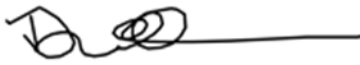






TO: The Honorable the Members of the Board of Regents

FROM: Douglas E. Lentivech


SUBJECT: Proposed Amendment to §63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacists

DATE: October 25, 2018

AUTHORIZATION(S):  

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt as an emergency action, the revised proposed amendment of paragraphs (2) and (4) of subdivision (b) and paragraph (1) and subparagraph (i) of paragraph (3) of subdivision (c) of §63.9 of the Regulations of the Commissioner of Education relating to the administration of vaccinations by pharmacists?

Reason for Consideration

Required by State statute (Part DD of Chapter 57 of the Laws of 2018) and review of policy.

Proposed Handling

The revised proposed amendment will be presented to the Full Board for adoption as an emergency action at the November 2018 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 June 2018 meeting of the Board of Regents, effective June 12, 2018. A Notice of Emergency Action and Proposed Rule Making was published in the State Register on June 27, 2018 for a 60-day public comment period. The Department received comments from one commenter.

A second emergency action was taken at the July 2018 Regents meeting, in order to ensure that the emergency rule remained continuously in effect until it could be permanently adopted at the September 17-18, 2018 Regents meeting.

However, after the adoption of the second emergency action at the July meeting, Department staff determined that the proposed rule inadvertently failed to amend the provisions of §63.9 of the Regulations of the Commissioner of Education to extend pharmacists' authority to administer medications for the treatment of anaphylaxis to patients two years of age and older, as required by Part DD of the Chapter 57 of the Laws of 2018. To address this unintentional omission, revisions were made to the proposed rule, as discussed in the Revisions to the Proposed Rule section below. Therefore, at the September 2018 Regents meeting, the second emergency action was repealed effective September 18, 2018, and the revised proposed rule was adopted on an emergency basis (third emergency), to ensure that the emergency rule, as revised, remains continuously in effect until the effective date of its adoption as a permanent rule. A Notice of Emergency Adoption and Revised Rule Making was published in the State Register on October 3, 2018 for an additional 30-day public comment period.

A copy of the revised proposed rule, an Assessment of Public Comment and a statement of facts and circumstances justifying the emergency action are attached. 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 14,000 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.

On January 25, 2018, in response to a severe influenza season in New York State, the Governor declared a state of emergency and issued Executive Order Number

176, which suspended and modified laws and regulations to authorize certified pharmacists to immunize children between the ages of two and eighteen to prevent influenza, pursuant to a non-patient specific order issued by a physician or nurse practitioner.

On April 12, 2018, the Governor signed Chapter 57 of the Laws of 2018 (Chapter 57), that included Part DD, which, effective immediately, inter alia, amended the Education Law in relation to administration of immunizations by certified pharmacists. Part DD of Chapter 57 was enacted, in part, to make seasonal influenza vaccines more readily available to children. Prior to the enactment of Part DD of Chapter 57, pharmacists could not administer seasonal influenza vaccine to patients under eighteen years of age, unless the Governor declared a state of emergency.

Part DD of Chapter 57 also expands the definition of an immunizing agent to include vaccines that are administered by inhalation. Part DD of Chapter 57 further authorizes licensed pharmacists to execute patient specific and non-patient specific orders prescribed by a physician or nurse practitioner to administer influenza vaccine to children between two and eighteen years of age. Additionally, it authorizes the Commissioner of Health to issue a statewide non-patient specific order for pharmacists to administer influenza vaccine to children between two and eighteen years of age when the Commissioner of Health determines that there is, or that there is the imminent threat of, an influenza outbreak.

In addition, Part DD of Chapter 57 amends the Public Health Law to require a certified pharmacist to report all immunizations administered to a patient under nineteen years of age to be reported to either the New York State Immunization Information System (NYSIIS) or if administered in New York City, to the Citywide Immunization Registry (CIR), as required by the Public Health Law or the New York City Health Code.

The proposed amendment to paragraph (2) of subdivision (b) of §63.9 of the Regulations of the Commissioner of Education authorizes pharmacists to immunize children between the ages of two and eighteen against seasonal influenza.

Paragraph (4) of subdivision (b) of §63.9 of the Regulations of the Commissioner of Education currently requires a certified pharmacist, when administering an immunization in a pharmacy, to provide for an area that provides for the patient's privacy and includes a posting of the most current "Recommended Adult Immunization Schedule" published by the Advisory Committee for Immunization Practices. The proposed amendment adds the requirement that the privacy area must also include education materials on influenza vaccinations for children, as determined by the Commissioner and Commissioner of Health.

Section 63.9(b)(4)'s existing requirements that the immunizations administered by certified pharmacists be reported to the attending primary health care practitioner, and to NYSIIS or the CIR will now also apply to influenza immunizations provided to

children between the ages of two and eighteen by certified pharmacists pursuant to Part DD of Chapter 57.

Additional amendments to paragraph (4) of subdivision (b) of §63.9 of the Regulations of the Commissioner of Education delete outdated references to reporting requirements regarding the administration of vaccinations by pharmacists prior to December 27, 2015.

Revisions to Proposed Rule

As discussed in the Procedural History section above, since the publication of a Notice of Emergency Action and Proposed Rule Making was published in the State Register on June 27, 2018, the proposed rule was revised to correct the inadvertent failure to extend pharmacists' authority to administer medications for the treatment of anaphylaxis to patients two years of age and older in accordance with the provisions of Part DD of Chapter 57 of the Laws of 2018, as follows:

- Paragraph (1) of subdivision (c) of §63.9 of the Regulations of the Commissioner of Education, which currently only authorizes the administration of medications for the treatment of anaphylaxis to patients 18 years of age and older, has been revised to authorize certified pharmacists to administer medications for the treatment of anaphylaxis to patients two years of age or older.
- Subparagraph (i) of paragraph (3) of subdivision (c) of the Regulations of the Commissioner of Education has been revised by removing the reference to "adult" and replacing it with "patients 2 years of age or older" in the anaphylaxis protocol provisions.

Related Regents Items

June 2018: [Proposed Amendment to §63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacists](http://www.regents.nysed.gov/common/regents/files/618ppca1.pdf)
<http://www.regents.nysed.gov/common/regents/files/618ppca1.pdf>

July 2018: [Proposed Amendment to §63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacists](http://www.regents.nysed.gov/common/regents/files/718brca9.pdf)
<http://www.regents.nysed.gov/common/regents/files/718brca9.pdf>

September 2018: [Proposed Amendment to §63.9 of the Regulations of the Commissioner of Education Relating to Administration of Vaccinations by Pharmacists](http://www.regents.nysed.gov/common/regents/files/918ppca1.pdf)
<http://www.regents.nysed.gov/common/regents/files/918ppca1.pdf>

Recommendation

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

VOTED: That paragraphs (2) and (4) of subdivision (b) and paragraph (1) and subparagraph (i) of paragraph (3) of subdivision (c) of §63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective November 17, 2018, 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 immediately conform the Regulations of the Commissioner of Education to the requirements of Part DD of Chapter 57 of the Laws of 2018, which include authorizing pharmacists to immunize children between the ages of two and eighteen against seasonal influenza pursuant to a patient specific order or a non-patient specific order.

Timetable for Implementation

The proposed amendment was initially adopted as an emergency rule at the June 11-12, 2018 Regents meeting and a second emergency action was adopted at the July 16-17, 2018 meeting to keep the emergency rule continuously in effect until the effective date of its adoption as a permanent rule. At the September 17-18, 2018 Regents meeting, the second emergency action was repealed and the revised proposed rule was adopted on an emergency basis (third emergency), both effective September 18, 2018. The September 2018 emergency rule will expire on November 16, 2018. If the Regents adopt the revised proposed amendment as an emergency rule (fourth emergency) at the November 2018 Regents meeting, it will become effective on November 17, 2018. It is anticipated that the revised proposed rule will be presented for permanent adoption at the December 2018 Regents meeting and take effect on December 26, 2018.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6802, 6902 and 6909 of the Education Law and Part DD of Chapter 57 of the Laws of 2018.

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

(b) Immunizations.

(2) Authorized immunization agents. A certified pharmacist who meets the requirements of this section shall be authorized to administer to [patients 18 years of age or older, immunizing agents to prevent influenza, pneumococcal, acute herpes zoster, meningococcal, tetanus, diphtheria or pertussis disease, pursuant to a patient specific order or a non-patient specific order.];

(i) patients 18 years of age or older, immunizing agents to prevent influenza, pneumococcal, acute herpes zoster, meningococcal, tetanus, diphtheria or pertussis disease, pursuant to a patient specific order or a non-patient specific order; and

(ii) patients between the ages of two and eighteen years of age, immunizing agents to prevent influenza, pursuant to a patient specific order or a non-patient specific order.

2. Paragraph (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education is amended, as follows:

(4) 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) . . .

(vi) 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) 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) 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;

[(viii)] (ix) 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;

[(ix)] (x) 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;

[(x)] (xi) 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

[(xi)] (xii) 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;

[(xii)] (xiii) 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

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

(a) [For administrations prior to December 27, 2015, when a licensed pharmacist administers an immunizing agent, he or she shall report such administration 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;

(b) For administrations on or after December 27, 2015,] 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.

3. Paragraph (1) of subdivision (c) of section 63.9 of the Regulations of the Commissioner of Education is amended, as follows:

(c) Anaphylaxis treatment agents.

(1) Pursuant to sections 6801 and 6802 of the Education Law, each pharmacist who is issued a certificate of administration pursuant to this section shall be authorized to administer medications for the emergency treatment of anaphylaxis to patients [18] 2 years of age or older.

4. Subparagraph (i) of paragraph (3) of subdivision (c) of section 63.9 of the Regulations of the Commissioner of Education is amended, as follows:

(3) Non-patient specific order and protocol.

(i) The certified pharmacist shall either maintain or ensure the maintenance of a copy of the non-patient specific order and protocol prescribed by a licensed physician or a certified nurse practitioner that authorizes such pharmacist to administer medications for the emergency treatment of anaphylaxis to [adults] patients 2 years of age or older, in accordance with the requirements of paragraph (1) of this subdivision. The order prescribed in subparagraph (ii) of this paragraph shall incorporate a protocol that meets the requirements of subparagraph (iii) of this paragraph. Such order and protocol shall

be considered a record of the patient who receives the anaphylaxis treatment agent and maintained as a record for the patient who receives the anaphylaxis treatment agent. A record of each patient shall be maintained in either:

(a) . . .

(b) . . .

8 NYCRR §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 Part DD of Chapter 57 of the Laws of 2018 (Part DD of Chapter 57), which amended the Education Law in relation to administration of immunizations by certified pharmacists. Part DD of Chapter 57 was enacted, in part, to make seasonal influenza vaccines more readily available to children, effective April 12, 2018. Prior to the enactment of Part DD of Chapter 57, pharmacists could not administer seasonal influenza vaccine to patients under nineteen years of age, unless the Governor declared a state of emergency.

Part DD of Chapter 57 also expands the definition of an immunizing agent to include vaccines that are administered by inhalation. Part DD of Chapter 57 further authorizes licensed pharmacists to execute patient specific and non-patient specific orders prescribed by a physician or nurse practitioner to administer influenza vaccine to children between two and eighteen years of age. Additionally, it authorizes the Commissioner of Health to issue a statewide non-patient specific order for pharmacists to administer influenza vaccine to children between two and eighteen years of age during an influenza outbreak.

In addition, Part DD of Chapter 57 amends the Public Health Law to require a certified pharmacist to report all immunizations administered to a patient under nineteen years of age to be reported to either the New York State Immunization Information

System (NYSIIS) or if administered in New York City, to the Citywide Immunization Registry (CIR), as required by the Public Health Law or the New York City Health Code.

The proposed amendment to paragraph (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education authorizes pharmacists to immunize children between the ages of two and eighteen against seasonal influenza.

The proposed amendment to paragraph (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education requires a certified pharmacist, when administering an immunization in a pharmacy, to provide for an area that provides for the patient's privacy, which includes education materials, as determined by the Commissioner and Commissioner of Health, on influenza vaccinations for children. It also requires reporting of the immunization to the attending primary health care practitioner, and to NYSIIS or the CIR.

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 June 2018 meeting of the Board of Regents, effective June 12, 2018. A Notice of Emergency Action and Proposed Rule Making was published in the State Register on June 27, 2018 for a 60-day public comment period. The Department received comments from one commenter, but those comments did not necessitate any revisions to the proposed amendment.

Because the June emergency action was set to expire on September 9, 2018, at the July 2018 Regents meeting, a second emergency action was adopted to ensure that the emergency rule adopted at the June 2018 Regents meeting remained continuously in effect until the effective date of its adoption as a permanent rule. However, after the

adoption of the second emergency action at the July meeting, Department staff determined that the proposed rule inadvertently failed to amend the provisions of section 63.9 of the Regulations of the Commissioner of Education to extend pharmacists' authority to administer medications for the treatment of anaphylaxis to patients two years of age and older, as required by Part DD of the Chapter 57. To address this unintentional omission, revisions were made to the proposed rule. Thereafter, at the September 17-18, 2018 Regents meeting, the second emergency action was repealed effective September 18, 2018, and the revised proposed rule was adopted on an emergency basis (third emergency), to ensure that the emergency rule, as revised, remains continuously in effect until the effective date of its adoption as a permanent rule. A Notice of Emergency Adoption and Revised Rule Making was published in the State Register on October 3, 2018 for an additional 30-day public comment period.

Since the Board of Regents meets at fixed intervals, the earliest the revised proposed rule can be presented for adoption, after expiration of the required 30-day comment period provided for in the State Administrative Procedure Act (SAPA) sections 202(4-a), would be the December 10-11, 2018 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the revised proposed rule, if adopted at the December meeting, would be December 26, 2018, the date the Notice of Adoption would be published in the State Register. However, Part DD of Chapter 57 of the Laws of 2018 became effective on April 12, 2018. If the rule were to lapse, it would impede the ability of pharmacists to continue to immunize children

between the ages of two and eighteen against seasonal influenza pursuant to a patient specific order or a non-patient specific order.

Therefore, a fourth emergency action is necessary at the November 2018 Regents meeting for the preservation of the public health and general welfare in order to continue to implement Part DD of Chapter 57 of the Laws of 2018, which is already in effect, to, inter alia, authorize pharmacists to immunize children between the ages of two and eighteen against seasonal influenza pursuant to a patient specific order or a non-patient specific order.

It is anticipated that the revised proposed rule will be presented for adoption as a permanent rule at the December 10-11, 2018 Regents meeting, which is the first scheduled meeting after publication of a Notice of Emergency Adoption and Revised Rule Making in the State Register and expiration of the 30-day public comment period as required by prescribed SAPA section 202(4-a).