Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

IRRC Number: 3272

(1) Agency
Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy

(2) Agency Number: **16A**
Identification Number: **5429**

(3) PA Code Cite: **49 Pa. Code §§ 27.12, 27.401-27.408**

(4) Short Title: **Administration of Injectable Medications, Biologicals and Immunizations**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Juan A. Ruiz, Board Counsel, State Board of Pharmacy; (717)783-7200; jruiz@pa.gov**
Secondary Contact: **Jacqueline A. Wolfgang, Acting Senior Regulatory Counsel, Department of State; (717) 783-7200; jawolfgang@pa.gov**

(6) Type of Rulemaking (check applicable box):

X Proposed Regulation
☐ Final Regulation
☐ Final Omitted Regulation
☐ Emergency Certification Regulation;
☐ Certification by the Governor
☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The rulemaking amends existing regulations at §§ 27.12, 27.401-27.407, and adds § 27.408 (relating to professional liability insurance). The main objective of the rulemaking is to amend Chapter 27 to conform to the amendments made to section 9.2 of the act, which were 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 authorize pharmacists to administer influenza immunizations by injectable or needle-free delivery methods to children ages nine to eighteen. Additionally, section 9.2 allows qualified and authorized pharmacy interns to administer injectable medications, biologicals and immunizations and administer influenza immunizations by injectable or needle-free delivery methods to children ages nine to eighteen. Section 9.2 also requires pharmacists who are authorized to administer injectable medications, biologicals and immunization to have professional liability insurance in the amount of $1,000,000 per occurrence or claims made.

(8) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized under sections 4(j), 6(k)(1) and (9) and 9.2 of the Pharmacy Act (act) (63 P.S. §§ 390-4(j), 390-6(k)(1) and (9) and 390-9.2).

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The proposed regulation is needed to conform the existing regulations to amendments to section 9.2 of the act (63 P.S. § 390-9.2) made by the act of June 26, 2015 (P.L. 29, No. 8) (Act 8 of 2015), and to further implement section 9.2 of the act.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

Section 9.2 of the act permits the Board to regulate a pharmacist's ability to administer injectable medications, biologicals and immunizations. This proposed rulemaking would amend Chapter 27 to conform to amendments made by 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 ages nine to eighteen. Additionally, section 9.2 now allows qualified and authorized pharmacy interns to administer injectable medications, biologicals and immunizations and administer influenza immunizations by injectable or needle-free delivery methods to children ages nine to eighteen. Section 9.2 of the act also requires pharmacists authorized to administer injectable medications, biologicals and immunizations to have professional liability insurance in the amount of $1,000,000 per occurrence or claims made.

The citizens of this Commonwealth will benefit from the ability to have their children receive needed immunizations for influenza at their local pharmacies instead of having to make medical appointments with their physician. In addition, this change in the law will benefit future pharmacists by allowing them to engage in this hands-on supervised pharmacy practice as an intern.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The proposed rulemaking is not more stringent and does not conflict with any Federal requirements.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

All surrounding states regulate the administration of injectable medications by pharmacists and pharmacy interns. New York allows the administration of immunizations to persons age 18 and older by a licensed pharmacist. (Education Law §§ 6806 and 6828 and Part 63 of the Commissioner's Regulations at § 63.9). Maryland allows the administration of immunizations to persons age 11 and older and allows influenza immunizations to persons age 7 and older by a licensed pharmacist or a licensed pharmacy intern under direct supervision under COMAR 10.34.32.03. West Virginia allows the administration of immunizations to persons 18 and older

by a licensed pharmacist or a licensed pharmacy intern under direct supervision under W. Va. Code § 15-12.3. New Jersey allows the administration of immunizations to persons age 18 and older and allows influenza immunizations to persons age 7 and older by a licensed pharmacist or licensed pharmacy intern under N.J.A.C. 45:14-63. Ohio allows the administration of immunizations to persons age 13 and older and allows influenza immunizations to persons age 7 and older by a licensed pharmacist or a licensed pharmacy intern under direct supervision in accordance with Ohio Admin. Code Rule 4729.41. Finally, Delaware allows the administration of immunizations to persons 18 and older by a licensed pharmacist or a licensed pharmacy intern under direct supervision under section 14.0 of Title 24 Regulated Professions and Occupations of the Delaware Administrative Code (relating to regulated professions and occupations).

Authorizing pharmacy interns to administer injectables does not negatively impact competition in this Commonwealth because the surrounding states incorporate similar versions of the proposed regulation. Citizens of this Commonwealth will benefit from the ability to have their children receive needed immunizations for influenza at their local pharmacies instead of having to make medical appointments with physicians. In addition, this change in the law will benefit future pharmacists by allowing them to engage in this hands-on supervised pharmacy practice as an intern. Therefore, the proposed regulation should not put Pennsylvania at a competitive disadvantage with the surrounding states.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The proposed rulemaking does not affect other regulations of the Board or other state agencies.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

In accordance with Executive Order 1996-1, the Board sent an exposure draft of this proposed rulemaking to pharmacy and professional associations, hospitals, pharmacy schools and other stakeholders that the Board has identified as having an interest in this rulemaking and received input from the following interested parties: Joseph Lavino, Pharm.D., R.Ph., J.D., Director of Pharmacy Regulatory Affairs for CVS Health; Dennis A. Giorno of Malady & Wooten, LLP; Edward Bechtel, R.Ph., licensed independent pharmacist and former Chair of the Pennsylvania State Board of Pharmacy; Bryan Dunwoody, Manager of Pharmacy Compliance for Ahold USA; Patricia A. Epple, Executive Director, Pennsylvania Pharmacists Association; Patricia D. Kroboth, Ph.D., Dean of the University of Pittsburgh School of Pharmacy; Jill McCormack, Director, State Government Affairs of the National Association of Chain Drug Stores; Mike Podgurski, R.Ph., President of the Pennsylvania Association of Chain Drug Stores and former member of the Pennsylvania State Board of Pharmacy; Julie L. Olenak, Pharm.D., Assistant Dean of Student Affairs Wilkes University School of Pharmacy; Margaret A. O'Grady, RN, MSN, OCN, President of the Pennsylvania Society of Oncology & Hematology; and Lisa A. Lawson, Pharm.D., Dean of Philadelphia College of Pharmacy. The Board discussed the

proposed rulemaking at numerous public meetings. Public meetings of the Board are routinely attended by interested parties and stakeholders, including representatives from the Pennsylvania Pharmacists' Association.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

All pharmacists and pharmacy interns who apply for or possess the authority to administer injectable medications, biologicals and immunizations will be impacted by the regulations. There are approximately 23,223 pharmacists and 4,936 pharmacy interns licensed by the Board and of those approximately 10,193 pharmacists currently have the authority to administer injectables. The Board averages approximately 1,100 new applications from pharmacists seeking the authority to administer injectables each year, and the Board registers an average of 1,200 pharmacy interns each year. The proposed rulemaking will allow pharmacy interns to enhance their intern experience through registration to administer injectable medications, biologicals and immunizations.

According to the Pennsylvania Department of Labor and Industry, as of 2017 (the most recent year for which data is available) most pharmacists work in pharmacies and drug stores (43%) and general medical and surgical hospitals (25%), while a minority of pharmacists work in electronic shopping and mail-order houses (online pharmacies) (6.00%); specialty hospitals (1.80%), the Federal government (1.80%), home health care services (1.46%), drugs and druggists' goods merchant wholesalers (1.36%), offices of physicians (0.68%) or are self-employed (1.32%).

Small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). According to the NAICS standards for the places where pharmacists work, a small business for pharmacies and drug stores is $30 million or less in average annual receipts. For general medical and surgical hospitals and specialty hospitals, a small business is $41.5 million or less in average annual receipts. Electronic shopping and mail-order houses are considered small businesses if they have $41.5 million or less in average annual receipts. The small business threshold for home health care services is $16.5 million or less in average annual receipts. For all other health and personal care stores, the small business threshold is $8 million or less in average annual receipts. The small business threshold for offices of physicians is $12 million or less in average annual receipts. Finally, in terms of wholesalers, medical, dental and hospital equipment and supplies merchant wholesalers are considered small businesses if they have 200 or less employees.

The Board is not able to estimate how many pharmacies are small businesses as the Board does not collect financial or employment information from pharmacies. Many pharmacies such as large retail chains would not qualify as "small businesses" under the SBA definition; however, the Board believes that some of the 3,402 licensed pharmacies may qualify as small businesses owned and operated by individuals. Most general medical and surgical hospitals and specialty hospitals in this Commonwealth do not qualify as small businesses. The Board does not have

sufficient information to determine the extent to which the remaining types of business where pharmacists work (online pharmacies, specialty hospitals, home health care services, drugs and druggist goods merchant wholesalers, offices of physicians) are small businesses. Whether pharmacists or pharmacy interns work in small or large businesses, this regulation will affect only those who apply for or possess the authority to administer injectable medications, biologicals and immunizations, and the Board expects the effects to be positive for pharmacists, pharmacy interns, pharmacies and other businesses. Citizens of this Commonwealth will benefit from the ability to have their children receive needed immunizations for influenza at their local pharmacies instead of having to make medical appointments with physicians. In addition, this change in the law will benefit future pharmacists by allowing them to engage in this hands-on supervised pharmacy practice as an intern.

Although the Board thinks this is unlikely, if small businesses voluntarily pay for pharmacy intern costs associated with the training and the application fee, there would be a fiscal impact. Additionally, to the extent that businesses voluntarily pay for professional liability insurance, there will also be a fiscal impact. The benefits, however, of allowing pharmacists to administer immunizations and allowing interns to administer injectables would likely outweigh the negative impact relating to these costs.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

All pharmacists and pharmacy interns who elect to engage in the practice of administering injectable medications, biologicals and immunizations would be required to comply with the provisions of this rulemaking. There are approximately 23,223 pharmacists and 4,936 pharmacy interns currently licensed by the Board and of those approximately 10,193 pharmacists currently have the authority to administer injectables. The Board has no way of knowing at this time how many of the 4,936 pharmacy interns or how many of the remaining 13,030 pharmacists may seek to obtain the authority to administer injectable medications, biologicals and immunizations. However, historically the Board has averaged approximately 1,100 pharmacist applicants for this authority in each of the past five years; and an average of 1,200 new pharmacy interns per year over the past five years. The proposed rulemaking will apply to individual pharmacists and pharmacy interns and will impose no requirements on pharmacies or other entities, including small businesses.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

Pharmacists and pharmacy interns who elect to participate in the administration of injectable medications, biologicals and immunizations will incur additional costs. While the proposed regulations require professional liability insurance in the amount of one million dollars, this requirement is reiteration of a statutory requirement in section 9.2 of the act, which was effective with Act 8 of 2015, and for which the Board does not have any discretion. Pharmacists who are authorized to administer injectables already must carry professional liability insurance that would cover administration of injectable medications, biologicals and immunizations; therefore, this cost impacted pharmacists when Act 8 of 2015 was effective.

Because Act 8 of 2015 expanded the ability of pharmacists to administer 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 only new cost associated with Act 8 of 2015 and this proposed regulation is the cost of professional liability insurance, which is often provided by their employer. The Board estimates the cost of professional liability insurance at approximately $415, annually.

Regarding the impact to pharmacy interns, most pharmacy schools have incorporated the required training reflected in the proposed regulations soon after the act was amended in 2015; therefore, many interns have already completed the required education. However, under the proposed regulation, if an intern completes the education more than three years prior to applying for this authority, the intern would be required to re-take the course. The average cost to attend an approved Pharmacy-Based Immunization Delivery course is $400. Thus, a currently registered pharmacy intern who chooses to apply for this authorization may incur costs of up to $430 – the cost of the course and the application cost. The Board's proposed amendment in § 27.407(a)(1) (relating to education requirements), which increases the length of time between completion of the required education and application for authority to administer injectable medications, biologicals and immunizations from two to three years, will lessen the fiscal impact to licensees who have to retake the course because the education will be valid for an additional year.

The benefits of regulations setting forth the expanded ability to administer injectable medications, biologicals and immunizations will enhance the quality of service for patients. Expanding authority to pharmacy interns is beneficial to those interns because they will be able to practice skills relating to injectables during internships. Prior to Act 8 of 2015, this Commonwealth risked loss of interns to out-of-state locations in neighboring states (New York, New Jersey, Maryland, Ohio and West Virginia) that allow pharmacy interns to immunize.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The benefits of ensuring the safe practice of administering injectable medications, biologicals and immunizations as set forth above greatly outweigh the costs of compliance and recordkeeping. Compliance requirements include professional liability insurance for pharmacists; supervision requirements; application fees; education; documentation of parental consent for patients under the age of 18; notification requirements to primary care providers; and professional liability insurance coverage record disclosure requirements. The citizens of this Commonwealth will benefit from the ability to have their children receive needed immunizations for influenza at their local pharmacies instead of having to make medical appointments with their physician. In addition, this change in the law will benefit future pharmacists by allowing them to engage in this hands-on supervised pharmacy practice as an intern. This will also help with providing more people to assist with administration of immunizations, especially during times of a pandemic.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Pharmacists that elect to participate in the administration of injectable medications, biologicals

and immunizations might incur additional costs to ensure their pharmacy operation complies with the safety and administration standards as required by the proposed regulations. It is believed that because this is an expansion of the authority to administer injectables that many Pennsylvania pharmacists are already operating under the requirements of the existing regulations. There are approximately 23,223 pharmacists and 4,936 pharmacy interns currently licensed/registered by the Board and of those approximately 10,193 pharmacists already have the authority to administer injectables. Thus, approximately 44% of currently licensed pharmacists hold an authorization to administer injectable medications, biologicals and immunizations. Under Act 8 of 2015 and the proposed regulations, professional liability insurance is the only new cost to pharmacists. Based upon the Board's average of approximately 1,100 new applications from pharmacists seeking the authority to administer injectables each year, the Board estimates an annual cost of $456,500. However, since Act 8 of 2015 requires compliance with professional liability requirements, the proposed regulations do not cause additional costs outside what the act already requires.

The Board has no way of knowing at this time how many of the existing 4,936 pharmacy interns will seek to obtain the authority to administer injectable medications, biologicals and immunizations. Assuming a similar ratio as pharmacists of 44%, 2,172 pharmacy interns would incur application costs of $65,160. The Board has no way of knowing how many existing pharmacy interns would need to repeat the approved training prior to applying. Assuming all of them may need to do so, the total costs to complete the training could be as high as $868,800. This would result in an initial cost to existing pharmacy interns of $933,960. In addition, the Board has issued an average of 1,200 pharmacy intern registrations annually. Assuming this trend continues, and that future interns will have already completed the required training and apply for this authorization, the Board estimates an average annual cost to pharmacy interns of $36,000 (the cost associated with the application fee).

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with the rulemaking.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

There may be minimal costs associated with tracking and issuing new credentials to the pharmacy interns when and if they decide to engage in the administration of injectables. Any costs would be borne by the licensees through application fees.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Pharmacists who engage in the administration of injectables already have recordkeeping requirements under the existing regulations. The recordkeeping and paperwork requirements under the proposed rulemaking include submission of forms to the Board (applications for authority to administer injectables and reactivation forms) the identification of the pharmacy intern and supervising pharmacist if the pharmacy intern administered the injectables, documentation of parental consent for patients under the age of 18, notification requirements to primary care providers, and professional liability insurance coverage record disclosure requirements. There does not appear to be any additional paperwork requirements to be placed upon the Commonwealth other than the issuance of additional authorizations should the interns choose to apply. However, those costs will be borne by the applicants through the application fee.

(22a) Are forms required for implementation of the regulation?

Yes.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

Although the agency is transitioning to online application processes, a sample application form is attached. (*See*, Attachment "A") The attached form is the representation of the online form used for pharmacists applying for authorization to administer injectable medications, biologicals and immunizations. The required information will be the same for pharmacy interns, with the exception of the professional liability insurance information found in question 2.

Also attached is a sample reactivation form for pharmacists whose authorization to administer injectable medications, biologicals and immunizations has lapsed. (*See*, Attachment "A") Pharmacy intern registrations do not lapse (they are only valid for up to 6 years and may not be renewed). Therefore, no reactivation form is required for pharmacy interns.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2020-21	FY +1 2021-22	FY +2 2022-23	FY +3 2023-24	FY +4 2024-25	FY +5 2025-26
SAVINGS:						
Regulated Community						
Local Government						
State Government						
Total Savings	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
COSTS:						

Regulated Community: **Pharmacists**	**$0**	**$456,000**	**$456,000**	**$456,000**	**$456,000**	**$456,000**
Pharmacy Interns	**$0**	**$933,960**	**$ 36,000**	**$ 36,000**	**$ 36,000**	**$ 36,000**
Local Government						
State Government						
Total Costs	**$0**	**$1,389,960**	**$1,389,960**	**$1,389,960**	**$1,389,960**	**$1,389,960**
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY 2017-18	FY 2018-19	FY 2019-20	Current FY (2020-21)
State Board of Pharmacy	**$2,472,419.19**	**$2,847,054.62**	**$2,845,000**	**$2,945,000 (budgeted)**

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(a) As outlined in Paragraph 15 above, the Board is unable to estimate the number of small businesses that are subject to the regulation because the Board does not track where licensees are employed.

(b) The recordkeeping and paperwork requirements under the proposed rulemaking include submission of forms to the Board (applications for authority to administer injectables and reactivation forms) the identification of the pharmacy intern and supervising pharmacist if the pharmacy intern administered the injectables, documentation of parental consent for patients under the age of 18, notification requirements to primary care providers, and professional liability insurance coverage record disclosure requirements.

(c) The Board does not expect this regulation to have an adverse impact on small businesses. If small businesses voluntarily pay for pharmacy intern costs associated with the training and the application fee or if the small business paid for professional liability insurance, there would be an impact; however, the benefits of the regulation would likely outweigh the negative impact relating to these costs. No pharmacist or pharmacy intern is required to apply for this authorization and may simply elect not to engage in the administration of injectable medications, biologicals and immunizations. It is anticipated that the revenues generated to a pharmacy in providing these services would outweigh the anticipated costs, or the pharmacy would not offer the services. The Board believes that the benefits of this regulation as it pertains to public protection through additional availability of providers of injectable medications, biologicals and immunizations, should vastly outweigh any costs involved.

(d) There are not any less intrusive or less costly alternatives methods.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

The Board has determined that there are no special needs of any subset of its licensees for whom special accommodations should be made.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered. Many of the new requirements in the proposed rulemaking (e.g., the professional liability insurance requirement) are a result of statutory requirements and are not subject to change. The Board believes that the regulations represent the least burdensome acceptable manner of accomplishing the Board's mandate in protecting the public health, safety and welfare with regard to administration of injectables.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the

regulation.

a) **The compliance/reporting requirements required of any business, including small businesses, under this proposed regulation is based on the industry standard for administering injectables and as such, promotes public health and safety. The Board did not consider making any exceptions for small businesses. To do so would compromise the safety of the consumers receiving injectable medications, biologicals and immunizations.**
b) **The regulations establish no schedules or deadlines for which small businesses need to be accommodated.**
c) **The Board does not believe the compliance/reporting requirements need to be simplified for small businesses.**
d) **The regulations do not contain any design or operational standards for which small businesses need to be accommodated.**
e) **The Board did not consider exempting small businesses from any part of the regulation. It would not be consistent with the public health, safety or welfare to make exceptions to the regulations.**

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

No specific data formed the basis for this proposed regulation. The regulation was needed to ensure public safety based on the expansion of the ability in Act 8 of 2015 to provide injectables by pharmacy interns and allowing minors to receive flu immunizations administered by pharmacists and pharmacy interns. The Board is merely amending its regulations to conform with the changes made to the current law.

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period: **30 days after publication as proposed.**

B. The date or dates on which any public meetings or hearings will be held: **The Board reviews all regulatory proposals at regularly scheduled board meetings. See item (30) below for a schedule of meeting dates.**

C. The expected date of delivery of the final-form regulation: **Fall 2021.**

D. The expected effective date of the final-form regulation: **Upon publication as final.**

E. The expected date by which compliance with the final-form

regulation will be required: **Upon publication as final.**

F. The expected date by which required permits, licenses or other approvals must be obtained: **N/A**

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled monthly public meetings. The Board will meet on the following remaining dates in 2020: September 1, October 13 and December 1.

ATTACHMENT "A"

PENNSYLVANIA STATE BOARD OF PHARMACY

REACTIVATION APPLICATION – AUTHORIZATION TO ADMINISTER INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS

(#854 137, Rev. 7/20)

Board of Pharmacy
PO Box 2649
Harrisburg, PA 17105-2649

Courier Address:
2601 N. Third Street
Harrisburg, PA 17110

Name:_____

Address:_____

_____

Authorization No.: RPI_____

Please make the check or money order in U.S. funds payable to the "Commonwealth of Pennsylvania." Fees are NOT refundable nor transferable. A processing fee of $20.00 will be charged for any check or money order returned by your bank, regardless of the reason for non-payment.

Name Change	Address Change
Indicate new name below and submit a photocopy of a legal document verifying name change (i.e. marriage certificate, divorce decree indicating retaking of a maiden name, other "legal" document indicating the retaking of a maiden name or a court order)	

Check the one applicable statement.

☐ 1. I have **not administered injectables** in Pennsylvania after my authorization to administer injectables expired and I am requesting inactive status. No fee is due. A signature and date are required below.

☐ 2. **Yes**, I have administered injectable medications, biologicals and/or immunizations in Pennsylvania after my authorization to administer injectables expired and I want to reactivate my authorization at this time by paying the renewal fee of $30.00 + the late fee of $5.00 per month, or part of the month. Note: The late fee is assessed for each month or part of the month after your authorization to administer injectables expired.

☐ 3. **No**, I have not administered injectable medications, biologicals and/or immunizations in Pennsylvania at any time after my authorization to administer injectables expired and I want to reactivate my authorization at this time by paying the renewal fee of $30.00.

The following questions must be answered if you are reactivating your authorization to administer injectable medications, biologicals and immunizations:

YES	NO	
		1. Do you maintain a current basic cardiopulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body **approved by the Board of Pharmacy?** A list of approved CPR providers/programs is posted at www.dos.pa.gov/pharm. **Note: A photocopy of the front and back of your CPR card/certificate and any necessary legend must be submitted with your reactivation forms.**
		2. Do you maintain the required professional liability insurance coverage in the amount of at least $1,000,000 per occurrence or claims made in relation to your authority to administer injectable medications, biologicals and immunizations?
		2. Is your Pennsylvania pharmacist license currently active and, if the Board is in a renewal period, is your pharmacist license renewed through the next renewal period?
		3. Have you met your continuing education requirements for this authorization?

I verify that this application is in the original format as supplied by the Department of State and has not been altered or otherwise modified in any way. I am aware of the criminal penalties for tampering with public records or information under 18 Pa.C.S. § 4911.

I verify that the statements in this application are true and correct to the best of my knowledge, information and belief. I understand that false statements are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities) and may result in the suspension, revocation or denial of my license, certificate, permit or registration.

Signature **(Mandatory)**: _____ Date_____

VERIFICATION OF PRACTICE / NON-PRACTICE

*** Your reactivation cannot be processed unless this page is completed ***

Name:_____

Address:_____

_____

Authorization No.: RPI_____

PROFESSION: PHARMACY

Be sure you are familiar with the definition of your profession from the licensing law which

pertains to the license you are renewing/reactivating, THEN answer the following questions.

1. Have you administered injectable medications, biologicals and/or immunizations in Pennsylvania since your Pennsylvania authorization to administer injectable medications, biologicals and immunizations lapsed or since you placed it on inactive status?

   CIRCLE ONE: YES NO

2. Have you been employed by the federal government in the practice of your profession and been administering injectable medications, biologicals, or immunizations since your Pennsylvania authorization to administer injectables, biologicals and immunizations lapsed or since you placed it on inactive status?

   CIRCLE ONE: YES NO

   If you responded "yes" to Question 2, when working for the federal government, did you use an authorization to administer injectable medications, biologicals and immunizations issued to you by another state? Please list the state that issued that authorization to you:_____

I verify that this application is in the original format as supplied by the Department of State and has not been altered or otherwise modified in any way. I am aware of the criminal penalties for tampering with public records or information under 18 Pa.C.S. § 4911.

I verify that the statements in this application are true and correct to the best of my knowledge, information and belief. I understand that false statements are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities) and may result in the suspension, revocation or denial of my license, certificate, permit or registration.

_____
(Signature of Licensee)

_____
(Date)

Continuing Education Requirements - Board Regulation Section 27.32:

(a) The Board will renew the license of a pharmacist who has completed a minimum of 30 contact hours (3 CEU) of continuing education during the preceding biennial renewal period. Beginning with the license period commencing on October 1, 2011, 2 of the required 30 contact hours shall be completed in courses from the ACPE topic designator "Patient Safety." In addition, for licensees with authority to administer injectable medications, biologicals and immunizations in accordance with section 9.2 of the act (63 P. S. § 390-9.2) and § 27.401 (relating to qualifications for authority), at least 2 of the required 30 hours must concern the administration of injectable medications, biologicals and immunizations, including, but not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events and related topics. Except as provided in subsection (h), only continuing education programs offered by ACPE-accredited providers of continuing pharmaceutical education targeted toward pharmacists are acceptable to the Board.

(e) A newly graduated licensee will be exempt from the requirements in subsection (a) for the license renewal immediately following licensure. A reciprocally licensed pharmacist will be required to show compliance with the requirements in subsection (a), but will have the number of hours required to be completed prorated, on a quarterly basis, from the date of licensure to the next date of renewal. For this purpose, each quarter will consist of 3 months, and will be credited for 3.75 contact hours (.375 CEU). The pharmacist will be required to begin accumulating contact hours at the beginning of the next quarter following licensure.

You are required to retain your official continuing education certificates of completion earned for this license renewal period, maintain current basic CPR certification from acceptable providers, and maintain professional liability insurance coverage in the amount of at least $1,000,000 per occurrence or claims made in accordance with Section 9.2(a)(6) of the Pharmacy Act until October 1, 2022. Proof of compliance must be provided to the Board or its agents when requested.

Please review the following before mailing in the required items. Have you:

- ☐ Completed the questions, marked the appropriate statements and provided other required information on the application, including signatures and dates?

- ☐ Reported a name/address change (if applicable)?

- ☐ Included the correct fee (check or money order made payable to the "Commonwealth of PA")? The reactivation fee is $30.00. If you practiced with an expired authorization, please also include the $5.00 per month late fee.

- ☐ Submitted a photocopy of the front and back of your CPR card/certificate, and any necessary legend, issued by a Board-approved CPR provider? Please visit the Board's web site at www.dos.pa.gov/pharm for a list of acceptable CPR providers/programs.

- ☐ Submitted photocopies of certificates of completion of the appropriate number of contact hours of ACPE-approved continuing education programs concerning the administration of injectable medications, biologicals and immunizations as described in Board Regulation § 27.32(a) (unless exempt)?

  Note: Do not submit all the continuing education that you earned for the current pharmacist license renewal. It will not be reviewed nor will it be returned to you.

Notice: If your application is over one year old and you have not met the requirements for the reactivation of your authorization, an entirely new application and fee must be submitted.

Pharmacy- Authorization to Administer Injectables- Application
Initial [redacted]

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
P. O. Box 2649
Harrisburg, PA 17105-2649

APPLICANT INFORMATION

PERSONAL INFORMATION

Last Name	[redacted]		First Name	[redacted]			
Middle Name	[redacted]		Suffix				
Full Name	[redacted]						
SSN	[redacted]	Date Of Birth	[redacted]	Age	[redacted]	Gender	

ADDRESS DETAILS

Street Address	[redacted]		
City/State/Zip	[redacted]		
County	[redacted]	Country	United States

CONTACT DETAILS

Phone number	[redacted]	Mobile Phone number	
Primary Email Address	[redacted]	Secondary Email Address	[redacted]

CHECKLIST ITEMS

Checklist name	Status	Submitted Date	Expiration Date
Application	Pending Review	06/26/2020	06/26/2021
Application Fee	Completed	06/26/2020	06/26/2021
CPR Certification	Pending Review	06/26/2020	
Education Verification	Not Received	06/26/2020	

STANDARD QUESTIONS

	Questions	Answer
1	I agree that I will hold and maintain a current basic cardiopulmonary resuscitation (CPR) certificate issued by an acceptable provider approved by the Board.	Y
2	I agree that while I hold an active authorization to administer injectable medications, biologicals and immunizations I will maintain professional liability insurance coverage in the amount of at least $1,000,000 per occurrence or claims made. I understand that failure to maintain insurance coverage as required will subject me to disciplinary proceedings.	Y
3	Have you completed the American Pharmacists Association's Pharmacy-Based Immunization Delivery certificate program, either through the American Pharmacists Association or one of their partners, upload a copy of your final Certificate of Achievement that verifies completion of the entire 20-hour program? (If you did not complete the American Pharmacists Association's Pharmacy-Based Immunization Delivery certificate program, make arrangements to have your education/training provider complete and directly submit to the Board office the "Education Verification" form.)	Y

RELATIONSHIP/ASSOCIATION REQUEST

License Number	Name	Relationship Type	Address	License Expiration Date
[redacted]	[redacted]	PRE REQUISITE	[redacted]	09/30/2020

PA VETERANS REGISTRY		
Questions		**Answer**
1	Have you served in the U.S. Armed Forces?	N
2	Thank you for your service. Would you like to register with the PA Veterans Registry? The PA Veterans Registry provides veterans with information about federal, state and local benefits, programs and services that are available to Pennsylvania veterans and links veterans with resources that can provide assistance. Registration is quick and easy, and provides the Department of Military and Veterans Affairs (DMVA) with a way to contact you regarding the benefits and services you may be eligible for. If you check "Yes," you will receive an email with instructions to assist you in registering.	

CONFIRMATION	
☑	All fees are non-refundable. Please check to continue with your transaction. (06/26/2020 21:48:42)

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

Lois P. Lara
BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

STATE BOARD OF PHARMACY
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5429

DATE OF ADOPTION: _____

BY: _____
Theresa M. Talbot, R.Ph.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: Marisa H. Z. Lehr

9/2/2020
DATE OF APPROVAL

(Deputy General Counsel
Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

PROPOSED RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27

§§ 27.12, 27.401—27.408

ADMINISTRATION OF INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS

The State Board of Pharmacy (Board) proposes to amend §§ 27.12, 27.401-27.407, and to add § 27.408 (relating to professional liability insurance) to read as set forth in Annex A.

Effective date

The proposed amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed amendments are authorized under sections 4(j), 6(k)(1) and (9) and 9.2 of the Pharmacy Act (act) (63 P.S. §§ 390-4(j), 390-6(k)(1) and (9) and 390-9.2).

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 proposed rulemaking would amend Chapter 27 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 ages nine to eighteen. Additionally, section 9.2 now allows a qualified and authorized pharmacy intern to administer injectable medications, biologicals and immunizations to persons who are more than eighteen years of age and administer influenza immunizations by injectable or needle-free delivery methods to children ages nine to eighteen. Section 9.2 also requires pharmacists authorized to administer injectable medications, biologicals and immunizations to maintain professional liability insurance a minimum of $1,000,000 per occurrence or claims made.

Description of the Proposed Amendments

Section 27.12 (relating to practice of pharmacy and delegation of duties) would be amended to add subsection (c)(4) allowing a pharmacy intern under the direct, immediate and personal supervision of a pharmacist to administer injectable medications, biologicals and immunizations provided the pharmacy intern and the pharmacist each hold an active authorization to administer injectable medications, biologicals and immunizations issued by the Board.

Section 27.401 (relating to qualifications for authority) would be amended to add language allowing a pharmacy intern to apply for the authority administer injectable medications, biologicals and immunizations.

Section 27.402 (relating to application and renewal procedures) would be amended to rename the heading of the section to "Application, renewal and reactivation procedures" to fully reflect the amendments made in this section. In § 27.402(a), the Board proposes amendments that include pharmacy interns in the application process for authority to administer injectable medications, biologicals and immunizations. In § 27.402((b), the proposed amendments make clear that only pharmacists are required to renew the authority to administer injectable medications, biologicals and immunizations. Under section 27.402(b)(2), pharmacy intern authority to administer injectable

medications, biologicals and immunizations is valid so long as their intern certificate is valid under § 27.26 (relating to pharmacy internship). Under § 27.26, pharmacy intern certificates are valid for 6 years and may not be renewed. In addition, the Board proposes to add subsection (c) pertaining to lapse and subsection (d) pertaining to reactivation. Subsection (d)(1) would allow a pharmacist to renew the authority to administer injectables after a brief lapse (less than 2 years) without having to retake the required education and training in § 27.407 (relating to education requirements). However, if a pharmacist's authority to administer injectable medications, biologicals or immunizations is lapsed for 2 or more years, subsection (d)(2) would require the pharmacist to retake and successfully complete the required education. Subsection (c) and (d) serve to codify the Board's current procedures.

Section 27.403 (relating to conditions for administration) would be amended to add language to allow a pharmacist or pharmacy intern to provide influenza immunizations by injectable or needle-free delivery to persons 9 years of age or older and to allow a pharmacy intern to administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age. Section 27.403(d) requires a pharmacist's direct, immediate and personal supervision of a pharmacy intern who administers injectable medications, biologicals and immunizations.

Further, the Board proposes to amend § 27.404(a) (relating to authority and requirements) to add language allowing a pharmacy intern to administer injections under an order or written protocol.

To conform with the amendments to section 9.2 of the act regarding parental consent, section 27.405 (relating to recordkeeping) would be updated to add language requiring documentation of written parental consent for minors who receive injections and to add a requirement to record the name or initials of a pharmacy intern and the supervising pharmacist if the pharmacy intern administered the injectable medication, biological or immunization.

The Board would amend § 27.406 (relating to notification requirements) to reduce the notification timeline from 72 hours to 48 hours in conformity with amendments to section 9.2 of the act, and to apply notification requirements to the administration of injectable medications, biologicals and immunizations by pharmacy interns. In addition, this section was amended to clarify which physician is to be notified when the administration has occurred under an order or a written protocol and who to notify if there is an adverse reaction, because there has been some confusion among the licensee population.

Section 27.407 (relating to education requirements) would apply the education requirements to pharmacy interns. Subsection (a)(1) would amend the education requirements by changing the evidence-based course time frame from 2 years to 3 years prior to application to accommodate the influx of students applying for the authorization, without disrupting the pharmacy schools' education curriculum. The Board proposed to remove subsection (a)(2)(xii) as a required course topic as it is not necessary for the performance of administering injectable medications.

The Board proposes to add § 27.408 (relating to professional liability insurance) to implement the amendments to section 9.2 of the act that require maintenance of professional liability insurance in the minimum amount of 1 million dollars per occurrence or claims made. Subsection (a) requires a pharmacist applying for authority to administer injectable medications, biologicals and

immunizations to certify the maintenance of professional liability insurance coverage in the amount of 1 million dollars per occurrence or claims made. Subsection (b) provides that only pharmacists who maintain the required professional liability insurance may engage in the practice of administering injectable medications, biologicals and immunizations and may supervise the administration by a pharmacy intern. Finally, subsection (c) provides that the pharmacist shall, upon request, make available to the Board all records relating to the pharmacist's maintenance of professional liability insurance.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have minimal fiscal impact on the Commonwealth and no fiscal impact on its political subdivisions. The 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.

The 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 (FY) 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 $1,000,000 ($415). The only new cost associated with Act 8 of 2015 and this proposed 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 $456,000 annually.

The 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 this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Juan A. Ruiz, Counsel, State Board of Pharmacy, by mail at P.O. Box 69523, Harrisburg, PA 17106-9523, or by email at RA-STRegulatoryCounsel@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-5429 (Injectable Medication, Biologicals and Immunizations), when submitting comments.

Theresa M. Talbott, R.Ph.
Chairperson

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.

* * * * *

(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.

* * * * *

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 [and], 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 [pharmacist] applicant has completed the required education and training in § 27.407 (relating to education requirements).

(3) Certification that the [pharmacist] 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.

(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.

[(c)] (e) A pharmacist or pharmacy intern shall administer injectable immunizations in accordance with treatment guidelines established by the Centers for Disease Control and Prevention and which have been 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.

* * * * *

§ 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 the age of 18, 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 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 [72] 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 [participating physician] patient's primary care provider, if known, and the participating/protocol physician, as soon as practicable, but no longer than [72] 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 patient's [physician] primary care provider and the participating/protocol physician, if applicable, as soon as practicable, [and in no event later] but no longer than 24 hours after learning of the adverse event or reaction.

§ 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 [2] 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.

[(xii) Authority and recordkeeping requirements as provided in this chapter.]

(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 $1,000,000 per occurrence or claims made.

(b) A pharmacist who does not maintain the required professional liability insurance in the minimum amount of $1,000,000 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.

* * * * *

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

October 8, 2020

The Honorable George D. Bedwick, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5429 - INJECTABLE MEDICATIONS BIOLOGICALS AND IMMUNIZATIONS

Dear Chairman Bedwick:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to 16A-5429 - Injectable Medications Biologicals and Immunizations.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Theresa M. Talbott, R.Ph., Chairperson
State Board of Pharmacy

TMT/JAR:aaw
Enclosure

cc: K. Kalonji Johnson, Acting Commissioner of Professional and Occupational Affairs
Kraig R. Kiehl, Deputy Secretary of Regulatory Programs
Marc Farrell, Deputy Director of Policy, Department of State
Cynthia Montgomery, Deputy Chief Counsel, Department of State
Jacqueline A. Wolfgang, Regulatory Unit Counsel, Department of State
Juan A. Ruiz, Board Counsel, State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5429
SUBJECT:	Administration of Injectable Medications, Biologicals and Immunizations
AGENCY:	DEPARTMENT OF STATE Bureau of Professional and Occupational Affairs State Board of Pharmacy

TYPE OF REGULATION

RECEIVED
OCT -8 2020
Independent Regulatory Review Commission

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Disapproved Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		Senate ~~*HOUSE*~~ *COMMITTEE ON PROFESSIONAL LICENSURE*
		MAJORITY CHAIR Robert M. Tomlinson
		MINORITY CHAIR Lisa M. Boscola
		House ~~*SENATE*~~ *COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE*
10/8/20	Emily L Cobb	MAJORITY CHAIR David Hickernell
10/8/20	Susan E Yerger	MINORITY CHAIR Harry A. Readshaw
		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

September 28, 2020

Worthington, Amber

From: Bulletin <bulletin@palrb.us>
Sent: Thursday, October 8, 2020 9:51 AM
To: Worthington, Amber
Subject: [External] Read: Proposed Rulemakin - 16A-5429 Injectable Medications, Biologicals and Immunizations
Attachments: [External] Read: Proposed Rulemakin - 16A-5429 Injectable Medications, Biologicals and Immunizations

Worthington, Amber

From: Bulletin <bulletin@palrb.us>
Sent: Thursday, October 8, 2020 10:20 AM
To: Tomlinson, Senator Robert; boscola@pasenate.com; jerry.livingston@pasenate.com; jmsmeltz@pasen.gov; Blauch, Tammy
Cc: Martin, Megan; Vincent Deliberato; Duane Searle; A.J. Mendelsohn; Wolfgang, Jacqueline; Worthington, Amber
Subject: [External] Delivery of Proposed Rulemaking – 16A-6712 Education Programs; 16A-5429 Injectables...; 16A-7103 Schedule of Civil Penalties
Attachments: 16A-6712 Boscola.pdf; 16A-6712 Tomlinson.pdf; 16A-5429 Boscola.pdf; 16A-5429 Tomlinson.pdf; 16A-7103 Tomlinson.pdf; 16A-7103 Boscola.pdf

We have attached Proposed Rulemakings 16A-6712, 16A-5429 & 16A-7103.

Please confirm receipt of this email by replying to all.

Thank you.

The Pennsylvania Code & Bulletin Office

Worthington, Amber

From: Martin, Megan <Mtmartin@os.pasen.gov>
To: Worthington, Amber
Sent: Thursday, October 8, 2020 10:36 AM
Subject: Read: Proposed Rulemaking – 16A-6712 Education Programs; 16A-5429 Injectables...; 16A-7103 Schedule of Civil Penalties

Your message

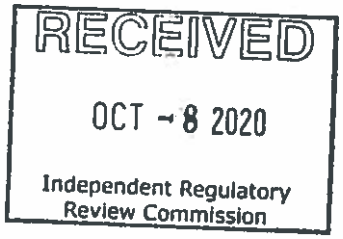
To:
Subject: Proposed Rulemaking – 16A-6712 Education Programs; 16A-5429 Injectables...; 16A-7103 Schedule of Civil Penalties
Sent: Thursday, October 8, 2020 2:35:46 PM (UTC+00:00) Monrovia, Reykjavik

was read on Thursday, October 8, 2020 2:35:32 PM (UTC+00:00) Monrovia, Reykjavik.

Worthington, Amber

From: Livingston, Jerry <Jerry.Livingston@pasenate.com>
Sent: Thursday, October 8, 2020 9:34 AM
To: Worthington, Amber
Subject: RE: Proposed Rulemaking – 16A-6712 Education Programs; 16A-5429 Injectables...; 16A-7103 Schedule of Civil Penalties

Received, thank you.
-JJ



J.J. Livingston

Executive Director
Senate Consumer Protection & Professional Licensure Committee

Senator Lisa M. Boscola, Democratic Chair
458 Main Capitol Building
Harrisburg, PA 17120
(717) 787-4236
Jerry.Livingston@pasenate.com

From: Worthington, Amber <agontz@pa.gov>
Sent: Thursday, October 8, 2020 9:32 AM
To: Bulletin <bulletin@palrb.us>; Livingston, Jerry <Jerry.Livingston@pasenate.com>; Blauch, Tammy <tblauch@pasen.gov>; jmsmeltz@pasen.gov; Martin, Megan <mtmartin@os.pasen.gov>
Cc: Wolfgang, Jacqueline <jawolfgang@pa.gov>
Subject: Proposed Rulemaking – 16A-6712 Education Programs; 16A-5429 Injectables...; 16A-7103 Schedule of Civil Penalties

■ EXTERNAL EMAIL ■

Pursuant to SR 318, authorizing the Legislative Reference Bureau to transmit regulations to the appropriate committees for consideration, we are submitting Proposed Rulemakings – 16A-6712 Education Programs; 16A-5429 Injectable Medications, Biologicals and Immunizations; & 16A-7103 Schedule of Civil Penalties to the Senate Committee on Consumer Protection & Professional Licensure.

Please provide written (email) confirmation that this rulemaking was received by each of Committee chairs office's.

Amber Worthington, PLS | *Supervising Legal Assistant*
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