






TO: The Professional Practice Committee

FROM: Douglas E. Lentivech 

SUBJECT: Proposed Amendment to Sections 63.4 and 63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacy Interns

DATE: April 25, 2019

AUTHORIZATION(S):  

SUMMARY

Issue for Decision

Should the Board of Regents adopt the addition of subdivision (d) to §63.4 and the amendment of subdivision (b) of §63.9 of the Regulations of the Commissioner of Education relating to the administration of vaccinations by pharmacy interns?

Reason for Consideration

Required by State statute (Chapter 359 of the Laws of 2018).

Proposed Handling

The amendment will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as a permanent rule at the May 2019 meeting of the Board of Regents.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the January 2019 meeting of the Board of Regents, effective January 15, 2019. A Notice of Emergency Adoption and Proposed Rulemaking was published in the

State Register on January 30, 2019 for a 60-day public comment period. The Department received multiple comments from one commenter.

Because the January emergency action was set to expire on April 14, 2019, at the April 2019 Regents meeting, a second emergency action was necessary to ensure that the emergency rule adopted at the January 2019 Regents meeting could remain continuously in effect until the effective date of its adoption as a permanent rule.

Since the publication of the proposed rule in the State Register, Department staff discovered that the proposed rule inadvertently cited Education Law §6808 in two of its provisions, instead of Education Law §6806. Consequently, non-substantial revisions were made as follows:

In §§63.4(d) and 63.9(b)(4), the citations to Education Law §6808 were replaced with citations to Education Law §6806 because Education Law §6806, not Education Law §6808, was the statute that was amended by Chapter 359 of the Laws of 2018 (Chapter 359). These changes were made to conform the proposed regulation to the statute.

A copy of the rule and Assessment of Public Comment are attached. Supporting materials are available upon request for the Secretary to the Board of Regents.

Background Information

Pharmacists licensed in New York State were first authorized to administer immunizations to prevent influenza and pneumococcal disease in December 2008. In order to administer such immunizations, a pharmacist must be certified by the Department following completion of a satisfactory training program. Since that time, more than 14,800 registered pharmacists in New York State have received the required certification. In 2012 and 2013, vaccinations against acute herpes zoster (shingles) and meningococcal disease, respectively, were added to the types of immunizations that appropriately certified pharmacists are authorized to administer. Additionally, in 2018, pharmacists were authorized to administer seasonal influenza immunizations to children between two and eighteen years of age.

On December 7, 2018, the Governor signed Chapter 359, which, effective immediately, *inter alia*, amended Education Law §6806 to allow the administration of immunizations by certain pharmacy interns who are certified to administer immunizations under the immediate and personal supervision of a licensed pharmacist certified to immunize. Chapter 359 was enacted, in part, to make immunizations more readily available and to provide certified pharmacy interns with valuable hands-on clinical experience, while under the oversight and supervision of a licensed pharmacist, who is certified to administer immunizations.

Chapter 359 permits a pharmacy intern to receive a certificate of administration which permits administration of immunizations under the immediate and personal supervision of a licensed pharmacist certified to administer immunizations; establishes procedures and requirements for a pharmacy intern to receive a certificate of

administration; and requires a patient to be informed that a pharmacy intern, certified to administer immunizations, will be administering the immunization and that the patient be given the option to have the immunization administered by the certified pharmacist.

Chapter 359 directs the Commissioner to promulgate regulations that establish standards for training of a pharmacy intern in the following areas: techniques for screening individuals and obtaining informed consent; techniques of administration; indications, precautions and contraindications in the use of an agent or agents; recordkeeping of immunization and information; and handling emergencies, including anaphylaxis and needlestick injuries. Chapter 359 also requires that to receive a certificate of administration, a pharmacy intern must submit an application, on a form prescribed by the State Education Department, from the dean or other appropriate official of the registered program that the intern has completed the required training pursuant to the Commissioner's Regulations.

The proposed addition of subdivision (d) to §63.4 of the Regulations of the Commissioner of Education establishes the requirements for a pharmacy intern to obtain a certificate to administer immunizations and establishes the required training for such certification. Additionally, as required by Chapter 359, Department staff have consulted with the New York State Department of Health regarding these proposed training requirement provisions.

The proposed amendment to subdivision (b) of §63.9 of the Regulations of the Commissioner of Education authorizes a certified pharmacist to delegate the administration of immunizations to a pharmacy intern who is properly trained and certified to administer immunizations under the immediate personal supervision of the certified pharmacist.

In addition, the proposed amendment to subdivision (b) of §63.9 of the Regulations of the Commissioner of Education requires the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, to be informed when a certified pharmacy intern will be administering the immunization and consent to it. The proposed amendment further provides that, if the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, does not consent, then the certified pharmacist will administer the immunization.

Related Regents Items

[January 2019: Proposed Amendment to §§63.4 and 63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacy Interns](http://www.regents.nysed.gov/common/regents/files/119ppca1.pdf) (<http://www.regents.nysed.gov/common/regents/files/119ppca1.pdf>)

[April 2019: Proposed Amendment to §§63.4 and 63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacy Interns](http://www.regents.nysed.gov/common/regents/files/419brca7-REVISED.pdf) (<http://www.regents.nysed.gov/common/regents/files/419brca7-REVISED.pdf>)

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That subdivision (d) of §63.4 of the Regulations of the Commissioner of Education be added, as submitted, and §63.9 be amended, as submitted, effective May 22, 2019.

Timetable for Implementation

If adopted at the May 2019 Regents meeting, the permanent rule will become effective on May 22, 2019.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6802, 6806, 6902 and 6909 of the Education Law and Chapter 359 of the Laws of 2018.

1. Subdivision (d) of section 63.4 of the Regulations of the Commissioner of Education is added, as follows:

(d) Requirements for a certificate to administer immunizations. No pharmacy intern shall administer immunizing agents without a certificate of administration issued by the department. For purposes of this section, a certified pharmacy intern shall mean a limited permit holder who is issued a certificate of administration pursuant to this subdivision. To meet the requirements for a certificate of administration, the pharmacy intern shall submit an application, on a form prescribed by the department. Each application shall contain an attestation by the dean or other appropriate official of the registered program that the applicant has completed the required training as specified in section 6806 of the Education Law and present satisfactory evidence of completion of the requirements set forth in one of the following subparagraphs:

(1) Training course. Completion of a training course in the administration of immunizations acceptable to the Commissioner and the Commissioner of Health, within the three years immediately preceding application for a certificate of administration. Such course shall include, but not be limited to, instruction in:

(i) techniques for screening patients and for obtaining informed consent;
(ii) techniques in the administration of immunizing agents, including the injection of a harmless, non-medicinal saline solution into voluntary recipients;

(iii) indications, precautions and contraindications in the use of immunizing agents;

(iv) handling of emergencies including needlestick injuries and anaphylaxis, including the use of medications required for emergency treatment of anaphylaxis;

(v) cardio-pulmonary resuscitation techniques; and

(vi) recordkeeping and reporting of immunizations and information; or

(2) A pharmacy intern that has completed a training course associated with Doctor of Pharmacy degree pursuant to the requirements in section 63.9(b)(3)(ii).

2. Subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education is amended, as follows:

(b) Immunizations

(1) ...

(2) ...

(3) ...

(4) With the exception of a certified pharmacy intern, a certified pharmacist shall not delegate the administration of immunizations to another person. For purposes of this section, a certified pharmacy intern shall mean a pharmacy intern who is certified to administer immunization as specified in section 6806 of the Education Law and has completed the requirements set forth in subdivision (d) of section 63.4 of this Part. Such a certified pharmacy intern may only administer immunizations under the immediate personal supervision of the certified pharmacist.

[(4)] (5) Standards, procedures and reporting requirements for the administration of immunization agents. Each certified pharmacist shall comply with the following requirements when administering an immunization agent pursuant to either a patient specific order or a non-patient specific order and protocol:

(i) . . .

(ii) . . .

(iii) . . .

(iv) . . .

(v) a certified pharmacist shall not allow a certified pharmacy intern to administer immunizations unless the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, is informed that the pharmacy intern will be administering the immunization and the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, consents to administration of the immunization by the certified pharmacy intern. If the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, does not consent to administration by the certified pharmacy intern, then the option to receive the immunization from a certified pharmacist shall be provided.

[(v)] (vi) a certified pharmacist shall provide written instructions to the recipient regarding the appropriate course of action in the event of contraindications or adverse reactions, which statements are required to be developed by a competent entity knowledgeable about the adverse reactions of the immunization agent which shall be administered, such as the Centers for Disease Control of the U.S. Department of Health and Human Services, which issues vaccine information statements;

[(vi)] (vii) a certified pharmacist, when administering an immunization in a pharmacy, shall provide for an area that provides for the patient's privacy, such area shall include:

(a) a clearly visible posting of the most current “Recommended Adult Immunization Schedule” published by the advisory committee for immunization practices (ACIP);

(b) education materials on influenza vaccines for children as determined by the commissioner and the commissioner of the department of health.

[(vii)] (viii) a certified pharmacist shall provide a copy of the appropriate vaccine information statement to the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, before administering the immunization;

[(viii)] (ix) a certified pharmacist shall provide to each recipient or other person legally responsible when the recipient is incapable of consenting to immunization, a signed certificate of immunization with the recipient’s name, date of immunization, address of administration, administering pharmacist, immunization agent, manufacturer and lot number. With the consent of the recipient or a person legally responsible when the recipient is incapable of consenting, the certified pharmacist shall communicate this information to the recipient’s primary health care practitioner, if one exists, within one month of the administration of such immunization, and such communication may be transmitted in electronic format;

[(ix)] (x) a certified pharmacist shall report any adverse outcomes as may be required by Federal law on the vaccine adverse event reporting system form of the Centers for Disease Control of the U.S. Department of Health and Human Services, or on the successor form;

[(x)] (xi) a certified pharmacist shall ensure that a record of all persons immunized including the recipient’s name, date, address of administration,

administering pharmacist, immunization agent, manufacturer and lot number is recorded and maintained in accordance with section 29.2(a)(3) of this Title;

[(xi)] (xii) to the extent required by the Public Health Law, the Education Law and/or the New York City Health Code, a certified pharmacist shall report the administration of any immunizations to the New York State Department of Health and/or the New York City Department of Health and Mental Hygiene, in a manner required by the Commissioner of Health of the State of New York or of the City of New York, as applicable. Such report shall not include any individually identifiable health information unless:

(a) such information is otherwise required by law; or

(b) the recipient has consented to the disclosure of such information, in which case the information may be included to the extent permitted by law; and

[(xii)] (xiii) each certified pharmacist shall provide information to recipients on the importance of having a primary health care practitioner, in a form or format developed by the Commissioner of Health;

[(xiii)] (xiv) each certified pharmacist shall, prior to administering the immunization or immunizations, inform the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, of the total cost of the immunization or immunizations, subtracting any health insurance subsidization, if applicable. In the case where the immunization is not covered, the pharmacist shall inform the recipient, or other person legally responsible for the recipient when the patient is incapable of consenting to the immunization, that the immunization may be covered when administered by a primary care physician or health care practitioner; and

[(xiv)] (xv) Reporting of administration of immunizing agent;

(a) when a licensed pharmacist administers an immunizing agent, he or she shall report such administration by electronic transmission or facsimile to the patient's attending primary health care practitioner or practitioners, if any, unless the patient is unable to communicate the identity of his or her primary health care practitioner, and, to the extent practicable, make himself or herself available to discuss the outcome of such immunization, including any adverse reactions, with the attending primary health care practitioner, or to the statewide immunization registry or the citywide immunization registry, as established pursuant to sections 2168 of the Public Health Law and 11.07 of the New York City Health Code, respectively.

Attachment B

8 NYCRR §§63.4 and 63.9

ASSESSMENT OF PUBLIC COMMENT

Since publication of a Notice of Emergency Adoption and Proposed Rule Making in the January 30, 2019 State Register, the State Education Department received the following comments:

1. COMMENT:

A New York State school of pharmacy professor noted that the citations to Education Law §6808 in §§63.4(d) and 63.9(b)(4) of the proposed rule appeared to be incorrect.

This commenter also supported the amendments to §63.4(d) because they provide schools the opportunity to train student interns in the specifics of becoming competent to administer vaccines under the supervision of a certified pharmacist. Commenter further asserted that New York's schools of pharmacy are eminently well-qualified to do this. Commenter sought clarification on how the required training courses in the administration of immunizations would be approved by the Commissioner and the Commissioner of Health,

Additionally, commenter asked whether a properly qualified pharmacy intern, under 63.4(d), in the beginning of his/her second year of pharmacy school and engaged clinically (administering vaccines) through the next third year, would need to repeat the required training to become certified to administer immunizations once he/she became a licensed pharmacist? Commenter asserted that this would be unnecessarily duplicative and a waste of resources.

DEPARTMENT RESPONSE:

Subsequent to the publication of the proposed rule in the State Register, Department staff discovered that the proposed rule inadvertently cited Education Law §6808 in two of its provisions, instead of Education Law §6806. Consequently, non-substantial revisions were made to replace the citations to Education Law §6808 with citations to Education Law §6806.

Regarding the approval of training programs, registered pharmacy programs need not obtain separate approval from SED to provide the training required for pharmacy interns to obtain a certificate of administration. Most, if not all, of these registered pharmacy programs presently include immunization administration as part of their respective curriculum and use the American Pharmacists Association (APhA) immunization certification program. Thus, the vaccination administration training that pharmacy interns will be taking has already been approved by SED.

In addition to the APhA immunization certification program, SED currently accepts completion of training in the administration of immunization agents received as part of a Doctor of Pharmacy degree program for licensed pharmacists seeking immunization certification. SED will accept this same training for pharmacy interns seeking immunization certification.

Students that have been engaged in continuous practice in the administration of immunization will not have to repeat this training to become certified to administer immunizations once they become licensed pharmacists. But they will have to submit the pharmacist immunization certification form to SED and attach a copy of an approved course completion certificate in immunization, as well as a copy of a current valid course completion card in Basic Life Support or its equivalent. As stated above,

acceptable training for this purpose includes completion of training in the administration of immunization agents received as part of a Doctor of Pharmacy degree program.

In cases where a student has not been engaged in continuous practice in the administration of immunizations, he/she would be required to retake the 20-hour coursework in order to obtain immunization certification once he/she becomes a licensed pharmacist. SED disagrees with the commenter's position that this retraining issue needs to be explicitly addressed in the final regulations and does not believe amendments are necessary. However, the commenter's suggestions are noted and may be addressed by the Department in future guidance.