care.

Second, PAMED and IRRC requested clarification as to the role of the supervising pharmacist regarding notification requirements. Specifically, PAMED asked three questions:

- 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?

Under the act and the regulations, the supervising pharmacist has the ultimate responsibility to ensure that the administration of the injectable is being done correctly, which includes the record keeping and notification requirements. See sections 9.2(a)(7) and (b) of the act and § 27.403 (relating to conditions for administration). The pharmacy intern, however, is authorized under the regulations in § 27.406 to notify the ordering prescriber, the participating/protocol physician and the primary care provider, if known. Section 27.406(a)(3) allows for either the supervising pharmacist or the pharmacy intern to make the proper notification. As to which one makes the notification, that should be decided between the supervising pharmacist and the pharmacy intern. Notably, however, the supervising pharmacist has the duty to ensure that the notification is done correctly.

Comments from the NACDS/PACDS

NACDS/PACDS supported the proposed rulemaking and noted the importance of this final-form rulemaking given the novel coronavirus (COVID-19) pandemic. The comment indicates that pharmacy interns would be an untapped source of vaccinators that could help assist with administering the flu vaccine and the COVID-19 vaccine. Since the publication of the proposed rulemaking, pharmacy interns have been authorized to administer vaccines. The act gave the pharmacy interns the authority to administer injectables. Originally, the Board was waiting to have the regulations in place to start issuing authorizations, however, due to the COVID-19 pandemic and noting that the statutory authority to issue the authorizations to pharmacy interns existed, the Board decided to issue the authorizations before the regulations were finalized. Therefore, since the Board has been issuing authorizations, NACDS/PACDS concern relating to losing students is no longer an issue. NACDS/PACDS also mentions amendments to the Federal Public Readiness and Emergency Preparedness (PREP) Act. The amendments to the PREP Act are in response to the COVID-19 pandemic and are outside the scope of this final-form rulemaking. Pharmacy interns have been administering vaccines, including the COVID-19 vaccine since it became available to administer. Also, the Board is not accepting pharmacy intern certificates as a substitute for an authorization to administer because the pharmacy intern certificate does not ensure that the pharmacy intern meets the Board's qualifications to administer injectables.

Comments from POMA

POMA applauds the Board for the strengthening clarification to include notification to the patient's primary care provider and for shortening the timeframe for the notification and supports the Board's efforts in this regard. POMA also notes that the notification is not always occurring and that some osteopathic physicians have expressed frustration when they do not have the knowledge that their patients have been vaccinated at a pharmacy. To address this concern, as explained in response to PAMED's comment, the Board amends the notification requirements to clarify that pharmacists and pharmacy interns administering injectable medications, biologicals or immunizations must request primary care provider information. This amendment ensures that pharmacists request primary care provider information. The Board understands that having the information is only the first step in the notification process. The existing and final-form regulations contain the notification requirements; however, enforcement of the notification requirements is currently handled by and will continue to be handled by the Bureau of Enforcement and Investigation and the Department of State Prosecution Division through the complaint process. If a physician or other individual knows of a pharmacist who has not or is not properly communicating with or notifying physicians, a complaint should be filed with the Bureau's Professional Compliance Office. Pharmacists who fail to notify, under the requirements of the regulations, of the administration of the injectable, or the supervising pharmacist in the case of a pharmacy intern performing the administration, could be subject to disciplinary action under the act and the regulations.

Supportive Comments

Comments from the Pennsylvania Society of Physician Assistants

The Pennsylvania Society of Physician Assistants is in favor of this final-form rulemaking and noted that the supervision of the pharmacy intern adds a layer of safety in the administration of injectable medications, biologicals and immunizations. The commentor also stated that the regulations add clarity to the notification process in the event of an adverse reaction.

Comments from the Pennsylvania Pharmacists Association

The Pennsylvania Pharmacists Association submitted a comment to IRRC and stated that it "wholeheartedly supports and agrees with these proposed regulations and urges for their finalization."

Comments from IRRC

IRRC had four comments regarding this final-form rulemaking. First, IRRC questioned whether the proposed regulations in § 27.402(b)(2) (relating to application and renewal procedures) were adequate to protect the health, safety and welfare of the citizens of this Commonwealth. IRRC expressed concern that pharmacy interns may be administering injectables without current training or education on the topic and also asked how the Board would ensure that pharmacy interns are current with cardiopulmonary resuscitation (CPR) certification. Under section 9.2(b) of the act, a pharmacy intern who has completed the required course of education and training may administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age and influenza immunizations by injectable or needle-free delivery methods to persons 9 years of age and older only under the direct, immediate and personal supervision of a pharmacist holding the authority to administer

injectable medications, biologicals and immunizations. As a part of the education and training for pharmacy interns, section 9.2(b) of the act requires completion of an academic and practical curriculum and maintenance of a current CPR certificate; it does not require supplemental training and education or completion of continuing education. Thus, the General Assembly determined that the initial training and education and maintenance of CPR is sufficient to ensure public safety. In addition to obtaining the initial education and training, which includes the CPR certificate, the Board notes that pharmacy interns are under the direct supervision of a supervising pharmacist, who must maintain a current authorization to administer injectables. The supervising pharmacist is responsible for ensuring that the pharmacy intern is aware of any changes to the practice of pharmacy which includes administering injectables. To make it clear that a current CPR certification is necessary, the Board adds § 27.402(b)(3) to clearly state that a pharmacist and a pharmacy intern must maintain current CPR certification when administering injectables.

Second, IRRC recommended amending § 27.403(e) to accurately reflect the language in the act. The Board agrees with this suggestion and amends the section to reflect the act.

Third, IRRC commented regarding the notification requirements under § 27.406 and asked for clarification regarding notification requirements for pharmacists when an injectable was administered by an intern under their supervision. The Board addressed these questions in its response to PAMED's questions. IRRC also asked for a definition of a "participating/protocol physician" or a reference to the Board's regulation that addresses protocol agreements between physicians and pharmacists. In response, the Board adds a definition for a "participating/protocol physician" in this final-form rulemaking in § 27.406(c). A "participating/protocol physician" is the physician or institution that has entered into a written protocol with a pharmacist under § 27.404(c)(1). The definition references § 27.404(c), which relates to written protocols for administering injectables.

Fourth, IRRC requested clarity on § 27.408 concerning professional liability insurance. Specifically, IRRC asked if the insurance covers negligent supervision by a pharmacist that is supervising a pharmacist intern that has the authorization to inject. IRRC also asked whether there is any insurance coverage if the pharmacist's supervision is proper, but the pharmacy intern is negligent in administering the injection. Professional liability insurance requirements set forth in § 27.408 provide protection to patients. The supervising pharmacist is responsible for the pharmacy intern's overall actions in the pharmacy. Significantly, a pharmacist cannot delegate the authority to administer injectable medications, biologicals and immunizations, but rather, may only allow a pharmacy intern to administer the injectables under direct, immediate and personal supervision. See section 3(f) of the act (63 P.S. § 390-3(f)) and section 9.2(b) of the act and § 27.12 (relating to practice of pharmacy and delegation of duties). If a supervising pharmacist fails to properly supervise a pharmacy intern where the pharmacy intern has committed some type of negligence, the Board would view the pharmacist as being incompetent, grossly negligent, or departing from, or failing to conform to, the standards of acceptable and prevailing pharmacy practice. See section 5(a)(12) of the act (63 P.S. § 390-5(a)(12)). This degree of supervision provides for accountability. Additionally, most pharmacies and health care institutions have liability insurance that covers the actions of its employees. Pharmacy interns who are employees of the pharmacy or institution would be covered under this type of policy. Thus, the professional liability insurance and supervision requirements protect the public regardless of whether a pharmacist or pharmacy intern administer the injection.

Fiscal Impact and Paperwork Requirements

This final-form rulemaking will have minimal fiscal impact on the Commonwealth and no fiscal impact on its political subdivisions. This final-form rulemaking will impose additional paperwork requirements upon the Board in the form of creating and processing applications for pharmacy interns; however, costs for processing applications would not adversely impact the Board because costs associated with processing applications are borne by the licensees through application fees. To implement Act 8 of 2015 and the proposed regulations, the Board created new forms and revised some existing forms, which had minimal fiscal impact to the Board.

This final-form rulemaking will have some financial impact in the form of fees and education for pharmacy interns who elect to apply for the authorization to administer injectable medications, biologicals and immunizations. The Board has no way of knowing how many pharmacy interns will apply for authorization to administer injectables but using the same percentage of pharmacists that applied for the authorization to administer injectables (44%), the total costs incurred for applications in Fiscal Year 2020-2021 would be approximately $65,160. Since most pharmacy schools have incorporated the required education into the curriculum, most pharmacy interns should not incur additional costs in education. Even assuming all applying pharmacy interns would either be required to take the initial education or would be required to repeat the training, the cost of education for the 44% of pharmacy interns would be $868,800. For subsequent years, the Board estimates an average annual cost to new pharmacy interns of $36,000 (the cost associated with the fee).

For pharmacists, because Act 8 of 2015 expanded the ability of pharmacists to perform immunizations to minors, pharmacists engaging in this activity already have the required training and equipment and no additional costs will be incurred by pharmacists. The Board estimates the total cost per pharmacist to be as follows: $400 for the approved Pharmacy-Based Immunization Delivery course, an application fee of $30 and the cost to obtain professional liability insurance in the amount of $1 million ($415). The only new cost associated with Act of 2015 and this final-form regulation is the cost of professional liability insurance. Assuming the Board continues to receive 1,100 new applications from pharmacists seeking the authority to administer injectables each year, the fiscal impact to pharmacists would be $456,500 annually.

This final-form rulemaking will impose additional paperwork requirements for licensees, including submission of forms to the Board (applications for authority to administer injectables and reactivation forms), recordkeeping (documentation of the pharmacy intern and supervising pharmacist for each administration), parental consent documentation, notification requirements to primary care providers and professional liability insurance coverage record disclosure requirements.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on October 8, 2020, the Board submitted a copy of the notice of proposed rulemaking, published at 50 Pa.B. 5844, to IRRC and to the Chairpersons of the SCP/PLC and the HPLC for review and comment.

Under section 5(c) of the Regulatory Review Act, the Board shall submit to IRRC, the HPLC and the SCP/PLC copies of the comments received during the public comment period, as well as other documents when requested. In preparing this final-form rulemaking, the Board has considered all comments from IRRC and the public. The Board received no comments from the HPLC or the SCP/PLC.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on May 18, 2022, this final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on May 19, 2022, and approved the final-form rulemaking.

Additional Information

Additional information may be obtained by writing to Melanie Zimmerman, Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 2540), (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form regulation.

(3) This final-form regulation does not include any amendments that would change the scope of the proposed rulemaking published at 50 Pa.B. 5844.

(4) This final-form rulemaking adopted by this order is necessary and appropriate for the administration of the act.

Order

The Board therefore orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 27, are amended by amending §§ 27.12, 27.401—27.407, and adding § 27.408 to read as set forth in Annex A with ellipses referring to the existing text of the regulations.

(b) The Board shall submit this final-form rulemaking to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Board shall submit this final-form rulemaking to the IRRC, the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee for approval as required by law.

(d) The Board shall certify this final-form rulemaking and deposit them with the Legislative Reference Bureau as required by law.

(e) This final-form rulemaking shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

JANET GETZEY HART, RPH,
Chairperson

(*Editor's Note*: See 52 Pa.B. 3294 (June 4, 2022) for IRRC's approval order.)

Fiscal Note: Fiscal Note 16A-5429 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

STANDARDS

§ 27.12. Practice of pharmacy and delegation of duties.

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(c) *Pharmacy interns.*

(1) A pharmacy intern may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

(2) A pharmacy intern may neither enter nor be in a pharmacy if a pharmacist is not on duty.

(3) A pharmacy intern working under the direct, immediate, personal supervision of a pharmacist may perform procedures which require professional skill and training. Examples of these procedures include: verifying ingredients, weighing ingredients, compounding ingredients and other similar processing of ingredients.

(4) A pharmacy intern working under the direct, immediate and personal supervision of a pharmacist may administer injectable medications, biologicals and immunizations if the pharmacist and the pharmacy intern each hold an active authorization to administer injectable medications, biologicals and immunizations issued by the Board, in accordance with §§ 27.401—27.408.

(d) *Pharmacy technicians.*

(1) A pharmacy technician may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

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ADMINISTRATION OF INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS

§ 27.401. Qualifications for authority.

A pharmacist or pharmacy intern may apply to the Board for authority to administer injectable medications, biologicals and immunizations. A candidate for authority to administer injectable medications, biologicals and immunizations shall meet the following requirements:

(1) The pharmacist holds an active license to practice pharmacy or the pharmacy intern holds an active intern registration in this Commonwealth.

(2) The pharmacist or pharmacy intern has completed a course of education and training which meets the requirements of § 27.407 (relating to education requirements).

(3) The pharmacist or pharmacy intern holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.

§ 27.402. Application, renewal and reactivation procedures.

(a) *Application.* An applicant for authority to administer injectable medications, biologicals and immunizations shall submit the following to the Board:

(1) An application obtained from the Board along with the fee required by § 27.91 (relating to schedule of fees).

(2) Certification that the applicant has completed the required education and training in § 27.407 (relating to education requirements).

(3) Certification that the applicant holds an acceptable, current CPR certificate.

(b) *Renewal.*

(1) A pharmacist who is the holder of the authority to administer injectable medications, biologicals and immunizations shall renew the authority every 2 years along with the pharmacist's license to practice pharmacy. Renewal requires completion of a form provided to the pharmacist by the Board in advance of the renewal period, payment of the fee specified by § 27.91, certification of completion of 2 hours of continuing education required by section 9.2 of the act (63 P.S. § 390-9.2) and § 27.32 (relating to continuing education), and proof of a current CPR certificate.

(2) A pharmacy intern's authority to administer injectable medications, biologicals and immunizations is valid so long as the intern remains registered under § 27.26 (relating to pharmacy internship) and may not be renewed.

(3) A pharmacist and a pharmacy intern must maintain a current CPR certificate at all times when administering injectable medications, biologicals or immunizations.

(c) *Lapse.* A pharmacist who intends to allow the authority to administer injectable medications, biologicals and immunizations to lapse shall notify the Board on the pharmacist's biennial license renewal form.

(d) *Reactivation.*

(1) A pharmacist who has had a lapsed authority for less than 2 years and seeks reactivation of the authority to administer injectable medications, biologicals and immunizations shall complete a form provided to the pharmacist by the Board, pay the renewal fee specified by § 27.91, complete 2 hours of continuing education required by section 9.2 of the act and § 27.32 and provide proof of a current CPR certificate.

(2) A pharmacist who has had a lapsed authority for 2 years or more and seeks reactivation of the authority to administer injectable medications, biologicals and immunizations shall complete a form provided to the pharmacist by the Board, retake and successfully complete the required education set forth in § 27.407, pay the renewal fee specified by § 27.91 and provide proof of a current CPR certificate.

§ 27.403. Conditions for administration.

(a) A pharmacist or pharmacy intern who is granted authority may administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age. A person is more than 18 years of age on the day following the person's 18th birthday.

(b) A pharmacist or pharmacy intern who is granted authority may administer influenza immunizations by injectable or needle-free delivery methods to persons 9 years of age or older.

(c) A pharmacist may not delegate the administration of injectable medications, biologicals and immunizations to another person.

(d) A pharmacy intern who has been authorized by the Board to administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age and influenza immunizations by injectable or needle-free delivery methods to persons 9 years of age or older under § 27.401 (relating to qualifications for authority) may do so only under the direct, immediate and personal supervision of a pharmacist who holds an active authority to administer injectable medications, biologicals and immunizations.

(e) A pharmacist or pharmacy intern shall administer injectable immunizations in accordance with treatment guidelines established by a physician and the Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices Guidelines or another competent authority approved by the Board.

§ 27.404. Authority and requirements.

(a) A pharmacist or pharmacy intern authorized by the Board to administer injectable medications, biologicals and immunizations may only do so under either an order or written protocol.

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§ 27.405. Recordkeeping.

(a) A pharmacist who administers an injectable medication, biological or immunization or who supervises the administration by a pharmacy intern shall maintain the following records regarding each administration for a minimum of 2 years:

(1) The name, address and date of birth of the patient.

(2) The date of the administration and site of the injection.

(3) The name, dose, manufacturer, lot number and expiration date of the medication, biological or immunization.

(4) The name and address of the patient's primary health care provider, as identified by the patient.

(5) The name or identifiable initials of the administering pharmacist. If the administration was performed by a pharmacy intern, the name or identifiable initials of the pharmacy intern and the supervising pharmacist.

(6) Documentation of informed consent for administration of injectable medications, biologicals and immunizations, and in the case of influenza immunizations administered to patients under 18 years of age, documentation of written parental consent.

(7) The nature of an adverse reaction and who was notified.

(b) A pharmacist who administers an immunization or supervises the administration by a pharmacy intern shall also maintain the following records regarding each administration for a minimum of 2 years:

(1) An identification of the Vaccine Information Statement (VIS) that was provided.

(2) The date of publication of the VIS.

(3) The date and to whom the VIS was provided.

(c) In an institution, the information required to be maintained in subsections (a) and (b) may be maintained in the patients' medical records.

§ 27.406. Notification requirements.

(a) A pharmacist or pharmacy intern administering injectable medications, biologicals or immunizations shall meet the following notification requirements:

(1) When administration has occurred under an order, the pharmacist or pharmacy intern shall notify the ordering prescriber and the patient's primary care provider, if known, as soon as practicable, but no longer than 48 hours after administration of the following:

(i) The identity of the patient.

(ii) The identity of the medication, biological or immunization administered.

(iii) The route of administration.

(iv) The site of the administration.

(v) The dose administered.

(vi) The date of administration.

(2) When the administration has occurred under a written protocol, the pharmacist or pharmacy intern shall notify the patient's primary care provider, if known, and the participating/protocol physician, as soon as practicable, but no longer than 48 hours after administration of the following:

(i) The identity of the patient.

(ii) The identity of the medication, biological or immunization administered.

(iii) The site of the administration.

(iv) The dose administered.

(v) The date of administration.

(3) In the event of any adverse event or reaction experienced by the patient either under an order or a written protocol, the pharmacist or pharmacy intern shall notify the ordering prescriber, the patient's primary care provider, if known, and the participating/protocol physician, if applicable, as soon as practicable, but no longer than 24 hours after learning of the adverse event or reaction.

(b) A pharmacist or pharmacy intern administering injectable medications, biologicals or immunizations shall request and document, if identified by the patient, the name and address of the patient's primary care provider.

(c) For purposes of this section, the term "participating/protocol physician" means the physician or institution that has entered into a written protocol with an authorized pharmacist, which governs the administration of injectable medications, biologicals and immunizations for a specific period of time or purpose as specified in § 27.404(c) (relating to authority and requirements).

§ 27.407. Education requirements.

(a) To apply for the authority to administer injectable medications, biologicals and immunizations, a pharmacist or pharmacy intern shall meet the following education requirements:

(1) Complete within the 3-year period prior to application an evidence-based course that meets the following criteria:

(i) Includes study material.

(ii) Includes hands-on training and techniques for administration.

(iii) Requires testing with a passing score.

(iv) Provides a minimum of 10 hours of instruction and experiential training.

(v) Complies with current guidelines and recommendations by the Centers for Disease Control and Prevention, ACPE or a similar health authority or professional body.

(2) The course must provide instruction on the following topics:

(i) Basic immunology and the human immune response.

(ii) Mechanics of immunity, adverse effects, dose and administration schedule of available vaccines.

(iii) Response to an emergency situation as a result of the administration of an injectable medication, biological or immunization.

(iv) Administration of subcutaneous, intradermal and intramuscular injections.

(v) Disease epidemiology.

(vi) Standards for immunization practices.

(vii) Vaccine-preventable diseases.

(viii) Recommended immunization schedules.

(ix) Vaccine storage and management.

(x) Biohazard waste disposal and sterile techniques.

(xi) Informed consent.

(b) The Board approves courses offered by ACPE-accredited providers and educational institutions that meet the criteria and provide instruction on the topics listed in subsection (a).

§ 27.408. Professional liability insurance.

(a) To qualify for authority to administer injectable medications, biologicals and immunizations, a pharmacist must certify the maintenance of professional liability insurance coverage in the minimum amount of $1 million per occurrence or claims made.

(b) A pharmacist who does not maintain the required professional liability insurance in the minimum amount of $1 million may not engage in the practice of administering injectable medications, biologicals and immunizations and may not supervise the administration by a pharmacy intern.

(c) A pharmacist shall, upon request, make available to the Board or its agents all records relating to the pharmacist's maintenance of professional liability insurance, including policies, cancelled checks, receipts or other proofs of premium payment.

[Pa.B. Doc. No. 22-1007. Filed for public inspection July 8, 2022, 9:00 a.m.]