



TO: The Professional Practice Committee

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: December 7, 2015

AUTHORIZATION(S):



SUMMARY

Issue for Decision

Should the Board of Regents adopt, as a permanent rule, the proposed amendment of paragraphs (1), (2) and (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education relating to the administration of vaccinations by pharmacists?

Reason(s) for Consideration

Required by State statute (L. 2015, Ch. 46).

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as a permanent rule at the December 2015 meeting of the Board of Regents. In addition, a second emergency action is necessary to ensure that the emergency rule adopted at the September 2015 Regents meeting remains continuously in effect until the effective date of its adoption as a permanent rule. A Statement of Facts and Circumstances Which Necessitate Emergency Action is attached.

Procedural History

The proposed amendment was adopted as an emergency rule at the September 2015 Regents meeting, effective September 17, 2015. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on October 7, 2015 for a 45-day public comment period. The Department received one comment on the proposed amendment.

Since publication of the proposed rule in the State Register, a non-substantial revision has been made in order to clarify the text of the proposed regulation. Section 63.9(b)(4)(xiii)(b) was revised to add a citation to section “11.07 of the New York City Health Code” to clarify the requirement that pharmacists administering immunizations shall report such administration to the patient’s attending primary health care practitioner or practitioners, 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.

A copy of the permanent rule, emergency rule, and an Assessment of Public Comment are attached. Supporting materials are available upon request from the Secretary of the Board of Regents.

Background Information

Since December 2008, pharmacists in New York State have been authorized to administer immunizations to prevent influenza and pneumococcal disease. In order to administer such immunizations, a pharmacist must be certified by the Department following the completion of a satisfactory training program. Since that time, 11,897 registered pharmacists in New York State have received the required certification. Studies reflect improvements in the State’s over-all immunizations rates, with significant improvements in the rates of immunization against influenza in minority communities.

In 2012, vaccinations against acute herpes zoster (shingles) were added to the list of immunizations that appropriately certified pharmacists are authorized to administer pursuant to a patient specific order.

Additionally, in 2013 pharmacists became authorized to administer immunizations against meningococcal disease. Pharmacists may administer this immunization pursuant to either patient specific orders or non-patient specific orders, as they may for influenza and pneumococcal disease.

On June 30, 2015, the Governor signed Chapter 46 of the Laws of 2015, which, inter alia, amends the Education Law in relation to the administration of certain immunizations by licensed pharmacists. Chapter 46 was enacted, in part, to address the surge New York State, like the United States as a whole, has experienced in the number of cases of pertussis in recent years. The Tdap (tetanus-diphtheria-acellular pertussis) vaccine is recommended by the Centers for Disease Control (CDC) for adults 19 years and older who have not received a dose of Tdap, especially those who have contact with infants. Allowing pharmacists to administer the Tdap vaccine will provide more opportunities for New Yorkers to get vaccinated and help reduce the cases of pertussis in this State.

Chapter 46 also makes it easier for New Yorkers to get the acute herpes zoster (shingles) vaccine, by authorizing pharmacists to administer that vaccine pursuant to a non-patient specific order when following the advisory committee for immunization practices (ACIP) recommendations. Prior to the enactment of Chapter 46, pharmacists could only administer this immunization pursuant to a patient-specific prescription, so an individual was required to first go to his or her doctor and obtain a prescription for it and then go to the pharmacy to receive the immunization.

In addition, Chapter 46 eases the requirement that non-patient specific orders for immunizations be issued by a physician or nurse practitioner practicing in the same county in which the immunization is administered, which has proven difficult to obtain in some rural areas.

The proposed amendment of paragraphs (1), (2) and (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner implement the licensed pharmacist immunization administration requirements of Chapter 46, which became effective June 30, 2015.

The proposed amendment to paragraph (1) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education amends the requirement that non-patient specific orders be issued by a physician or nurse practitioner practicing in the same county in which the immunization is administered to allow orders to be issued by a physician or nurse practitioner in an adjoining county as well. The proposed amendment also provides that if the Commissioner of Health determines that there is an outbreak of disease, or that there is the imminent threat of an outbreak of disease, then the Commissioner of Health may issue a non-patient specific order applicable statewide.

In addition, the proposed amendment to paragraph (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education authorizes certified pharmacists to administer immunizations to prevent tetanus, diphtheria or pertussis disease pursuant to a patient specific order or a non-patient specific order and to administer immunizations to prevent acute herpes zoster (shingles) pursuant to a non-patient specific order, in addition to their current immunization authority to administer immunizations to prevent acute herpes zoster pursuant to a patient specific order.

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 to inform the person legally responsible for the recipient when the patient is incapable of consenting to the immunization or immunizations, of potential side effects and adverse reactions, orally and in writing, prior to immunization. It also requires the certified pharmacist to administer the immunization or immunizations according to the most current recommendations by ACIP, provided, however, that a pharmacist may administer any immunization authorized when specified in a patient specific prescription. The proposed amendment further 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 a clearly visible posting of the most current "Recommended Adult Immunization Schedule" published by ACIP. The proposed amendment further requires each certified pharmacist, prior to administering the

immunization or immunizations, to 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. It also requires each certified pharmacist, in the case where the immunization is not covered, to inform the recipient, or the 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.

Recommendation

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

VOTED: That paragraphs (1), (2) and (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective December 30, 2015; and it is further

VOTED: That paragraphs (1), (2) and (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective December 16, 2015, 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 ensure that the emergency rule adopted at the September 2015 Regents meeting, as revised, remains continuously in effect until the effective date of its adoption as a permanent rule.

Timetable for Implementation

The proposed amendment was adopted as an emergency rule at the September 16-17, 2015 Regents meeting, effective September 17, 2015. The September emergency rule will expire on December 15, 2015. If adopted at the December 2015 Regents meeting, the second emergency rule will take effect on December 16, 2015 and the permanent rule will take effect on December 30, 2015.

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 Chapter 46 of the Laws of 2015, which amended Education Law sections 6527, 6801, 6802 and 6909, which include authorizing licensed pharmacists to administer immunizations to prevent tetanus, diphtheria or pertussis disease pursuant to a patient specific order or a non-patient specific order, and to administer immunizations to prevent acute herpes zoster (shingles) pursuant to a non-patient specific order in addition to their current immunization authority to administer immunizations to prevent acute herpes zoster pursuant to a patient specific order.

Since publication of the proposed rule in the State Register on October 7, 2015, a nonsubstantial revision has been made in order to clarify the text of the proposed regulation. Section 63.9(b)(4)(xiii)(b) was revised to add a citation to section “11.07 of the New York City Health Code” to clarify the requirement that pharmacists administering immunizations shall report such administration to the patient’s attending primary health care practitioner or practitioners, 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.

The proposed amendment was adopted as an emergency rule at the September 16-17, 2015 meeting of the Board of Regents, effective September 17, 2015, and has now, as revised, been adopted as a permanent rule at the December 14-15, 2015 Regents meeting. Pursuant to SAPA §203(1), the earliest effective date of the permanent rule is December 30, 2015, the date a Notice of Adoption will be published in the State Register. However, the September emergency rule will expire on December

15, 2015, 90 days after its filing with the Department of State on September 17, 2015. Emergency action is therefore necessary for the preservation of the public health and general welfare to ensure that the proposed amendment adopted by emergency action at the September 2015 Regents meeting, as revised, remains continuously in effect until the effective date of its permanent adoption.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6802 and 6909 of the Education Law and Chapter 46 of the Laws of 2015

1. Paragraph (1) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education is amended, effective December 30, 2015, as follows:

(b) Immunizations.

(1) Pursuant to section 6801 of the Education Law, a pharmacist with a certificate of administration issued by the department pursuant to paragraph (3) of this subdivision shall be authorized to administer immunization agents prescribed in paragraph (2) of this subdivision to patients therein specified, provided that:

(i) . . .

(ii) with respect to non-patient specific orders:

(a) the immunization is prescribed or ordered by a licensed physician or a certified nurse practitioner with a practice site in the county or adjoining county in which the immunization is administered; [or] and

(b) [if the immunization is administered in a county with a population of 75,000 or less, the immunization shall be prescribed or ordered by a licensed physician or certified nurse practitioner with a practice site in the county in which the immunization is administered or in an adjoining county.] if the commissioner of health determines that there is an outbreak of disease, or that there is the imminent threat of an outbreak of disease, then the commissioner of health may issue a non-patient specific regimen applicable statewide.

2. Paragraph (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education is amended, effective December 30, 2015, as follows:

(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,[:

(i)] immunizing agents to prevent influenza, pneumococcal, [disease or] acute herpes zoster, meningococcal, tetanus, diphtheria or pertussis disease, pursuant to a patient specific order or a non-patient specific order.]; and

(ii) immunizing agents to prevent acute herpes zoster, pursuant to a patient specific order.]

3. Paragraph (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education is amended, effective December 30, 2015, 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) a certified pharmacist shall inform each recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, of potential side effects and adverse reactions, orally and in writing, prior to immunization and shall administer the immunization or immunizations according to the most current recommendations by the advisory committee for immunization practices (ACIP), provided, however, that a pharmacist may administer any immunization authorized when specified by a patient specific prescription;

(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 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;

(vii) . . .

(viii) . . .

(ix) . . .

(x) . . .

(xi) 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) 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) 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.

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(i) . . .

(ii) with respect to non-patient specific orders:

(a) the immunization is prescribed or ordered by a licensed physician or a certified nurse practitioner with a practice site in the county or adjoining county in which the immunization is administered; [or] and

(b) [if the immunization is administered in a county with a population of 75,000 or less, the immunization shall be prescribed or ordered by a licensed physician or certified nurse practitioner with a practice site in the county in which the immunization is administered or in an adjoining county.] if the commissioner of health determines that there is an outbreak of disease, or that there is the imminent threat of an outbreak of disease, then the commissioner of health may issue a non-patient specific regimen applicable statewide.

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(i)] immunizing agents to prevent influenza, pneumococcal, [disease or] acute herpes zoster, meningococcal, tetanus, diphtheria or pertussis disease, pursuant to a patient specific order or a non-patient specific order.]; and

(ii) immunizing agents to prevent acute herpes zoster, pursuant to a patient specific order.]

3. Paragraph (4) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education is amended, effective December 16, 2015, 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) a certified pharmacist shall inform each recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, of potential side effects and adverse reactions, orally and in writing, prior to immunization and shall administer the immunization or immunizations according to the most current recommendations by the advisory committee for immunization practices (ACIP), provided, however, that a pharmacist may administer any immunization authorized when specified by a patient specific prescription;

(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 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;

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(xi) 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) 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

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(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

ASSESSMENT OF PUBLIC COMMENT

Since publication of a Notice of Emergency Adoption and Proposed Rule Making in the October 7, 2015 State Register, the State Education Department received the following comment:

COMMENT:

The New York City Department of Health and Mental Hygiene requested an additional citation for the reporting requirement to the citywide immunization registry, by pharmacists, to reflect section 11.07 of the New York City Health Code.

DEPARTMENT RESPONSE:

The Department concurs with this nonsubstantial change, which is consistent with regulation and practice, and has amended the proposed rule accordingly.