



THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

TO: The Honorable the Members of the Board of Regents

FROM: Douglas E. Lentivech


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

DATE: July 3, 2018


AUTHORIZATION(S):


SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt, as a second emergency action, the proposed amendment of paragraphs (2) and (4) of subdivision (b) 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 proposed amendment will be presented to the Full Board for adoption as an emergency action at the July 2018 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 June 2018 meeting of the Board of Regents, effective June 12, 2018. A Notice of Emergency Action and Proposed Rulemaking was published in the State Register on June 27, 2018. Because the June emergency action will expire on September 9, 2018, a second emergency action is necessary to ensure that the emergency rule remains continuously in effect until it can be permanently adopted at the September 17-18, 2018 Regents meeting and take effect as a permanent rule. A Notice of Emergency Adoption will be published in the State Register on August 1, 2018. Supporting materials for the proposed rule are available upon request from the Secretary of 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 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.

Paragraph (4) of subdivision (b) of section 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 of the Laws of 2018.

Additional amendments to paragraph (4) of subdivision (b) of section 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.

Related Regents Items

[June 2018](http://www.regents.nysed.gov/common/regents/files/618ppca1.pdf): Proposed Amendment to Section 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>)

Recommendation

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

VOTED: That paragraphs (2) and (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective

September 10, 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

If adopted at the July 2018 Regents meeting, the emergency rule will take effect on September 10, 2018.

It is further anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the September 17-18, 2018 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.

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.

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, 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. Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for 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 September 17-18, 2018 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed rule, if adopted at the September meeting, would be October 3, 2018, the date the Notice of Adoption would be published in the State Register. However, the June emergency rule will expire on September 10, 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, emergency action is necessary at the July 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 proposed rule will be presented for adoption as a permanent rule at the September 17-18, 2018 Regents meeting, which is the first scheduled meeting after the 60-day public comment period prescribed in SAPA for State agency rule makings.