



**TO:** 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:** September 4, 2012

**AUTHORIZATION(S):**

### SUMMARY

#### Issue for Decision

Should the Board of Regents amend 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 and the Board of Regents for action as an emergency measure at the September 2012 meeting of the Board of Regents. A Statement of the Facts and Circumstances Which Necessitate Emergency Action is attached.

#### Procedural History

A Notice of Emergency Adoption and Proposed Rule Making will be published in the State Register on October 3, 2012. 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 October 16, 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 immediately conform the Regulations of the Commissioner to timely implement the requirements of Chapter 116 of the Laws of 2012, which authorizes qualified pharmacists to administer acute herpes zoster immunizations, effective October 16, 2012.

## **Timetable for Implementation**

If adopted at the September Regents meeting, the emergency rule would take effect on October 16, 2012, the effective date of the new law. It is anticipated that the proposed amendment will be presented to the Board of Regents for permanent adoption at the December Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 45-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, 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 October 16, 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.

## 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.

Because the Board of Regents meets at fixed intervals, the earliest the proposed amendment can be presented for adoption, after expiration of the required 45-day public comment period provided for in State Administrative Procedure Act (SAPA) section 202(1) and (5), would be the December 10-11, 2012 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment, if adopted at the December meeting, would be December 26, 2012, the date a Notice of Adoption would be published in the State Register. However, the provisions of Chapter 116 of the Laws of 2012 will become effective on October 16, 2012.

Emergency action is necessary for the preservation of the public health and general welfare in order to enable the State Education Department to immediately establish requirements to timely implement Chapter 116 of the Laws of 2012, so that certified pharmacists can begin to treat patients in need of this vaccination, currently recommended for all patients who have had chicken pox and are now 50 years of age or older. Herpes zoster infection, better known as Shingles, is extremely painful, and only a small number of patients who should be receiving the vaccine have been vaccinated.

It is anticipated that the proposed amendment will be presented for adoption as a permanent rule at the December 10-11, 2012 meeting of the Board of Regents, after publication in the State Register and expiration of the 45-day public comment period on proposed rule makings required by the State Administrative Procedure Act.