






TO: The Honorable the Members of the Board of Regents

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: March 28, 2019

AUTHORIZATION(S):  

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt, as a second emergency action, the proposed addition of subdivision (d) to section 63.4 and the proposed amendment of subdivision (b) of section 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 proposed amendment will be presented to the Full Board for adoption as an emergency rule at the April 2019 meeting of the Board of Regents. A copy of the proposed rule and a statement of facts and circumstances justifying the emergency action are attached.

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. Because the January emergency action will expire on April 14, 2019, a second emergency action is necessary to ensure that the emergency rule remains continuously in effect until it can be permanently adopted at the May 6-7, 2019 Regents meeting and take effect as a permanent rule. A Notice of Emergency Adoption will be published in the State Register on May 1, 2019. Supporting materials are available upon request from 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 of the Laws of 2018 (Chapter 359), which, effective immediately, inter alia, amended Education Law section 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 section 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 section 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 section 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 Sections 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>

Recommendation

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

VOTED: That subdivision (d) of section 63.4 of the Regulations of the Commissioner of Education be added, as submitted, effective April 15, 2019, and section 63.9 be amended, as submitted, effective April 15, 2019 as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to conform the Regulations of the Commissioner of Education to the requirements of Chapter 359 of the Laws of 2018, which authorizes the administration of immunizations by a pharmacy intern, certified to administer immunizations, after completing required training, under the immediate and personal supervision of a licensed pharmacist certified to administer immunizations.

Timetable for Implementation

If adopted at the April 2019 Regents meeting, the emergency rule will become effective April 15, 2019.

It is further anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the May 6-7, 2019 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act.

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 6808 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 6808 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); and [the 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;

(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

STATEMENT OF FACTS AND CIRCUMSTANCES

WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment to the Regulations of the Commissioner of Education is necessary to implement Chapter 359 of the Laws of 2018 (Chapter 359), which amended Education Law section 6806, effective December 7, 2018, to allow the administration of immunizations by a pharmacy intern, certified to administer immunizations, under the immediate and personal supervision of a licensed pharmacist certified to administer immunizations. 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 must be given the option of having 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 the Commissioner to promulgate rules and regulations relating to the documentation required from the dean or other appropriate official of the registered program that the pharmacy intern has completed the required training.

The proposed addition of subdivision (d) to section 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 coursework for such certification.

The proposed amendment to subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education authorizes a certified pharmacist to delegate the administration of immunizations to a pharmacy intern that 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 section 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.

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. Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for permanent adoption, after expiration of the required 60-day comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the May 6-7, 2019 Regents meeting. Furthermore, pursuant to SAPA 203(1), the earliest effective date of the proposed rule, if adopted at the May meeting would be May 22, 2019, the date the Notice of Adoption would be published in the State Register. However, the January emergency rule will expire on April 15, 2019. If the rule were to lapse, it would impede the ability of certified pharmacy interns to continue to administer immunizations to the public, which would adversely impact the public's access to immunizations against several diseases, including, but not limited to, seasonal influenza. It would further impede the ability of certified pharmacy interns to gain valuable hands on clinical experience by administering immunizations to the public.

Therefore, emergency action is necessary at the April 2019 meeting for the preservation of the public health and general welfare in order to continue to implement

Chapter 359, which is already in effect, to, inter alia, authorize the administration of immunizations by a pharmacy intern, certified to administer immunizations, after completing required training, under the immediate and personal supervision of a licensed pharmacist certified to administer immunizations, in order to improve the public's access to immunizations and provide certified pharmacy interns with valuable hands on clinical experience.

It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the May 6-7, 2019 Regents meeting, which is the first scheduled meeting after the 60-day public comment period prescribed in SAPA for State agency rule makings.