



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

TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

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

DATE: December 3, 2012

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents adopt as a permanent rule the amendments to paragraphs (1) and (2) 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.

Proposed Handling

This matter will come before the Professional Practice Committee for recommendation and to the Full Board for permanent adoption at the December 2012 Regents meeting. In addition to the permanent adoption, a second emergency action is necessary at the December meeting to ensure that the emergency rule adopted at the September Regents meeting remains continuously in effect until the effective date of its

adoption as a permanent rule. A Statement of the Facts and Circumstances Which Necessitate Emergency Action is attached.

Procedural History

The proposed amendment was adopted as an emergency rule at the September Regents meeting, effective October 16, 2012. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on October 3, 2012. No public comments have been received. A copy of the proposed rule is 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, nearly 8,000 registered pharmacists in New York State have received the required certification. Studies reflect improvements in the State's over-all immunization rates, with significant improvements in the rates of immunization against influenza in minority communities.

On July 18, 2012, the Governor signed Chapter 116 of the Laws of 2012, which authorizes pharmacists to immunize patients against acute herpes zoster, commonly known as shingles, a very painful condition. Unlike the vaccinations to protect against influenza and pneumococcal disease, which may be administered by pharmacists pursuant to either patient specific orders or non-patient specific orders, the new law allows for only patient-specific prescriptions for immunizations to prevent acute herpes zoster. The proposed amendment conforms the Commissioner's regulations to the new law by adding the acute herpes zoster vaccination. Both the new law and the proposed amendment to the regulations become effective on October 16, 2012.

Section 6802(22) of the Education Law provides that non-patient specific immunization orders authorized to be executed by pharmacists may be issued only by physicians and nurse practitioners with a practice site in the county in which the immunization is administered or, if the population of that county is not more than 75,000, in an adjoining county. It is proposed that section 63.9(b)(1)(ii) of the Regulations of the Commissioner be amended to clarify that such restriction applies only to non-patient specific orders. The current regulation imposes the county limitation on all immunizations by pharmacists. The statutory language, however, appears to place that limitation only on immunizations administered pursuant to non-patient specific orders. The proposed amendment is consistent with the statutory language and would enable patients who have a direct relationship with a physician or nurse practitioner to

receive the appropriate immunizations pursuant to patient specific orders without regard to the county limitation.

Recommendation

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

VOTED: That paragraphs (1) and (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective December 26, 2012, and it is further

VOTED: That paragraphs (1) and (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education be amended, as submitted, effective December 17, 2012, 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 Regents meeting remains continuously in effect until the effective date of its adoption as a permanent rule.

Timetable for Implementation

The proposed rule was adopted as an emergency action at the September 10-11, 2012 Regents meeting, effective October 16, 2012. The September emergency rule will expire on December 16, 2012. If adopted at the December 10-11, 2012 Regents meeting, the 2nd emergency rule will take effect on December 17, 2012 and the permanent rule will take effect on December 26, 2012.

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 116 of the Laws of 2012, which amends Education Law sections 6527, 6801, 6802 and 6909, to authorize pharmacists who have been certified to administer immunizations to also administer vaccinations to prevent acute herpes zoster.

The proposed amendment was adopted as an emergency rule at the September 10-11, 2012 meeting of the Board of Regents, effective October 16, 2012, and has now been adopted as a permanent rule at the December 10-11, 2012 Regents meeting. Pursuant to SAPA §203(1), the earliest effective date of the proposed amendment is December 26, 2012, the date a Notice of Adoption will be published in the State Register. However, the September emergency rule expires on December 16, 2012, 90 days after its filing with the Department of State on September 18, 2012. A lapse in the rule would disrupt the administration of herpes zoster vaccinations by qualified pharmacists. Emergency action is therefore necessary for the preservation of the public health and general welfare to ensure that the emergency rule adopted at the September Regents meetings remains continuously in effect until the effective date of the permanent rule.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 6527, 6801, 6802 and 6909 of the Education Law, and Chapter 116 of the Laws of 2012

Paragraphs (1) and (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education are amended, effective December 26, 2012, as follows:

(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, [pursuant to either a patient specific order or a non-patient specific order and protocol] provided that:

(i) the pharmacist meets the requirements for a certificate of administration prescribed in paragraph (3) of this subdivision and the order and protocol meet the requirements set forth in paragraph (5) of this subdivision; and

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

(a) the immunization is 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

(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.

(2) Authorized immunization agents. A certified pharmacist who meets the requirements of this section shall be authorized to administer;

(i) immunizing agents to prevent influenza or pneumococcal disease to patients 18 years of age or older, 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.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 6527, 6801, 6802 and 6909 of the Education Law, and Chapter 116 of the Laws of 2012

Paragraphs (1) and (2) of subdivision (b) of section 63.9 of the Regulations of the Commissioner of Education are amended, effective December 17, 2012, as follows:

(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, [pursuant to either a patient specific order or a non-patient specific order and protocol] provided that:

(i) the pharmacist meets the requirements for a certificate of administration prescribed in paragraph (3) of this subdivision and the order and protocol meet the requirements set forth in paragraph (5) of this subdivision; and

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

(a) the immunization is 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

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