PROPOSED RULEMAKING

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Administration of Injectable Medications, Biologicals and Immunizations

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

Effective Date

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

Statutory Authority

This proposed 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).

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 (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 but under 19 years of age. 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 18 years of age and administer influenza immunizations by injectable or needle-free delivery methods to children 9 years of age or older but under 19 years of age. 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.

Description of the Proposed Amendments

Section 27.12 (relating to practice of pharmacy and delegation of duties) is proposed to 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) is proposed to 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) is proposed to 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 § 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) is proposed to 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, § 27.405 (relating to recordkeeping) is proposed to be amended 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 proposes to 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 is proposed to be 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) is proposed to be amended to 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 pro-

poses to delete 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

This proposed rulemaking will have minimal fiscal impact on the Commonwealth and no fiscal impact on its political subdivisions. This proposed 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 proposed 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 8 of 2015 and this proposed rulemaking 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.

This proposed 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 e-mail at RA-STRegulatoryCounsel@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-5429 (Injectable Medication, Biologicals and Immunizations), when submitting comments.

THERESA M. TALBOTT, RPh,
Chairperson

Fiscal Note: 16A-5429. No fiscal impact; (8) recommends adoption.

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.*

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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 **[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.

[(b)] (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.

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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 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-year]** **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).

(*Editor's Note*: The following text is proposed to be added and printed in regular type to enhance readability.)

§ 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. 20-1450. Filed for public inspection October 23, 2020, 9:00 a.m.]

STATE BOARD OF OCCUPATIONAL THERAPY EDUCATION AND LICENSURE

[49 PA. CODE CH. 42]

Educational Programs

The State Board of Occupational Therapy Education and Licensure (Board) proposes to amend §§ 42.1 and 42.13 (relating to definitions; and application for licensure) to read as set forth in Annex A.

Effective Date

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

Statutory Authority

Section 5(b) of the Occupational Therapy Practice Act (act) (63 P.S. § 1505(b)) authorizes the Board to "adopt rules and regulations not inconsistent with law as it deems necessary for the performance of its duties and the proper administration of this law." Section 8(2) of the act (63 P.S. § 1508(2)) sets forth the requirements for licensure, which include completion of "the academic requirements of an approved educational program in occupational therapy recognized by the board with the advice and consultation of recognized national accrediting agencies and professional organizations including the American Occupational Therapy Association. . ."

Background and Need for the Amendments

Under the Board's existing regulations at § 42.13(a)(2), an applicant must meet "the academic requirements of an educational program in occupational therapy approved by the Board, or an equivalent program as defined in § 42.1." Regarding educational programs, the Board's existing regulations do not specify which programs are "approved by the Board." In the United States, the Accreditation Council for Occupational Therapy Education (ACOTE) is the only accreditation agency that accredits occupational therapy programs, and thus, ACOTE approved educational programs are the only programs approved by the Board. Significantly, the Board's proposed regulations serve to codify the Board's current practices and procedures and do not change the Board's current educational program standards. In drafting this proposed rulemaking, as required by section 8(2) of the act, the Board consulted with the American Occupational Therapy Association (AOTA) through the Pennsylvania Occupational Therapy Association (POTA) as well as the only national accrediting agency that currently accredits occupational therapy programs, ACOTE.

In accordance with the requirements of Executive Order 1996-1 (4 Pa. Code §§ 1.371—1.382) (amended February 6, 1996), the Board sent an exposure draft of this proposed rulemaking to interested parties, including AOTA, POTA, ACOTE and the National Board for Certification in Occupational Therapy (NBCOT). AOTA, POTA, ACOTE and NBCOT all support the proposed regulations. Specifically, AOTA, which is the national professional association representing the interests of more than 213,000 occupational therapists, occupational therapy assistants and students of occupational therapy, including approximately 3,900 members in this Commonwealth stated that "AOTA supports the Board's proposed amendments which would repeal the definition of 'Equivalent Program' in § 42.1 and insert in § 42.13 a requirement that an applicant for licensure as an OT or OTA successfully complete an education programs for OTs or OTAs that is accredited by. . .ACOTE, recognized by the Board, or accredited by an accrediting agency recognized by the United States Department of Education. We fully support this revision to the Board's regulations as it will not require the Board to change its regulations if the entry level degree for OTs or OTAs changes in the future and it makes the licensing requirements clear for individuals seeking licensure in the state." POTA commented, "[t]hat this is forward thinking and allows the licensure board some options to determine which programs that they want to recognize, within the parameters of a nationally accredited program."

The Board spent significant time discussing this proposed rulemaking during six public board meetings, with representatives from NBCOT, POTA and occupational therapy programs from two educational institutions in this Commonwealth attending one or more meetings.

Description of the Proposed Amendments

The Board proposes to amend § 42.1 by deleting the definition of "equivalent programs." As more fully discussed as follows, the Board's proposed amendments are more specific than the existing regulations because the amendments set forth the educational programs recognized by the Board. Because the Board proposes to delete the reference to "equivalent programs" in § 42.13(a)(2), and this term is not used anywhere else in the regulations, there is no reason to provide a definition for this term.

The Board proposes to amend § 42.13(a)(2) by requiring applicants to successfully complete an educational program that is either accredited by ACOTE or another national programmatic accrediting agency recognized by the United States Department of Education and approved by the Board. Currently, and historically, there has been only one accreditation agency for educational programs in occupational therapy—ACOTE. Thus, the Board has historically approved educational programs that are ACOTE accredited. Although the Board is not aware of any other national accrediting agencies that accredit occupational therapy programs, the Board proposes a provision that would allow the Board to review and consider other national accrediting agencies in the event other agencies begin accrediting occupational therapy programs. The Board also proposes amendments to § 42.13(a)(3) to clarify the existing fieldwork experience requirements to reflect the proposed amendments made in paragraph (2).

The proposed amendments are consistent with the Board's current practice and procedures and do not change the Board's existing educational program requirements, but rather, serve to clarify and codify those requirements.

Fiscal Impact and Paperwork Requirements

The Board does not anticipate any fiscal impact or paperwork requirements relating to these amendments because applicants are already required to meet these requirements.

Sunset Date

The Board continuously monitors the cost effectiveness of the Board's 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 any 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, recommendations or objections regarding this proposed rulemaking to the Regulatory Counsel, State Board of Occupational Therapy Education and Licensure, P.O. Box 69523, Harrisburg, PA 17106-5923 or RA-STRegulatoryCounsel@pa.gov within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-6712 (Educational Programs) when submitting comments.

KERRI L. HAMPLE, OTD, OTR/L,
Chairperson

Fiscal Note: 16A-6712. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 42. STATE BOARD OF OCCUPATIONAL THERAPY EDUCATION AND LICENSURE

GENERAL PROVISIONS

§ 42.1. Definitions.

* * * * *

Commissioner—The Commissioner of Professional and Occupational Affairs.

[*Equivalent program*—A masters or certificate program in occupational therapy approved by the Board.]

Licensee—An individual who has been licensed under the act as an occupational therapist or an occupational therapy assistant.

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LICENSURE

§ 42.13. Application for licensure.

(a) To apply for licensure, an applicant shall pay the required fee and submit evidence satisfactory to the Board, on forms provided by the Board, that the applicant meets the following criteria:

(1) Is of good moral character.

(2) **[Has met the academic requirements of an educational program in occupational therapy approved by the Board, or an equivalent program as defined in § 42.1 (relating to definitions).]** **Has successfully completed an educational program for occupational therapists or occupational therapy assistants that is either:**

(i) Accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) or predecessor organizations.

(ii) Approved by the Board and accredited by a national programmatic accrediting agency recognized by the United States Department of Education.

(3) Has successfully completed a period of supervised fieldwork experience **[at a recognized educational institute or a training program approved by the educational institution where the academic requirements were met]** **as a part of an accredited educational program as required by paragraph (2)** as follows:

(i) For an occupational therapist, a minimum of 6 months of supervised fieldwork.

(ii) For an occupational therapy assistant, a minimum of 2 months of supervised fieldwork.

(4) Has passed the licensure examination or has qualified for a waiver of the licensure examination under § 42.12 (relating to waiver of licensure examination).

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[Pa.B. Doc. No. 20-1451. Filed for public inspection October 23, 2020, 9:00 a.m.]

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

[49 PA. CODE CH. 43b]

Schedule of Civil Penalties—Crane Operators

The Commissioner of Professional and Occupational Affairs (Commissioner) proposes to add § 43b.28 (relating to schedule of civil penalties—crane operators) to read as set forth in Annex A.

Effective Date

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

Statutory Authority

Section 3108(a)(1) of 63 Pa.C.S. (relating to civil penalties), authorizes the Commissioner, after consultation with licensing boards within the Bureau of Professional and Occupational Affairs (Bureau), to promulgate a schedule of civil penalties for violations of the respective acts or regulations of the licensing boards.

Background and Need for the Rulemaking

Section 3108(a)(1) authorizes agents of the Bureau to issue citations and impose civil penalties under schedules adopted by the Commissioner in consultation with the Bureau's boards and commissions. Section 3108(a)(1) citations streamline the disciplinary process by eliminating the need for formal orders to show cause, answers, adjudication and orders, and consent agreements. At the same time, licensees who receive a citation under section 3108(a)(1) retain their due process right to a hearing prior to the imposition of judgment. The use of section 3108(a)(1) citations has increased steadily since 1996, when the program was first implemented, and has become an important part of the Bureau's enforcement efforts. Section 3108(a)(1), authorizes the Board, as a licensing board within the Bureau, to levy a civil penalty of not more than $10,000 on any licensee or unlicensed person who violates any provision of the act or Board regulations. However, section 3108(a)(1)(iii) limits the civil penalty levied by citation to no more than $1,000 per violation.

Section 702(b) of the Crane Operator Licensure Act (act) (63 P.S. § 2400.702(b)) authorizes the State Board of Crane Operators (Board) to levy a civil penalty of up to $1,000 on a crane operator who violates a provision of the act, on an individual who operates a crane in violation of the act, or on an individual who holds himself out as a crane operator without being properly licensed. Section 703(a)(3) of the act (63 P.S. § 2400.703(a)(3)) further authorizes the Board to suspend or revoke the license of a crane operator who has willfully or repeatedly violated any of the provisions of the act or the Board's regulations.

This is the first time that the Board will participate in the citation program under section 3108(a)(1). The Commissioner and the Board believe that it is necessary to implement the civil penalties contained in this proposed rulemaking to act as a deterrent for violations of the statutory and regulatory requirements listed in the schedule of civil penalties and to streamline the disciplinary process to be more efficient and cost effective.

Description of Proposed Amendments

The Commissioner, in consultation with the Board, proposes to add § 43b.28 to establish a schedule of civil penalties for five enumerated offenses, including: operating a crane without a license, employing an unlicensed individual to operate a crane, holding oneself out as a crane operator or using the title "licensed crane operator" when not licensed to do so, practicing on a lapsed or expired license and failing to notify the Board in writing within 10 days of criminal proceedings in a court case against a licensed crane operator.

Operating a crane without a license is a serious infraction of both section 501(a) of the act (63 P.S. § 2400.501(a)) and the Board's regulation at § 6.41(a) (relating to unlicensed crane operation). An unlicensed individual who has not been properly trained to operate a crane could cause extensive damage to property as well as cause bodily harm to individuals at a construction site. Therefore, the Commissioner, in consultation with the Board, would propose a civil penalty of $750 for a first offense of operating a crane without a license. The Board determined that the penalty for a second offense should be higher than the $1,000 maximum which may be imposed by citation. Therefore, subsequent offenses would require formal disciplinary action.

Just as operating a crane without a license is a serious matter, so is employing, allowing, directing, retaining or hiring an unlicensed individual or independent contractor to operate a crane, which is a violation of section 501(b) of the act and the Board's regulation at § 6.43(a) (relating to aiding and abetting unlicensed crane operation). Therefore, the proposed civil penalty for a first offense would be $1,000, the maximum civil penalty that may be imposed by citation. Subsequent offenses would result in formal disciplinary action.

Additionally, persons who are not licensed by the Board may not hold themselves out as being able to operate a crane or use the title "licensed crane operator," as provided in section 501(e) of the act and the Board's regulation at § 6.41(a). To do so would trigger a civil penalty of $500 for the first offense, $750 for the second offense and formal action for subsequent offenses.

Operating a crane on a lapsed or expired (unregistered) license is a violation of the Board's regulation at § 6.31(a) (relating to duration of license), which requires all licensed crane operators to register biennially to retain the right to operate a crane. This proposal would progressively increase the civil penalty for continuing violations based on the length of time that the licensee continues to operate cranes while the license has lapsed. For a first offense, the Commissioner would propose a civil penalty of $50 per month, not to exceed $1,000, the maximum that may be imposed by citation. Lapses of over 24 months (more than one biennial period) would be met with formal action. For a second offense of up to 12 months, the proposed civil penalty would be $100 a month, not to exceed $1,000. Second offenses for a license lapsed over 12 months would result in formal action. Likewise, third or subsequent offenses would require formal action.

Finally, the Commissioner, in consultation with the Board, proposes a civil penalty of $750 for a first offense of failing to notify the Board in writing within 10 days of criminal proceedings in a court case against the crane operator, which is a violation of the Board's regulation at § 6.42(f) (relating to impaired operation of a crane and reportable conditions, incidents or events). Second and subsequent offenses would require formal action.

Fiscal Impact and Paperwork Requirements

This proposed rulemaking would have no adverse fiscal impact on the Commonwealth or its political subdivisions,

and would reduce the paperwork requirements of both the Commonwealth and the regulated community by eliminating the need for orders to show cause, answers, consent agreements and adjudication and orders for those violations subject to the citation process under section 3108(a)(1). The only fiscal impact would be borne by those persons who violate the act or regulations of the Board and are subject to the civil penalties proposed by the new schedule. However, this impact could be avoided by simply complying with the act and regulations of the Board. Additionally, the impact would be incurred whether the Commissioner adopts this schedule of civil penalties or not, as currently all violations require formal disciplinary action.

Sunset Date

The Commissioner and the Board continuously monitor the effectiveness of their 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 Commissioner 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 Commissioner, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to the Regulatory Counsel, Department of State, P.O. Box 69523, Harrisburg, PA 17106-9523 or by e-mail at RA-STRegulatoryCounsel@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-7103 (Schedule of civil penalties—crane operators), when submitting comments.

K. KALONJI JOHNSON,
Commissioner

Fiscal Note: 16A-7103. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 43b. COMMISSIONER OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Subchapter A. SCHEDULE OF CIVIL PENALTIES, GUIDELINES FOR IMPOSITION OF CIVIL PENALTIES AND PROCEDURES FOR APPEAL

(*Editor's Note*: The following section is proposed to be added and printed in regular type to enhance readability.)

§ 43b.28. Schedule of civil penalties—crane operators.

STATE BOARD OF CRANE OPERATORS

Violation under 63 P.S.	*Violation under 49 Pa. Code*	*Title/Description*	*Penalties*
Section 2400.501(a)	§ 6.41(a)	Operating a crane without a license	1st Offense—$750 Subsequent offenses—formal action
Section 2400.501(b)	§ 6.43(a)	Employing, allowing, directing, retaining or hiring an unlicensed individual or independent contractor to operate a crane	1st Offense—$1,000 Subsequent offenses—formal action
Section 2400.501(e)	§ 6.41(a)	Holding oneself out as being able to operate a crane or using the title "licensed crane operator" or the abbreviation "L.C.O." without a license	1st Offense—$500 2nd Offense—$750 Subsequent offenses—formal action
	§ 6.31(a)	Operating a crane on a lapse or expired (unregistered) license	1st Offense—Up to 24 months, $50 per month not to exceed $1,000; over 24 months—formal action 2nd Offense—Up to 12 months, $100 per month not to exceed $1,000; over 12 months—formal action Subsequent offenses—formal action

Violation under 63 P.S.	*Violation under 49 Pa. Code*	*Title/Description*	*Penalties*
	§ 6.42(f)	Failing to notify the Board in writing within 10 days of the institution of criminal proceedings in a court case against the crane operator	1st Offense—$750 Subsequent offenses—formal action

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